

# DEVELOPMENT AND EVALUATION OF A MOBILE HEALTH INTERVENTION TO IMPROVE PHYSICAL ACTIVITY AND SLEEP HEALTH IN ADULTS: THE SYNERGY STUDY

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## DEVELOPMENT AND EVALUATION OF A MOBILE HEALTH INTERVENTION TO IMPROVE PHYSICAL ACTIVITY AND SLEEP HEALTH IN ADULTS: THE SYNERGY STUDY

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A thesis submitted in fulfilment of the requirements for the degree of:

### DOCTOR OF PHILOSOPHY IN BEHAVIOURAL SCIENCE

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Beatrice Murawski

19/04/2019

### Acknowledgement by the Supervisors

By signing below, I confirm that Beatrice Murawski contributed as follows to the published paper/s/scholarly work presented in Chapters 3 through 7, for which I am a co-author.

For all publications/scholarly work, where applicable, Beatrice has:

- Contributed to the development of research questions
- Contributed to the conceptualisation of research design and methods
- Contributed to the development and modification of data collection tools
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### **PUBLICATIONS ARISING FROM THIS THESIS**

Five of the eight chapter of this thesis form a series of papers of which I, Beatrice Murawski, am the lead author. At the time of the final submission, three of these papers were published and two papers were under review.

#### Manuscripts in peer-reviewed journals

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**Murawski B**, Wade L, Plotnikoff RC, Lubans DR, Duncan MJ. A systematic review and meta-analysis of cognitive and behavioral interventions to improve sleep health in adults without sleep disorders. Sleep Med Rev 40 (2018) 160–169.

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Duncan MJ, **Murawski B**, Short CE, Rebar AL, Schoeppe S, Alley S, Vandelanotte C, Kirwan M, Activity trackers implement different behaviour change techniques for activity, sleep and sedentary behaviours. Interact J Med Res (2017) doi:10.2196/ijmr.6685.

Rayward AT, **Murawski B**, Plotnikoff RC, Vandelanotte C, Brown WJ, Holliday EG, Duncan MJ. A randomised controlled trial to test the efficacy of an m-health delivered physical activity and sleep intervention to improve sleep quality in middle-aged adults: The Refresh Study Protocol, Contemp Clin Trials 73 (2018) 36-50.

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Duncan MJ, Brown WJ, Burrows TL, Collins CE, Fenton S, Glozier N, Kolt GS, Morgan PJ, Hensley M, Holliday EG, **Murawski B**, Plotnikoff RC, Rayward AT, Stamatakis E, Vandelanotte C. Examining the efficacy of a multicomponent m-Health physical activity, diet and sleep intervention for weight loss in overweight and obese adults: randomised controlled trial protocol. BMJ Open (2018) 8:e026179.

Oftedal S, Burrows T, Fenton S, **Murawski B**, Rayward AT, Duncan MJ. Feasibility and preliminary efficacy of an m-health intervention targeting physical activity, diet and sleep quality in shift-workers. Int J Env Res Pub He 16(20) (2019) 3810.

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### LIST OF ABBREVIATIONS

AAQ	Active Australia Questionnaire
ABS	Australian Bureau of Statistics
ANZCTR	Australian New Zealand Clinical Trials Registry
ARIA	Accessibility and Remoteness Index of Australia
BCF	Baseline carried forward
BCTs	Behaviour change techniques
BMI	Body mass index
CAMPUS	Cognitive-Affective Model of Perceived User Satisfaction
CBT-I	Cognitive Behavioural Therapy for Insomnia
CG	Control group
CHD	Coronary heart disease
CI	Confidence interval
CVD	Cardiovascular disease
DALY	Disability-adjusted life years
EM	Expectation Maximisation
ESS	Epworth Sleepiness Scale
GLMM	Generalised linear mixed models
GP	General practitioner
HR	Hazard ratio
HREC	Human Research Ethics Committee
HRQOL	Health-related quality of life
ICC	Intra-class correlation coefficient
ICTRP	International Clinical Trials Registry Platform
IG	Intervention group
ISI	Insomnia Severity Index
KMO	Kaiser-Meyer-Olkin
LPA	Light physical activity
Μ	Mean
MET	Metabolic Equivalents of Task
MOS-SLP9	Medical Outcomes Study Sleep Problem Index-II
MVPA	Moderate-to-vigorous intensity physical activity
NHANES	National Health and Nutrition Examination Survey

OSA	Obstructive sleep apnoea
OR	Odds ratio
PA	Physical activity
PCA	Principal component analysis
PMR	Progressive muscle relaxation
PRCPAN	Priority Research Centre for Physical Activity and Nutrition
PSQI	Pittsburgh Sleep Quality Index
QOL	Quality of life
QWB	Quality of well-being
RCT	Randomised controlled trial
RR	Risk ratio
RSS	Research Student Support
RT	Resistance training
SCT	Social Cognitive Theory
SD/SE	Standard deviation/standard error
SHI	Sleep Hygiene Index
SMD	Standardised mean difference
SOL	Sleep onset latency
STEPS	Sleep Treatment and Education Program for Students
TST	Total sleep time
VPA	Vigorous physical activity
WASO	Wake after sleep onset
WHO	World Health Organization

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### **THESIS ABSTRACT**

### Background

Large proportions of the adult population report insufficient physical activity and poor sleep health in the absence of a clinical sleep disorder. Both behaviours have a substantial impact on overall health and well-being and are thought to share a bi-directional relationship. This implies insufficient physical activity and poor sleep health should be targeted in combination. Intervention strategies that are delivered using mobile health (mhealth) solutions show promising effects and improve the reach of behaviour change interventions to improve public health. To date, there is no published evidence to show that an m-health trial to improve physical activity and sleep health in combination would be efficacious. Though key to the development of such a trial, no previous reviews have compiled the evidence from sleep interventions with particular focus on adults who report poor sleep health without a clinically-diagnosed sleep disorder. Moreover, there is limited understanding of the psychosocial mechanisms in a behaviour change intervention targeting multiple behaviours, and there are no instruments available to measure these mechanisms in the context of sleep health.

### Objectives

To address these gaps, the thesis had one primary aim and three related secondary aims. The primary thesis aim was to test the efficacy of a theory-based m-health intervention (The Synergy Study) to improve physical activity and sleep quality in adults. The three secondary thesis aims were: (1) to review the evidence from studies that have examined the effectiveness of cognitive and behavioural interventions to improve sleep health in adults without sleep disorders; (2) to develop and test the psychometric qualities of an instrument for the assessment of the psychosocial determinants of sleep hygiene practice; and, (3) to examine potential mediators of changes in physical activity, sleep quality and sleep hygiene in the Synergy Study.

#### **Methods and Results**

#### Primary Aim (Chapter 6)

The Primary Aim was investigated in the Synergy Study, a two-arm randomised waitlistcontrolled trial including 160 Australian adults reporting insufficient physical activity and poor sleep quality at screening. The intervention consisted of a mobile application (referred to as 'app') that was built for participants to utilise educational resources, goalsetting, self-monitoring and feedback strategies. In addition, participants received personalised support including weekly progress reports, tool sheets and prompts for 12 weeks. The primary endpoint of the intervention occurred at three months and participants completed follow-up assessments at six months. All assessments were conducted online using self-report measures. Minutes of moderate-to-vigorous intensity physical activity (MVPA) and sleep quality were co-primary outcomes and the study also assessed a range of secondary outcomes (i.e., resistance training, sitting time, sleep hygiene, sleep timing variability, insomnia severity, daytime sleepiness, quality of life, and depression, anxiety and stress symptoms). Baseline-adjusted between-group differences using complete cases were examined using generalised linear mixed models and logistic regression models. sensitivity analyses were conducted following predicted mean matching and chained equation modelling to impute missing data. The Synergy Study showed that compared to the control group, participants who received the intervention reported significantly better sleep quality at three months (p = 0.009), but not at six months. There was no evidence of an intervention effect on MVPA (p = 0.139). At three months, significant betweengroups differences in favour of the intervention were observed for the following secondary outcomes: resistance training (p = 0.004), subjective sleep quality (p = 0.017), sleep onset latency (p = 0.013), waketime variability (p = 0.018), sleep hygiene (p =0.027), insomnia severity (p = 0.002) and stress symptoms (p = 0.003). At six months, the majority of these differences were maintained, and additional improvements were found for bedtime variability (p = 0.023), sleepiness (p < 0.001), daytime dysfunction (p= 0.039) and anxiety symptoms (p = 0.003).

#### Secondary Aim 1 (Chapter 3)

Four major electronic databases were searched using pre-defined search strings to locate original research published as English language full-text. Two reviewers independently

screened and selected eligible articles, extracted data and assessed study quality. The synthesis provided a descriptive summary of study characteristics and quantitative results based on meta-analyses using random-effects models. Combined estimates were presented using Hedge's g. Established methods were used to assess between-study heterogeneity (Q-statistics, I-statistics), publication bias (Rosenthal's classic failsafe N) and the impact of unpublished data (Duval and Tweedie's trim and fill method). This study showed that cognitive and behavioural interventions improve sleep quality in adults with poor sleep health who do not have a clinical sleep disorder (g = -0.54).

#### Secondary Aim 2 (Chapter 4)

Existing items to assess the psychosocial determinants (i.e.., self-efficacy, perceived capability, environment, social support, intention and planning) of physical activity and diet were adapted to focus on practices pertaining to sleep hygiene such as keeping regular bed and wake times, reducing the impact of stimuli and exercising regularly. Baseline data from the Synergy Study were analysed to examine scale unidimensionality by way of Principal Component Analyses. Measures of the scales' internal consistency were reported as Cronbach's alphas. A separate sample including 20 participants was recruited to assess levels of test-retest reliability using intra-class correlation coefficients. The new instrument consisted of seven scales and demonstrated acceptable psychometric qualities with good to excellent internal consistency ( $\alpha = 0.76-0.92$ ) and good to excellent test-retest reliability (ICC = 0.61-0.84).

#### Secondary Aim 3 (Chapter 7)

Using data from the Synergy Study, this aim was addressed in a mediation analysis. For the purpose of this study, missing data were imputed using Expectation Maximisation. A range of psychosocial factors were hypothesised to mediate changes in physical activity, sleep quality and sleep hygiene as a result of the intervention. In addition, physical activity was examined as a behavioural mediator of sleep quality and vice versa; and sleep hygiene as a mediator of changes in sleep quality. Each of the hypothesised causal chains was assessed in a single mediator model. Following Preacher and Hayes' approach to mediation analysis, bias-corrected bootstrapped confidence intervals, calculated using PROCESS 2 for SPSS were used for the interpretation of results. The analyses demonstrated that MVPA was mediated by a number of psychosocial factors (i.e., self-

efficacy, perceived capability, environment, social support, intention and planning). Neither of the two sleep outcomes (sleep quality and sleep hygiene) were mediated by any of the hypothesised psychosocial mediators. There was no evidence for a bidirectional relationship between physical activity and sleep quality. However, sleep hygiene mediated sleep quality.

#### Conclusion

The thesis presents new findings on how to improve physical activity and sleep health in combination using an m-health intervention that incorporated personalised support, with particular focus on insufficient physical activity and poor sleep health in adults without diagnosed sleep disorders. Furthermore, it provides a new method to assess the psychosocial determinants of sleep hygiene practice, which is key to the promotion of good sleep health; and offers novel insights into the role these psychosocial factors play as mechanisms (mediators) of intervention efficacy in a multiple behaviour change intervention. Supported by the findings arising from the thesis and in the context of previous research, a number of gaps remain to be addressed in future studies. Additional multiple health behaviour trials with potential for wide reach are needed to make health behaviour strategies accessible to a large proportion of the general adult population. These studies should aim to recruit samples that are representative of the general adult population (i.e., increase proportion of male participants and those with low socioeconomic status). More studies with specific focus on individuals with sub-clinical sleep problems are needed to broaden the extent to which the evidence pinpoints effective interventions in this population group. Lastly, the overall understanding of the psychosocial mechanisms of behaviour change in multiple behaviour interventions, the measurement of, as well as investigations into these mechanisms also require additional attention. Taken together, this knowledge could have the potential to improve public health.

### **CHAPTER 1. INTRODUCTION**

Chapter 1 provides the overall rationale for the studies presented in this thesis. It lists the thesis aims developed to address this rationale and related gaps in the literature, followed by an overview of the thesis structure.

### 1.1 Rationale

In healthy individuals, any given 24-hour cycle is characterised by sustained engagement in, or intermittent shifting between, different movement behaviours. These movement behaviours can be placed on a continuum ranging from sleep, to sedentary behaviour, to light or low-intensity physical activity through to moderate-to-vigorous intensity physical activity (see Figure 1.1) [1].

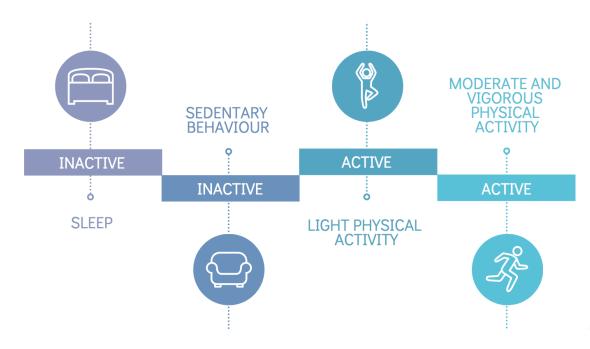


Figure 1.1. An illustration of the movement behaviour continuum

Each behaviour on this continuum contributes to total daily energy expenditure and influences a person's disposition to disease and premature death [2,3]. For optimal wellbeing, adults are encouraged to obtain sufficient sleep (good quality sleep of adequate duration), minimise prolonged periods of sedentary time and be physically active [4]. However, the majority of adults obtain insufficient sleep, engage in excessive and prolonged sedentary time and/or are insufficiently physically active [5]. At 80% and 56%, respectively, insufficient (i.e., less than recommended) physical activity and poor sleep health are highly prevalent [6,7]; hence, both risk behaviours can be considered major public health concerns. Moreover, there is evidence that many adults (52%) report both being insufficiently physically active and having poor sleep health [8,9], which may put those individuals at even greater risk of chronic disease and premature mortality [10]. Therefore, an intervention that aims to improve both physical activity and sleep health, has the potential to yield greater health outcomes than an intervention that targets a single behaviour [11]. In support of global promotions targeting physical activity and sleep health, scalable multi-behaviour interventions are needed [4,12].

Despite past and ongoing efforts to prompt changes in health behaviour by way of scientific trials, educational campaigns and regional and local health schemes [13], insufficient physical activity continues to be a public health concern [6]. Poor sleep health, on the other hand, has been understudied in a public health context, with the majority of research having focussed on clinical sleep disorders [14]. Systematic reviews show that interventions to improve physical activity, across a variety of delivery modes, settings and population groups, have small to moderate effects on physical activity (d =0.20-0.30) and fail to demonstrate maintenance effects at long-term follow-up (>15 months) [15–17]. While there is robust evidence showing that clinical sleep treatments such as Cognitive Behavioural Therapy for Insomnia (CBT-I) improve sleep quality ( $d \approx$ 0.40) [18,19], comparatively little is known about sleep interventions that specifically target individuals not suffering from clinical sleep disorders. Non-clinical interventions usually are conducted in highly homogenous population groups (e.g., college students) and limited by their purely educational nature, and to date, have provided mixed evidence [20,21]. Given that a high proportion of adults with poor sleep health do not have a clinical sleep disorder, it is important to determine which interventions are efficacious in this population group.

The purpose of this thesis is to improve the understanding of how physical activity and sleep health can be improved concurrently in adults without a sleep disorder and to examine the psychosocial mechanisms that influence behaviour change in this context. The thesis is presented as a series of individual studies that are linked to this overarching aim. The specific aims of the thesis are presented below.

### 1.2 Research aims of this thesis

**Primary Aim:** To test the efficacy of an intervention (the Synergy Study) to improve adults' physical activity and sleep quality in combination using a theory-based mobile health approach.

**Secondary Aim 1:** To synthesise the evidence from sleep interventions in adults who report poor sleep health but do not have a clinically diagnosed sleep disorder and to describe the components and strategies used in these interventions.

**Secondary Aim 2:** To develop an instrument to assess the psychosocial determinants of sleep hygiene practice and to test the instrument for its psychometric qualities.

**Secondary** Aim 3: To examine the psychosocial and behavioural mediators of intervention efficacy in the Synergy Study and to determine whether these mediators differ between physical activity and sleep quality and sleep hygiene.

### 1.3 Thesis structure

The thesis is organised into eight chapters. This introduction is followed by a literature review and five chapters that address the thesis' aims (Chapters 3–7). Chapters 3 to 7 are presented in journal article format. The final chapter provides an integrated discussion including a summary for each study and directions for future research.

At the time of submission of this thesis, three out of the five studies were published or revised for publication and two studies were under review. Due to the studies in this thesis having been published individually, there is some replication of information in these chapters. Studies that were previously published using American English spelling and punctuation (in line with journal requirements) have been converted to Australian English spelling and punctuation to provide consistency throughout the thesis.

#### 1.3.1 Chapter 1: Introduction

The opening chapter of this thesis has introduced the rationale for intervening in physical activity and sleep in combination, based on their independent and joint influences on health.

#### 1.3.2 Chapter 2: Literature review

The second chapter provides a summary of the literature. It describes the amount of physical activity and sleep recommended for adults and the health benefits associated with sufficient physical activity and good sleep health. It also provides an overview of the prevalence of insufficient physical activity and poor sleep health and the associated economic burden. These sections are followed by a brief summary of factors associated with physical activity and sleep and a summary of findings from interventions to improve physical activity, and those targeting adults who report poor sleep health but who do not have a clinical sleep disorder. The literature review then explores the co-occurrence of physical activity and sleep and how the two behaviours affect each other. This is followed by a brief summary of the evidence from previous intervention studies that have attempted to combine physical activity and sleep, while the final section describes the theoretical frameworks that have guided the work presented in this thesis.

#### 1.3.3 Chapter 3: Systematic review and meta-analysis

A systematic review with meta-analysis was conducted to examine the efficacy of cognitive and behavioural interventions to improve sleep health in adults without sleep disorders (Secondary Aim 1). Chapter 3 presents the version of the study that was published in *Sleep Medicine Reviews* (2017/2018 Impact Factor: 10.602) [22].

#### 1.3.4 Chapter 4: Instrument development and psychometric evaluation

The fourth chapter presents the findings from a study that developed an instrument to assess the psychosocial determinants of sleep hygiene and examined the psychometric qualities of the scales (Secondary Aim 2). Revisions of the manuscript of this study are currently under review [23].

#### 1.3.5 Chapter 5: Study Protocol

A protocol that described the rationale and development of an intervention to improve adult physical activity and sleep, the Synergy Study, was published in *BMJ Open* (2017/2018 Impact Factor: 2.413) [24]. This paper is presented in Chapter 5.

#### **1.3.6 Chapter 6: Empirical evaluation of intervention efficacy (Study outcomes)**

The sixth chapter follows with the main findings from the Synergy Study including all primary and secondary outcomes assessed at three and six months. The manuscript of this study was published in the *American Journal of Preventive Medicine* (2017/2018 Impact Factor: 4.127) [25].

# **1.3.7** Chapter 7: Explanatory evaluation of intervention efficacy (Mediation analyses)

Chapter 7 presents findings from a study of potential mechanisms (mediators) of intervention efficacy in the Synergy Study (Secondary Aim 3). The manuscript of this study is currently under review [26].

#### 1.3.8 Chapter 8: Discussion

The final chapter of this thesis summarises the findings from the studies outlined above and appraises each study for its strengths and weaknesses. The chapter concludes with recommendations for future research and comments on the overall significance of the contributions that arose from this research.

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# **CHAPTER 2. LITERATURE REVIEW**

The objective of Chapter 2 is to give an overview of the literature related to the health benefits of physical activity and sleep, and the correlates and determinants of these behaviours. The chapter also provides a summary of the efficacy of interventions targeting physical activity and sleep health – individually and in combination, the co-occurrence and bi-directionality of physical activity and sleep health and concludes with a summary of theoretical frameworks of health behaviour.

## 2.1 Physical activity

Physical activity is defined as any movement of the body caused by muscular activation that causes changes in energy expenditure [1]. Physical activity occurs during, but is not limited to exercise, organised or leisure-time sport, work-related tasks or household chores [1], and is typically described by level of intensity. Moderate-intensity physical activity typically causes an increase in heart and breathing rates, but still allows a person to have a conversation, while vigorous-intensity physical activity causes a person's heart to beat rapidly and is accompanied by a shortness in breath that makes it too difficult to have a conversation [2].

The World Health Organization (WHO) lists a number of reasons for physical inactivity in otherwise healthy adults. These include lower levels of leisure-time and occupational activity, the use of motor vehicles as a preferred mode of transport and changes in urban design and density, which have unfavourable effects on physical activity due to increased violence, traffic, pollution and the lack of space that promotes physical activity (e.g., parks, sidewalks) [3]. At an intrapersonal level, the most commonly reported barriers to uptake and maintenance of regular physical activity are lack of time, limited accessibility, costs, as well as attitudes, cognitions and behaviours that do not support physical activity [4].

## 2.1.1 Physical activity recommendations for adults

Studies have shown that even small amounts of physical activity can have positive effects on overall health and well-being [5]. However, for optimal health, the Australian 'Physical Activity and Sedentary Behaviour Guidelines' advise adults engage in physical activity on most or all days of the week [6]. The recommended cumulative minimum per week is 150 minutes of physical activity at moderate intensity or 75 minutes at vigorous intensity – or any combination of the two – complemented by activities with particular effect on muscle strength (e.g., resistance training) on at least two days per week [6].

### 2.1.2 Health benefits associated with sufficient physical activity

Population data from Australian adults suggest that substantial reductions (13-26%) in disease burden, including heart disease, dementia, diabetes and some types of cancer, can be achieved through regular physical activity [7]. A study including data from 130,000 participants in 17 different countries examined the benefits of physical activity and found for those who engaged in sufficient physical activity (150-750 min/week), the risk of allcause mortality was 28% lower and the risk of cardiovascular disease (CVD) was 20% lower, with additional risk reductions of 19% and 12%, respectively observed for those who reported higher levels of physical activity (>750 min/week) [8]. In addition to reduced risks of chronic disease and early mortality, the promotion of physical activity is driven by the broad spectrum of benefits it confers, such as weight management, maintenance of muscle tone and bone density, altered brain plasticity, improved sleep and enhanced mental health (including mood, depression and anxiety) [9-12]. A systematic review has shown consistent positive associations between physical activity and perceived quality of life in various population groups (i.e., healthy adults, elderly and comorbid populations) [13]. This is consistent across all sub-domains that comprise quality of life, including physical health, mental health and social and emotional well-being [14].

The magnitude of health benefits from physical activity can vary by volume, intensity (i.e., light, moderate, vigorous) and type (e.g., cycling, tennis) of physical activity, but there appears to be no lower threshold of activity at which health benefits accrue [5,15,16]. Therefore, interventions should encourage any degree of increase in the amount of physical activity individuals would typically engage in, whilst guiding study participants to work towards meeting or exceeding physical activity guidelines to maximise health benefits. With particular focus on the benefits of a given dose and intensity of physical activity, a systematic review has shown that moderate-to-vigorous intensity physical activity (MVPA) of 60–75 minutes per day can offset the risk of any amount of daily sedentary behaviour on cardiovascular disease mortality [17]. In addition, studies have shown that the health risks associated with prolonged sitting time can be reduced by breaking up longer periods of sitting with short bouts of light-intensity

physical activity (e.g., 2-minute bouts of walking every 20 minutes) [18]. Although considerable support for light-intensity, or *incidental* physical activity has emerged in the literature [19,20], the evidence shows that MVPA still confers greater overall health benefits than light-intensity physical activity, making it the target behaviour with best return on investment [21]. It is important to note however, that the strength of association between physical activity and specific health benefits/risks varies depending on which method is used to measure these variables. For example, in comparison to self-report, the negative associations between MVPA and multiple markers of overweight and obesity (i.e., BMI, waist circumference, percent body fat) are more pronounced for objectively measured physical activity [22]. This may indicate that many large cohort studies, which solely rely on self-report data underestimate the risks associated with insufficient physical activity.

Resistance training (also referred to as *muscle strengthening exercise* [6]) is another, mostly anaerobic type of physical activity with promising effects on health that appear to be pertinent in a wide range of population groups (e.g., those with co-morbidities and individuals of various age groups) [23-25]. The evidence shows regular resistance training reduces the risk of early death by 23% [26]. This risk is further reduced in those who meet guidelines for both aerobic exercise *and* resistance training (29% risk reduction relative to those not meeting guidelines) [26]. Nonetheless, resistance training is infrequently targeted as part of intervention studies that aim to improve physical activity [27]. Given the added health benefits, interventions targeting physical activity should incorporate resistance training to better leverage its potential to enhance gains from participation in aerobic exercise [28].

## 2.1.3 The prevalence of insufficient physical activity

Physical inactivity is one of four key factors contributing to the worldwide pandemic of CVD [29]. According to the World Health Organization's (WHO), approximately one third of adults worldwide are not sufficiently active, with some population groups reporting a prevalence of insufficient physical activity as high as 80% [12]. In Australia, less than 50% of adults meet the recommended amount of moderate- and vigorous-intensity physical activity (aerobic exercise), less than a quarter meet resistance training guidelines and only 15% meet both, aerobic exercise *and* resistance training guidelines [30,31]. Only a very small proportion (11%) of adults accumulate levels of physical

activity (defined in this study as at least 8000 METs per week) that are thought to eliminate chronic disease risks, with a larger proportion of male adults participating in higher levels of physical activity compared to females [7].

### 2.1.4 The economic burden associated with insufficient physical activity

A reduction in the global prevalence of physical inactivity by 10% to 25% could help prevent between 533,000 and 1.3 million deaths per year [32]. In 2013, the global economic burden associated with insufficient physical activity totalled 67.5 million US Dollars (US\$) of direct and indirect costs and more than 13.4 million disability-adjusted years of life (DALYs) [33]. In 2013, the estimated economic burden in Australia due to physical inactivity equated to approximately 805 million Australian Dollars (AU\$), made up of 640 million in direct costs (i.e., healthcare) and 165 million in indirect costs (e.g., productivity loss) [33]. These figures highlight the need for effective interventions with wide reach [34].

## 2.1.5 Factors associated with physical activity

Like many other health behaviours (e.g., diet, sleep), regular participation in physical activity is influenced by numerous factors, most of which interact in complex and dynamic ways [35]. These factors can help identify target groups that are most in need (e.g., subgroups of the population that are least likely to be physically active), but interventions may also address specific factors to maximise behaviour change. Therefore, the conceptualisation of effective physical activity interventions requires a good understanding of these factors. An overview of correlates and determinants that are known to influence physical activity is provided in Table 2.1.

Ecological models acknowledge that health behaviour and behaviour change depend on a range of different factors that may act as correlates and/or as determinants of behaviour [36]. The various levels on which these factors can be placed comprise the intrapersonal, interpersonal, organisational, community and public policy levels [36]. It is noteworthy that ecological models are not exclusive to a single theory but provide a framework that accommodates a large variety of theoretical constructs [36]. The literature also suggests interventions targeting multiple levels may be more effective than those with a focus on factors at a single level [36]. However, this is not always feasible due to the constraints of many clinical trials (i.e., time, funding). Although the following sections acknowledge the influence of factors within a person's broader environment, those at the intrapersonal level were of main interest in this thesis, since the Synergy Study (Chapter 5) was conceptualised to target behaviour change at the individual level using an intervention that is potentially scalable.

## Factors at the individual level

The sociodemographic variables associated with physical activity are well established [37]. Younger age and male gender are consistently correlated with higher physical activity levels [38]. The same applies for individuals with higher education levels, lower body weight, better health status and lower stress levels [38]. The Australian Health Survey 2011–12 found that nationwide, higher levels of physical activity were associated with a higher household income, better self-assessed health, and lower body mass index (BMI) [39].

A large number of studies have been undertaken to also identify psychosocial and behavioural correlates of physical activity [40]. These may include a person's history of physical activity (e.g., past exercise behaviour) [41], as well as cognitions and perceptions related to physical activity (e.g., self-efficacy, intentions) [38], which are known to bolster a person's likelihood of being physically active [42]. Based on systematic reviews of the evidence, further factors that are consistently positively associated with the initiation and/or the maintenance of physical activity include, but are not limited to being habitually physically active, intending to be physically active, having high levels of selfefficacy and perceived behavioural control, outcome expectations and self-regulatory skills (e.g., goal-setting, planning) [43,44]. At the behavioural level, the evidence shows individuals who do not engage in other risk behaviours (e.g., smoking) are more likely to be more physically active [44]. Moreover, multiple indicators of sleep health are also associated with physical activity. As summarised in a review of the bi-directional relationship between physical activity and sleep [45], poor quality sleep is predictive of lower physical activity not only in the short term (i.e., the following day) [46] but also in the longer term (up to two years later) [47]. Consistent with the focus of this thesis, a more detailed summary describing the bi-directional associations between physical activity and sleep is provided in Section 2.3.

The use of technology is an additional factor with substantial impact on health behaviour [48]. Studies have shown that adults who watch more TV and those who accumulate additional screen-time from computer and Internet use are more likely to be physically inactive than those who accumulate less screen-time (i.e., less TV exposure and less time using computers or the Internet due to not having permanent access) [49,50]. Screen-time is thought to cultivate engagement in prolonged periods of sedentary time, which tends to be inversely associated with overall physical activity [51].

## Factors at the social level

The level of support a person receives from friends, peers and family members can have a strong influence on activity uptake and long-term participation [44]. Studies have shown that social support, having friends who also exercise and exercising together with others (i.e., in groups) were factors that consistently predict activity levels [38,41,52,53]. The cultural norms and beliefs of the social environment a person identifies with also influence health behaviour. For example, individuals from cultures or social groups that favour physical activity have increased odds of meeting physical activity guidelines (OR = 1.47) [54]. Thus, an understanding of these factors is important when developing interventions for potentially diverse groups of participants [55].

### Factors at the environmental level

Correlates of physical activity at the environmental level include the natural and built environment (i.e., surroundings, facilities) [36]. A review of reviews showed consistent associations for factors such as access to physical activity facilities, high residential density, the availability of exercise equipment and a high level of perceived 'walkability' (defined as a set of environmental attributes associated with increased probability of walking) [56]. Perceptions of neighbourhood safety are also known to be associated with physical activity and tend to depend on the presence of structures such as sidewalks and lighting, as well as low levels of crime in an area, all of which are associated with higher levels of physical activity [57].

## 2.1.6 Interventions to improve physical activity in the adult population

Interventions to improve physical activity can be delivered using a variety of modes including face-to-face contact and technology-based options (e.g., delivered through a website or smartphone app. The evidence shows that traditional (i.e., face-to-face

delivered) physical activity interventions are effective, but on average yield only moderate effects (Cohen's  $d \approx 0.30$ ) [59,60]. Several factors, including personal contact, are known to contribute to intervention effectiveness [61] but this limits the scalability of an intervention [62]. Given the high prevalence of physical inactivity, interventions with wide-reaching potential are needed, for which a technology-based approach is favourable over one requiring face-to-face contact [63].

Technology-based intervention delivery has been described as a useful avenue for the promotion of behaviour change [64,65], and typically includes components such as websites, Email, and/or interactive phone technology (mobile apps) [66]. Technologybased interventions commonly utilise digital media that are deemed to have an influential presence in many people's lives and the added advantage of being cost-effective and accessible from varying locations [65,67]. A systematic review of technology-based (i.e., web-based) interventions to improve physical activity in adults concluded that approximately 62% of interventions included in the synthesis achieved significant changes in physical activity [68]; however, estimates were not pooled in this study to obtain an overall effect size. Moreover, this review also showed technology-based interventions were as effective as those involving face-to-face contact or non-digital (print-based) components and efficacy did not differ between interventions targeting multiple behaviours and those targeting physical activity as a single behaviour [68]. In line with the scope of this thesis, the following section focuses on physical activity interventions delivered primarily using mobile health (m-health) solutions, which represent one of many technology-based delivery modes.

M-health is defined as "medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants, and other wireless devices" [69]. Individual m-health interventions have shown promising improvements in health behaviour (i.e., physical activity) [70,71]. Goal-setting and self-monitoring are two commonly operationalised m-health features and both are associated with greater intervention efficacy [72]. Though promising, the overall effects shown in m-health trials are of small to moderate magnitude and some meta-analyses have shown that the observed improvements in physical activity frequently lack statistical significance [73,74]. Thus, as highlighted in reviews of the rapidly emerging evidence, there is a need for additional studies and stronger research designs before clear conclusions about the effectiveness of m-health interventions can be drawn [70,75].

## Table 2.1

# Summary of correlates and determinants of adult physical activity

		Trost [41]	Bauman [38]		Rhodes* [58]	
		Correlates	Correlates	Determinants	Correlates	
Individual Level	Age	_	_	?	?	
	Gender (male)	+	+	?	?	
	Ethnicity (white)	+	+	?	?	
	Higher education	NR	+	?	NR	
	Higher income	+	+	?	?	
	Risk behaviour (e.g., drug use)	NR	_	?	+	
	Alcohol	?	NR	NR	?	
	Smoking	_	NR	NR	?	
	Overweight/obesity	_	_	?	NR	
	Health status	NR	+	+	+	
	Hypertension	NR	_	?	NR	
	Depression	NR	_	?	NR	
	Stress	?	?	_	NR	
	Attitudes	?	NR	NR	?	
	Barriers to exercise	_	_	?	?	
	Expectations (benefits/outcomes)	+	?	+	?	
	Intention to exercise	+	+	+	+	

## Table 2.1

Individual Level		<b>Trost</b> [41]	Bauman [38]		Rhodes* [58
		Correlates	Correlates	Determinants	Correlates
	Self-efficacy	+ +	+ +	+ +	+ NR
	Stage of change (level of readiness)				
	Previous physical activity	+	+	+	NR
	Perceived effort	_	_	?	NR
	Action planning	NR	?	+	NR
Social Level	Marital status	_	?	?	?
	Occupation (blue collar)		-	?	NR
	Occupational status (employed)	NR	NR	NR	?
	Job strain	NR	_	?	NR
	Working hours	NR	_	?	NR
	Working overtime	NR	_	?	NR
	Social isolation	_	NR	NR	NR
	Social support (general)	NR	+	?	+
	Social support (spouse/family)	+	+	?	NR
	Social/subjective norms	NR	Х	?	+
	Observation of others exercising	+	NR	NR	NR

# Summary of correlates and determinants of adult physical activity

## Table 2.1

## Summary of correlates and determinants of adult physical activity

		Trost [41]	Bauman [38]		Rhodes* [58]
		Correlates	Correlates	Determinants	Correlates
Environmental Level	Access to facilities	+	+	?	NR
	Proximity to facilities	NR	+	?	NR
	Footpaths/trails	NR	+	NR	NR
	Walkability	NR	+	?	NR
	Perceived aesthetics	NR	+	?	NR
	Heavy traffic	?	NR	NR	NR
	Hilly terrain	+	NR	NR	NR
	Neighbourhood safety	+	NR	NR	NR
	Presence of sidewalks	?	NR	?	NR
	Unattended dogs	?	NR	NR	NR
	Urban locations	_	+	?	NR
	Coastal residence	NR	NR	NR	NR
	Connectivity (street grid)	NR	+	?	NR
	Urban locations	_	+	?	NR

*Note.* + positively associated; – negatively/inversely associated; ? not associated or inconclusive; NR not reported/examined; associations may apply to different subgroups (e.g., middle-aged adults) or specific types of physical activity (e.g., leisure-time physical activity); \* this review focused specifically on factors influencing resistance training; NB. This table is not intended to provide a full account of the evidence that is available, but rather a representation of the large variety of factors across different levels. Therefore, only factors that were examined by at least two comprehensive reviews are listed.

A review of app-based interventions including 21 studies to improve physical activity, most of which showed promising effects, found that using a mixture of components for the delivery of an intervention (e.g., app combined with text messages or other materials), rather than relying on intervention delivery through an app alone showed greater effects [75]. There is concern about commercially available apps failing to incorporate evidence-based behaviour change techniques (BCTs), such as those frequently reported in research-specific apps (e.g., feedback, self-monitoring, goal-setting), and placing major emphasis on a high level of aesthetic appeal and functionality [76]. Thus, many intervention trials use specifically developed apps to ensure the standardisation of contents, use of evidence-based strategies and unrestricted monitoring of app usage [77].

Alongside the many advantages and novel opportunities for providers and participants [78], digitalised solutions also introduce unique challenges such as homogenous study samples (e.g., self-selection bias and overrepresentation of female participants), low adherence and high attrition rates [68,71,79-81]. There is however, no clear evidence that shows these limitations can be overcome by the introduction of a face-to-face component.

# 2.1.7 Factors influencing the efficacy of technology-based physical activity interventions

A number of factors influence the magnitude of improvement in technology-based physical activity interventions. For example, greater effects are observed for participants who report lower baseline activity levels and therefore have more room for improvement [67]. In the context of intervention delivery, studies with multiple exposure points (spread over periods of two to 12 months), those with a longer overall intervention period, more frequent contact, a dynamic user interface and some level of tailoring (e.g., personalised feedback in relation to progress/goals) were found to be more effective, relative to studies with fewer points of exposure, shorter duration, less frequent contact, a more static user interface and little tailoring [67,68,82]. The evidence also shows the use of educational materials enhances intervention effects, potentially by fostering uptake and adherence [67]. Previous studies have also indicated that app usage is positively associated with changes in health behaviour (i.e., physical activity) [75]. However, the optimal amount of app usage needed to maximise intervention effects remains to be defined. Further, it is possible that different patterns of usage (i.e., timing, frequency and intensity) are insufficiently understood to optimise behaviour change. Importantly, app usage metrics

represent only one of several measures that capture information about participants' engagement in m-health interventions [83]. Participant engagement is directly linked to intervention compliance and participant retention, both of which determine exposure and thus, influence the effect of an intervention on hypothesised outcomes [83]. A summary of methodologies measuring engagement in m-health interventions suggested that a combination of multiple methods, including those that acknowledge the importance of perceptions and other psychological factors (e.g., self-report measures such as usability or aesthetics) is likely to provide rich insights into engagement [83]. These measures may be used to better understand how participants engage with an intervention and how usage and engagement are related to behaviour change.

It is typically assumed that theoretically informed interventions are more effective than non-theory-based interventions [84,85]; however, a recent review suggested it is the composition of evidence-based intervention content (i.e., BCTs), rather than the use of theoretical frameworks that makes interventions effective [86]. This finding is consistent with that of a systematic review of web-based physical activity interventions, which reported that the proportion of interventions that yield significant improvements in physical activity is the same for theoretical interventions as for non-theoretical interventions [68]. Nonetheless, there are individual theoretical constructs, which appear to play an important role in the context of behaviour change. For example, a review of 27 physical activity interventions showed that most interventions that effectively improved self-efficacy were also effective in improving behaviour (i.e., physical activity) [87]. However, none of the studies included in this review were delivered using a mobile app. Further, there are no reviews that have examined psychosocial mediators of physical activity using m-health interventions in non-clinical population groups and it is unclear if such effects can be established in an m-health intervention combining multiple behaviours. It is possible that the lack of mediation analyses in this context is partially attributable to the lack of comprehensive and validated instruments to assess psychosocial factors as mediators of behaviour change. Although there is some evidence showing specific BCTs (i.e., goal-setting, self-monitoring) increase the efficacy of m-health interventions, it appears there are no studies that have examined if this occurs through changes in self-efficacy or other psychosocial factors [72]. Moreover, when tested as a mediator of intervention efficacy, the evidence becomes less conclusive, with only a fifth of mediation analyses identifying self-efficacy as a significant effect mediator [88].

Further psychosocial factors that were previously identified as mediators in physical activity interventions include self-regulatory processes and cognitions such as action planning and perceived behavioural control [88-90]. The evidence shows that an improvement in these mediators is associated with improvements in physical activity [88-90]. However, the overall evidence for the role of psychosocial constructs as mediators of behaviour change remains mixed and therefore requires further investigation [88]. It is plausible that some interventions do not succeed to change the exact same mechanism that was hypothesised to change as a result of exposure to the intervention, or that there are issues with the measurement of psychosocial mediating variables and how this aligns with theory [68].

The factors mentioned above may lend guidance on how to best conceptualise behaviour change interventions. A number of studies have examined the quantity of behaviour change techniques (BCTs) used in relation to intervention efficacy and found interventions that report using more BCTs are more effective than those reporting fewer BCTs [91]. However, it is also important to consider how individual components are implemented and presented to participants and which strategies are leveraged to stimulate behaviour change. A number of frameworks and taxonomies have been developed to facilitate the selection, implementation and description (i.e., reporting) of BCTs [92-95]. As seen in a review of 19 studies conducted in older adults, there are various BCTs with moderating effects on the long-term effectiveness of physical activity interventions (d =0.29) [96]. Studies, for example, that provided participants with feedback were more effective at increasing physical activity (d = 0.40) than studies that did not use feedback strategies (d = 0.19) [96]. This review also found that interventions were more effective (d = 0.42), if they provided instructions on how to be physically active, relative to interventions not providing instructions (d = 0.23) [96]. Studies that promote selfmonitoring of behaviour also show significantly greater effects than those without a selfmonitoring component [91,97]. Further, the evidence shows participants also gain confidence in their ability to engage in a given behaviour through specific and meaningful goal-setting, structured action planning and the positive reinforcement of efforts towards the behaviour [87,98]. Enhanced levels of perceived capability in turn predict engagement in physical activity [42,99]. Despite growing recognition for multi-behaviour interventions [100,101], there is relatively little understanding of how BCTs operate across two or more behaviours and further research is warranted to improve this.

## 2.2 Sleep health

Carskadon and Dement define sleep as "[...] a recurring, reversible neuro-behavioral state of relative perceptual disengagement from and unresponsiveness to the environment." [102]. Sleep health incorporates multiple indicators such as sleep quality, duration and timing, as well as feelings of satisfaction with sleep and alertness during wake times [103]. The concept of sleep health has emerged from a comparatively new field of research that distinguishes itself from traditional clinical sleep medicine, in that it maintains a strong focus on health promotion, rather than the treatment of sleep disorders [103]. For ease of exposition, the thesis refers to sleep health as a whole, except where specific knowledge on individual indicators of sleep health was available.

Causes of poor sleep health range from high levels of stress, to working nightshifts and having poor overall health, to environmental factors such as noise and light [104-106]. However, problems with sleep health are also frequently attributable to inadequate *sleep hygiene*, which involves practices such as the excessive consumption of caffeine and alcohol, or exposure to light-emitting devices (e.g., smartphones, computers, TVs) at bedtime [107,108]. Therefore, the promotion of sleep health commonly includes evidence-based recommendations that aim to improve sleep hygiene [106].

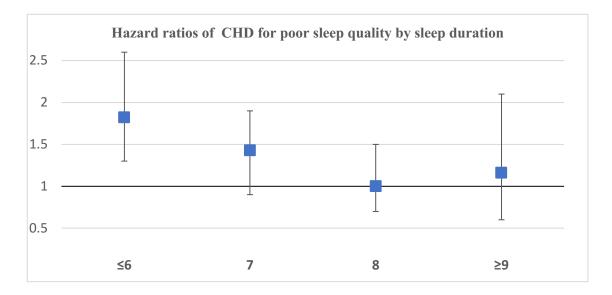
Clinical diagnosis of a sleep disorder (i.e., insomnia) according to DSM–5 criteria is based on a minimum duration of symptoms including distress or impairment in functioning due to difficulties initiating or maintaining sleep or suffering from nonrestorative sleep for at least one month [109]. Thus, any symptoms not meeting these criteria in regard to severity or duration can be considered sub-clinical.

## 2.2.1 Sleep recommendations for adults

Public health recommendations primarily focus on the duration of sleep and advise a total sleep time of seven to nine hours per night for adults (aged 18–64 years) to maintain optimal health [110]. However, several studies have highlighted that, not only the quantity of sleep but also the quality and timing of sleep, are important to maintain optimal health [111-114]. This further highlights the importance of promoting sleep health as a whole.

## 2.2.2 Health benefits associated with good sleep health

Individuals who achieve and maintain good sleep health have a lower chronic disease risk (e.g., heart disease, type-2 diabetes), tend to report greater emotional stability (e.g., mood) and find it easier to maintain a healthy weight [115-118]. For instance, compared with individuals who report optimal sleep duration (7–9 hours/night) and good sleep quality, the risk of coronary heart disease is up to 79% higher in those with sub-optimal sleep duration and poor sleep quality (see Figure 2.1) [119]. The evidence also shows consistent associations between sleep duration and the risk of early mortality [120-123]. However, for various health outcomes, the risks associated with sleep duration often follow a U-shaped curve, where risks (i.e., for chronic disease or mortality) tend to be lowest near the midpoint, typically approximating the seven-to-nine-hour window that is defined as optimal sleep duration [119,124,125]. It is possible however, that there are unique mechanisms causing an increase in chronic disease risk on either side of the window of optimal sleep duration, which is why it is important to assess and report both short and long sleep duration as separate outcomes [126].



*Figure 2.1.* Coronary heart disease (CHD) risk by sleep duration for individuals reporting poor sleep quality (reference group: good sleep quality). Graph reproduced based on data reported by Hoevenaar-Blom et al. (2011).

A study that assessed various cardiometabolic outcomes in relation to sleep duration and sleep insufficiency (perceived as sleep not having had a restorative effect; over the past month) in a population sample including 31,000 participants, reported that short sleep duration (<5h/night, relative to 7h/night) significantly predicted a greater BMI, higher blood pressure, higher levels of cholesterol as well as higher odds for heart attack and

stroke [127]. In this study, sleep insufficiency predicted a higher BMI, higher blood pressure and higher cholesterol levels, whereas long sleep duration (>9h/night, relative to 7h/night) predicted higher odds for heart attack and stroke [127]. It is noteworthy the literature (see Table 2.1) reports conflicting findings for a number of these relationships (e.g., CHD, obesity) [119,122,123,127-129]. However, this could be due to differences in how individual indicators of sleep health are measured and defined.

There is further evidence showing disrupted sleep and sub-optimal sleep duration are both associated with reduced quality of life (QOL) [108,130]; and sub-optimal sleep duration and poor sleep quality increase the risk of depression [131,132]. However, the relationship between sleep and depression is bi-directional in nature [133]. Similarly, some types of sleep disorders may develop as a result of poor health, which is the case for obstructive sleep appoea that is highly common in individuals who are either overweight or obese (up to 94% in obese men) [134,135]. This may exacerbate symptoms of poor sleep health that are already highly common in individuals with an unhealthy BMI. A cross-sectional study in younger adults (n = 2,100 University students) showed individuals with short sleep duration (<6h/night) are more likely to be overweight or obese than those who report 7–9h of sleep/night (OR = 2.72), as are young adults with long sleep duration (>10h/night; OR = 3.38) [136]. The likelihood of being overweight or obese is also higher (OR = 1.45) for those reporting poor quality sleep (defined as a PSQI score above 5), compared to individuals with good quality sleep (PSQI  $\leq$ 5) [136]. According to a recent review however, the overall evidence for a U-shaped relationship between sleep duration and obesity remains mixed, due to other studies showing no associations [137]. In addition, the cross-sectional associations reported for sleep duration and certain health outcomes (i.e., BMI, obesity) are not supported in longitudinal analyses [138,139]. This suggests additional research be conducted to examine causality in this relationship.

The benefits associated with optimal sleep health occur as a result of sufficient rest and recovery and are partly due to optimal hormone balance, enhanced cell metabolism and appropriate brain activation [140-143]. However, there is limited understanding of the underlying mechanisms for many of the unique relationships between other indicators of sleep health and health outcomes [123]. Much of the research examining the health effects of poor sleep health has either focussed on clinical populations or may or may not

statistically adjust for the presence of a clinical sleep disorder in analyses, and few studies examine the role of poor sleep in those without a clinically diagnosed disorder. The Australian Sleep Health Foundation has aimed to quantify this in a 2017 report, which showed that 20.7% of the Australian population reported insufficient sleep that was not due to a clinical disorder [144]. The overall health consequences of insufficient sleep in this group were associated with 8,655 DALYs in 2016–17, or 3.7% of the total DALYs associated with insufficient sleep [144]. This highlights the need for further research into poor sleep health, specifically targeting those with sub-clinical symptoms who may have no access to clinical treatment due to not meeting diagnostic criteria, yet still have an increased risk of ill health.

### 2.2.3 The prevalence of poor sleep health

It is estimated that globally, a quarter of adults indicate not sleeping well and more than 10% of individuals report high levels of sleepiness due to insufficient sleep [145]. Inadequate sleep duration is very common with up to 27% of the population sleeping less than seven and up to 41% sleeping more than nine hours per night [146,147]. National survey data from the United States have shown almost half the adult population (45%) reports having problems falling asleep at least once per week, while sleep quality ratings in the fair or poor categories are also very common (35%) [108]. These estimates vary considerably between countries, which is partly due to diverse population characteristics such as ethnicity and cultural practices (e.g., taking siestas) [148]. Available data indicate relative stability in sleep duration over time [147,149], and some countries even report a slow, but noticeable increase in sleep duration [150]. At the same time, it appears there is a rising demand for the treatment of sleep problems and an increase in the use of overthe-counter sleep medications [151,152]. An explanation for the rising prevalence of poor sleep health, despite seemingly consistent quantity of sleep (i.e., sleep duration), could be that the quality of sleep has decreased [147,153]. That is, sleep may have become more fragmented or disturbed due to cognitive restlessness, unsupportive daytime and bedtime behaviours, including greater variation in bed and wake times, as well as exposure to external stimuli (such as use of technology at bedtime). Global data however, are generally focused on sleep duration, which has resulted in a lack of insights into other parameters that comprise healthy sleep (e.g., sleep quality, sleep/wake timing, sleep continuity).

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Overview of sleep health indicators in relation to different health outcomes

	Short sleep (<5h/night)	Short sleep (<6h/night)	Long sleep (>9h/night)	Poor sleep quality	Difficulty falling asleep	Difficulty staying asleep
All-cause mortality [122,123]	NR	RR = 1.10	RR = 1.23	HR = 1.78° (age ≤45) HR = 1.70° (age >45)	HR = 1.78° (age ≤45) HR = 1.89° (age >45)	HR = $1.28^{\circ}$ (age $\leq 45$ ) HR = $1.31^{\circ}$ (age $>45$ )
Heart attack <sup>c</sup> [127]	$OR = 2.52^{a}$	$OR = 1.19^{a}$	$OR = 1.86^{a}$	NR	NR	NR
CVD <sup>d</sup> [119]	NR	$HR = 1.25^{a}$	$HR = 1.04^{a}$	$HR = 1.22^{b}$	NR	NR
CHD <sup>d</sup> [119]	NR	$HR = 1.33^{a}$	$HR = 0.85^{a}$	$HR = 1.34^{b}$	NR	NR
Stroke <sup>c</sup> [127]	$OR = 1.62^{a}$	$OR = 1.08^{a}$	$OR = 1.84^{a}$		NR	NR
Type-2 diabetes [128,129]	NR	$OR = 1.43^{e,f}$	NR	$OR = 2.12^{\circ}$	HR = 1.24° (males); HR = 1.28° (females)	HR = 1.62 <sup>e</sup> (males); 1.97 <sup>e</sup> (females)
Obesity <sup>c</sup> [127,136]	$OR = 1.36^{a}$	$OR = 2.72^{e}$	$OR = 0.98^{a}$	$OR = 1.45^{b,e}$	NR	NR
Depression [131,132]	NR	$OR = 3.67^{e}$	$OR = 2.22^{e}$	$OR = 2.65^{d}$	NR	NR

*Notes*. <sup>a</sup> reference category: 7h/night; <sup>b</sup> reference category: good sleep quality; <sup>c</sup> unadjusted results; <sup>d</sup> analyses adjusted for age and sex; <sup>e</sup> adjusted for multiple covariates; <sup>f</sup> reference category: 6-8h/night; CVD = cardiovascular disease; CHD = coronary heart disease; HR = hazard ratio; NR = not reported; RR = risk ratio; OR = odds ratio. In Australia, approximately one third of adults report problems with one or several indicators of sleep health, such as sleep duration, sleep continuity, as well as daytime functioning and mood [154]. For some indicators (i.e., feelings of fatigue upon waking), the prevalence can be as high as 45% [151]. It is important to note that indicators of poor sleep health (i.e., sub-clinical sleep problems) are much more prevalent than clinical sleep disorders such as chronic insomnia (13%–33%), or sleep apnoea (up to 25%) [151]. An overview of the prevalence of various sleep problems, including some of the most common chronic sleep disorders as reported by Australian adults, is provided in Table 2.3.

The evidence shows that a large number of Australian adults report going to bed (>50%) and waking (>30%) at different times from day to day [155]. In addition, more than 40% use the Internet before bedtime, which also contributes to poor sleep health [107]. Such practices often manifest themselves as waking up feeling unrefreshed (i.e., excessive sleepiness), the severity of which tends to correspond with the overall health risk associated with poor sleep health [117].

Table 2.3

The	prevalence	of poor	sleep	health	in A	lustralian	adults
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Indicator	Prevalence (in %)		
Inconsistent bedtimes [155]	53%		
Night time awakenings [107]	47% in females		
Feeling unrefreshed upon waking [151]	45%		
Difficulty falling asleep [107]	40% in females; 26% in males		
Sleepiness, fatigue, irritability [107]	39%		
Inconsistent wake times [155]	34%		
Perceived insufficient sleep [144]	33%		
Long sleep duration (>8 hours/night) [111]	22%		
Poor sleep quality [111]	20%		
Short sleep duration (<7 hours/night) [114]	24%		
Chronic insomnia [107]	23% in females; 17% in males		
Very short sleep duration (<5.5 hours/night) [107]	12%		
Breathing pauses (obstructive sleep apnoea) [107]	14% in males; 9% in females		

### 2.2.4 The economic burden associated with poor sleep health

Problems with sleep, including those below the clinical threshold for diagnosis result in significant costs related to absenteeism from work, loss of productivity and increase the risk of injury and accidents [156]. Approximately one third of adults admit to driving in an unfit state (due to excessive sleepiness) or having made errors affecting their work when feeling sleepy [151]. In Australia, during the 2016–2017 financial year, the costs associated with productivity loss per person reporting problems with their sleep were AU\$ 2,418 [144]. The total number of DALYs lost due to inadequate sleep in the same year exceeded 220,000, which converts to a value of AU\$ 40 billion in lost well-being, and an additional AU\$ 26.2 billion of financial costs as a consequence of poor sleep health [144].

### 2.2.5 Factors associated with sleep health

Similar to physical activity, sleep health is also influenced by a wide variety of factors that occur at multiple levels and thus, can be described in the context of an ecological model [48,157]. Consistent with the structure of Section 2.1.5 that presented factors associated with physical activity, the following sections summarise factors at the individual, the social and the environmental level. An overview is provided in Figure 2.2.

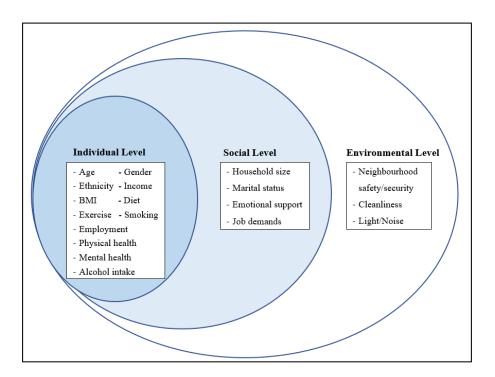


Figure 2.2 Factors determining poor sleep health

## Factors at the individual level

Based on cohort data including more than 300,000 US adults, a range of individual level predictors were identified as risk factors for insufficient sleep (i.e., "During the past 30 days, for about how many days have you felt you did not get enough rest or sleep?") [158]. In this study, age was the strongest sociodemographic predictor of insufficient sleep, with higher levels of insufficient sleep reported in younger adults [158]. This evidence is inconsistent with that of other indicators of sleep health such as total sleep time, wake after sleep onset and sleep efficiency, all of which tend to get worse with age [159]. It is possible that perceptions of daytime dysfunction and its impact differ for older adults or depend on other factors specific to age such as emotional response to stress [160,161]. Other sociodemographic predictors that showed a moderate influence on insufficient sleep in this study were female gender, being of White ethnicity and from a larger household [158]. A review of the factors that affect the various indicators of sleep health also found that being a parent is a determinant of short sleep duration, frequent insufficient sleep and high levels of daytime sleepiness [162].

The socioeconomic predictors identified in the cohort study cited above were higher income, being a student and employed or unable to work, all of which had a moderate to high level of influence on insufficient sleep [158]. In addition, increased insufficient sleep was predicted by being a smoker (moderate to high influence) [158]. Findings based on data from an Australian cohort also showed that adults who were smokers reported more frequent insufficient sleep, as did those who frequently consumed fast food [163]. Interestingly, the same study found no clear associations for alcohol consumption and exercise (assessed as predictors of insufficient sleep), whereas cross-sectional studies assessing other indicators of sleep health have shown strong associations for both behaviours. For example, a study using objectively measured physical activity data reported that sufficiently physically active adults (i.e., meeting guidelines) were less likely (RR = 0.65) to feel sleepy, compared to those who were insufficiently physically active [164]. Section 2.3 of this chapter, which is dedicated to the bi-directional relationship between physical activity and sleep, provides further detail in this regard. Inconsistent findings for alcohol consumption in relation to sleep could be due to the quick onset of sleep following excessive alcohol consumption, as frequently reported by those who drink [165]. Although people who frequently drink alcohol tend to have

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positive perceptions of their sleep health based on being able to fall asleep quickly, studies have demonstrated that interrupted sleep (wake after sleep onset due to dehydration or withdrawal symptoms) is common in individuals who report high alcohol consumption [165].

Poor overall health is another factor that strongly predicts frequent insufficient sleep and the evidence shows these associations are consistent for both mental and physical health [158]. Importantly, though mental health problems can develop as a consequence of poor sleep health, they can also act as antecedents of it [166], with many individuals who report mental health problems such as depression, loneliness or chronic stress also reporting sleep problems [167-169]. Higher stress levels can influence sleep and there are multiple factors that increase perceived levels of stress, including high demands and conflicts at the workplace. In a sample of Swedish adults, higher demands at work predicted sleep disturbances [170] and a review of the evidence reported similar associations for poor sleep quality and short sleep duration [162]. This underpins the need to consider stress management strategies (e.g., relaxation training) when designing interventions to improve sleep health, as seen for commonly administered non-pharmacological interventions for chronic insomnia [171].

A study that examined factors affecting sleep duration found that individuals with long work hours ( $\geq$ 8 hours/day) tended to have shorter total sleep time (TST) due to waking up earlier (by 40-91 minutes), compared with those who had shorter work hours (<8 hours) [172]. Similar findings were reported in another study, which also identified that those who worked multiple jobs had the highest odds (OR = 1.61) for reporting insufficient sleep duration on workdays (6 hours or less/night) [173]. This study also found that people with less education, who were unemployed, had a lower income and who did not have a partner tended to trade sleep duration for TV watching, which is likely to postpone sleep [173]. The general use of screen media (including TVs, laptops, smartphones, tablets and other light-emitting devices) was found to be associated with shorter sleep duration, less consistent sleep timing and poorer sleep quality [162]. Therefore, recommendations that address sleep hygiene practices should include clear messages about the avoidance of screen use at bedtime.

## Factors at the social level

In the context of sleep, social support tends to be limited to bedpartners, close family members or housemates, who may either encourage good sleep practices or interfere with them. Lack of emotional support, as well as psychological conflict with a co-habiting partner are all associated with poorer sleep health (including sleep duration, quality and insufficiency), whereas being married is associated with more optimal sleep duration, better sleep continuity and less frequent insufficient sleep [158,162].

*Social jetlag* refers to the misalignment between the body's natural clock (circadian rhythm), which dictates when a person feels the need to sleep, and the scheduling of social activities (including work), with detrimental effects on sleep health [174,175]. This misalignment often causes sleep deficiencies (i.e., insufficient sleep duration), as individuals spend time engaging in social activities, which limits sleep opportunities and reduces sleep duration [176]. In a sample of 837 Australian adults, this has been associated with going to sleep later than intended on work days (OR = 1.9), longer total sleep time on free days (OR = 2.8), as well as using computers (OR = 1.7), phones (OR = 1.6) and the internet (OR = 1.7) at bedtime [175].

Individual habits (i.e., napping) and the underlying perceptions of how much sleep is needed are thought to be largely influenced by cultural norms and ethnicity [48,177]. The evidence shows that short sleep duration is more common in racial or ethnic minority groups (e.g., African-American) [178,179]. Interestingly, sleep disturbance (defined as difficulty falling asleep, staying asleep, or sleeping too much) was shown to be more common in non-Hispanic White women than in Black/African-American, Hispanic/Latino, and Asian minorities, whereas no differences in sleep disturbances were found for males [180]. Assessing a broader range of sleep health indicators, another study found a higher likelihood (OR = 1.59) for longer sleep onset latency in black/African-Americans (relative to non-Hispanic White Americans) [181]. Regrettably, most studies that have used population data to examine patterns and trends of sleep health in Australian adults do not report results stratified by ethnicity inclusive of Aboriginal or Torres Strait Islander minorities [151,182,183]; hence, there is very little insight into the sleep health of these population groups.

## Factors at the environmental level

Few studies have sought to examine environmental determinants of sleep health. However, there is some evidence for the negative impacts of a disadvantaged neighbourhood (i.e., security, lighting, cleanliness) on multiple indicators of sleep health, including sleep duration, sleep quality and sleep onset latency [162]. A study using data from six different countries examined associations between neighbourhood safety and various parameters of sleep and found that a more positive perception of the neighbourhood environment was strongly associated with lower odds for having poor sleep quality, but inconsistently associated with sleep duration [184]. Poorer neighbourhood safety (e.g., high rates of crime and violence) was associated with a lower likelihood of long sleep duration in some countries (OR = 0.61 for South Africa) and an increased likelihood for poor sleep quality in other countries (OR = 1.47 for Ghana) [184]. A more recent study examining the associations between neighbourhood disadvantage (i.e., safety, disorder, crime) and various objectively measured indicators of sleep health also found significant associations for several sleep health indicators and reported better sleep efficiency, shorter times for wake-after-sleep-onset (WASO) and lower likelihood of short sleep duration in relation to a less disadvantaged neighbourhood environment [185].

In the context of sleep health, the term *environment* is often used to describe a person's bedroom arrangements (e.g., calming atmosphere, adequate temperature, fresh air and minimal disturbance from sources of light or noise) [186-188], which are known to promote good sleep [106,158]. However, as a component of sleep hygiene, the bedroom environment is better positioned at the individual level, as most of its aspects are relatively easy to modify by the individual. The evidence shows that individuals who modify their bedroom environment accordingly (e.g., reduced noise, adequate temperature) also report better sleep quality than those who do not observe these recommendations [186]. Nonetheless, some individual practices of sleep hygiene also have a social component (i.e., drinking alcohol at late-night social gatherings), thus sleep hygiene as a whole can be described as set of strategies that determines sleep health at multiple levels.

Last, the variation in light exposure due to geographical location and seasonal fluctuation dictates how much or how little stimulation an individual is exposed to through natural

daylight, which affects parameters of sleep health via the regulation of melatonin [177]. Therefore, early morning exposure to bright daylight is recommended to support the maintenance of a healthy sleep-wake cycle [189]. Since the occurrence of daylight cannot be modified, its impact on sleep health can be controlled by the individual by way of adequate self-regulation (e.g., use of an eye mask, installation of curtains/blinds). As seen for the majority of these factors, each individual indicator of sleep health is influenced by different factors and this may indicate that a wide spectrum of mechanisms drives the overall impact of sleep on health and well-being. Moreover, it is possible that there is overlap between the different levels, at which aspects of a given factor are more or less dominant than others.

### 2.2.6 Interventions to improve sleep health in the adult population

Chapter 3 presents the findings from a systematic review and meta-analysis of sleep interventions in adults without clinical sleep disorders, which is the population group of interest in this thesis. Although this review reported promising effects of cognitive and behavioural interventions on sleep quality (g = -0.54), its conclusions were limited by the small number of studies that were identified (n = 11) and little diversity among study samples. Moreover, only a small proportion of included studies (n = 2) were delivered remotely, and none of the studies used a smartphone app. Therefore, the findings from this systematic review were not used as the sole source of evidence that informed the development of the Synergy Study (Chapter 5). Due to the very limited amount of evidence in sub-clinical population groups, the following subsection of Chapter 2 includes a brief outline of interventions that are commonly delivered in clinical populations, with particular emphasis on non-pharmacological treatment and delivery modes that do not require face-to-face contact.

Although pharmacological approaches are known to be effective for the short-term treatment of insomnia [190], the use of sleep medication is often not advised, because of its side effects and high risk for dependency [191]. Non-pharmacological solutions for the treatment of chronic insomnia were shown to be equally effective [192]. They typically include cognitive therapy, stimulus control, relaxation training, sleep hygiene practice and regular exercise [193,194]. Cognitive behavioural therapy for insomnia (CBT-I) is considered the gold standard treatment for insomnia [171,195]. Traditional CBT-I has three objectives and each objective consists of specific strategies serving the

purpose of eliminating factors that cause insomnia: (1) stimulus control and sleep restriction to address poor regulation of sleep drive, (2) cognitive therapy to counteract sleep-related anxiety (e.g., worry and rumination) and (3) sleep hygiene education to manage sleep-interfering behaviours [196]. Reviews have shown that CBT-I produces moderate to large improvements in insomnia (d = 0.30-0.80) [191,197-199], with effects maintained at the long-term follow-up (up to 18 months) [198,200]. Non-practitioner delivered CBT-I that commonly utilises computer- or web-based modes of delivery is increasingly used [195,201] and has shown equivalent effectiveness (pooled betweengroup effect g = 0.05) relative to practitioner-delivered (face-to-face) CBT-I [201,202]. However, it is unclear what implications the lack of face-to-face support has on the individual components of traditional CBT-I [201]. For example, the restoration of a healthy sleep drive through sleep restriction initially involves a substantial reduction of total sleep time and may at first cause adverse effects (e.g., excessive fatigue) [196]; it thus requires professional guidance and strict adherence to a treatment time frame. Therefore, sleep restriction might not be a suitable intervention component for interventions targeting non-clinical sleep problems by means of an m-health approach, where ongoing monitoring and support by a professional cannot be provided and symptoms are insufficiently severe for participants to even be sensitive to this type of treatment. This was shown in a study, where sleep restriction did not prove to be effective for participants whose insomnia symptoms were less severe at baseline [203]. Moreover, because CBT-I treatment as a whole usually requires a patient referral based on clinical diagnosis, it cannot be considered an accessible treatment option for those who do not meet diagnostic criteria [195,204].

A systematic review including 16 sleep interventions (e.g., CBT-I, sleep education, bibliotherapy) summarised the evidence from studies that specifically used an m-health mode of delivery [205]. The review found such interventions are effective and the use of mobile apps in addition to interventions involving face-to-face contact showed equal or superior efficacy at improving sleep quality and insomnia severity, relative to traditional interventions alone [205]. An additional conclusion of this study was that mobile apps are a treatment avenue that has clear advantages over traditional intervention delivery (e.g., portability), but also implied that higher attrition rates (up to 72%) may be introduced by using a remote delivery mode [205]. Nevertheless, the studies included in this review either comprised samples of clinically ill participants (e.g., OSA patients, war

veterans), or population groups in which natural sleep was unlikely to occur (e.g., firsttime mothers, menopausal women, airline pilots), which reduces the generalisability of these findings for the sub-clinical population group.

A key feature of sleep is the lack of consciousness needed to take control over it [206]. In other words, sheer intention and volition are not enough for a person to achieve better sleep and to secure sufficient rest and recovery. Sleep hygiene is a set of modifiable behavioural strategies that are known to promote good sleep and consist of practices a person can consciously engage in prior to sleeping or upon waking [106]. Irish and colleagues provided a comprehensive summary of recommendations that consist of (1) *caffeine avoidance*, (2) *nicotine avoidance*, (3) *alcohol avoidance*, (4) *regular exercise*, (5) *stress management*, (6) *bedroom noise reduction*, (7) *regular sleep timing*, and (8) *daytime nap avoidance* [106]. The level of evidence on the efficacy per component or domain of sleep hygiene varies, however as a whole, sleep hygiene was deemed essential for the improvement of sleep health [45,207].

The use of light emitting devices (e.g. smartphones, laptops, etc.) is an additional and newly emerging factor to negatively affect sleep onset as well as next-morning alertness [208]. With the large number of adults (44%) who state using the Internet at bedtime every night, this behaviour requires to be actively targeted as part of interventions that implement sleep hygiene [151]. Studies using sleep hygiene as a standalone component have been shown to improve sleep quality [209]. Though in clinical population groups, interventions that employ sleep hygiene only were shown to be inferior (i.e., little to no effect) in comparison to multi-component treatments such as CBT-I [207]. However, the comparative effectiveness of sleep hygiene relative to other interventions has been established for clinical population groups only. Moreover, there is insufficient evidence to draw any conclusions regarding the effectiveness of individual intervention components for sub-clinical population groups.

Sleep hygiene recommendations often vary with regard to the total number of recommendations and level of information they incorporate [207]. Moreover, it often seems unclear whether participants are merely provided with a list of recommended practices, which assume that knowledge and information are sufficient to drive the adoption of new practices, or if interventions deliver specific strategies that are key to behaviour change and facilitate the daily implementation of recommended practices

[210,211]. This is particularly problematic for practices such as obtaining regular exercise. Although commonly promoted as part of good sleep hygiene [106], and therefore promoted in many interventions that implement sleep hygiene, there is little information on the behavioural strategies used to promote regular exercise. Although it is uncertain if participants receive instructions that are more detailed than what is reported in the published literature, the potential of interventions promoting regular exercise may not be utilised to its full extent, unless specific strategies are provided [106]. That is, participants may not succeed at increasing their physical activity levels and therefore lose out on the additional benefits this could have on sleep health and overall health.

### 2.2.7 Factors influencing the efficacy of sleep interventions

Factors which have been shown to increase intervention efficacy in clinical populations might be useful to inform interventions in non-clinical populations, given the lack of evidence from non-clinical trials. In the context of CBT-I intervention efficacy, these factors include a longer study duration and higher level of participant support [201]. A systematic review of digital (i.e., technology-based) CBT-I identified a number of additional effect moderators, showing reduced intervention efficacy in the presence of psychiatric co-morbidities, older age, as well as low willpower, which in turn affects intervention adherence [212]. This review also reported evidence for a mediation effect through sleep-related thoughts and beliefs (e.g., attitudes) [212]. A sleep hygiene awareness study in shift workers demonstrated that self-efficacy acted as a moderator of intervention efficacy, whereby lower levels of self-efficacy interfered with participant adherence (i.e., practice of sleep hygiene) [213]. In a sample of chronic insomniacs, baseline dispositions of sleep-related cognitions and beliefs were shown to predict sleep improvements in a CBT-I intervention, with a greater treatment response shown in those who had more maladaptive sleep-related thoughts and beliefs at baseline [214]. However, this appears to be one of the only studies that examined the effects of psychosocial factors on changes in sleep in an intervention. There are few experimental studies that have tested the utility of social cognitive theories, or aimed to explain behaviour change (i.e., intervention efficacy) through pre-specified mediators in a non-clinical sample beyond those detailed above. Moreover, in the context of sleep interventions, psychosocial factors to date have been examined as moderator or mediator variables mostly with regards to intervention adherence (e.g., completing a sleep diary) [215].

## 2.3 The relationship between physical activity and sleep

A wide spectrum of proposed mechanisms has been identified that explain the relationship between physical activity and sleep [216]. Physical activity is thought to cause changes in cognitive and emotional arousal, central nervous system activation [217,218], as well as changes in hormone secretion, heart rate and heart rate variability [219,220], which in turn affects sleep. Daytime sleepiness and high levels of fatigue are thought to contribute to physical inactivity in individuals with poor sleep health [221]. A prospective study found that emotional regulation is a key mechanism driving this relationship – in both directions [222].

There is growing evidence from cross-sectional and longitudinal studies confirming a bidirectional relationship between physical activity and sleep health [45,223-225]. Crosssectional studies generally show positive associations between physical activity and sleep quality [225,226]. Research into the temporal associations between physical activity and sleep health shows mixed findings, depending on the level of intensity of physical activity, the sleep outcome in question and the method of assessment used (i.e., self-report versus objective measures) [216,227]. Moreover, the majority of studies have assessed this relationship in the context of chronic insomnia [228,229]. There is evidence indicating that individuals without chronic sleep problems (i.e., insomnia) tend to be more physically active, compared to those with chronic sleep problems [230]. Data from a small, non-clinical sample have shown lower levels of next-day physical activity following a night of short sleep (<6h/night) [231]. As seen in other studies, next-day physical activity is also predicted by variations in subjective sleep quality, sleep onset latency [46,229] and objectively measured sleep efficiency, [232] with higher activity levels observed in those who report better sleep health (i.e., better quality sleep, shorter sleep onset latency and greater sleep efficiency). Longitudinal studies report similar associations. For example, a study that examined the two-year relationship between physical activity and sleep detected bi-directionality between physical activity and sleep quality, but not between physical activity and sleep duration [233].

In an experimental context, moderate- and high-intensity exercise were shown to have significant positive effects of moderate size on sleep quality (Standardised Mean Difference, SMD = 0.47) and sleep onset latency (SMD = 0.58), but no significant effects on other sleep health indicators (i.e., sleep duration, sleep efficiency, sleep disturbance,

daytime dysfunction) [234]. Effects however, may differ between acute and regular exercise. A meta-analysis of studies in individuals with normal sleep has shown moderate positive effects for acute exercise on sleep duration (g = 0.42), but no significant effect on sleep onset latency or wake after sleep onset [235]. This study reported a linear median increase in sleep duration by 10 minutes due to exercise, which was consistent with a previous meta-analysis [236]. These meta-analyses further tested a range of moderators with a potential effect on the relationship between exercise and sleep health and found significant effects for gender, age, participant fitness and exercise duration [235,236]. Regular exercise has been shown to produce moderate to large (d = 0.74) improvements in sleep quality [216]. However, it is unclear if improvements in sleep vary by the type of activity performed. Reviews to date have reported that low-impact physical activity (e.g., yoga, walking), aerobic based exercises and resistance training are all associated with improvements in sleep [216,237]. In the context of mortality risk, a review of resistance training indicated that aerobic exercise in combination with resistance training produces greater effects than either component alone [26], though there appear to be no reviews that have addressed the comparative effectiveness of different types of physical activity on sleep health. A more recent meta-analysis synthesised the effect of acute and that of regular exercise on different indicators of sleep [216]. This study reported small positive effects for acute exercise on sleep duration (d = 0.22), sleep onset latency (d =0.17) and sleep efficiency (d = 0.25); small positive effects for regular exercise on sleep duration (d = 0.25), and sleep efficiency (d = 0.30); small-to-medium positive effects on sleep onset latency (d = 0.35); and large positive effects on sleep quality (d = 0.74) [216]. For some indicators (i.e., sleep onset latency), effect sizes for acute exercise were more pronounced in males, but this was not observed for regular exercise. Age had a moderating effect for regular exercise on sleep onset latency, with reduced benefits seen in older adults, which was not the case for acute exercise [216]. As seen in the above summarised literature, there is growing evidence from both, observational and experimental studies. What these studies have in common is they show the relationship between physical activity and sleep varies based on the different parameters that characterise each behaviour and the method of assessment.

As a consequence of the bi-directional relationship portrayed above, insufficient physical activity and poor sleep health also frequently co-occur in the adult population [114]. From a public health perspective, this may raise concerns, but also represents a unique

opportunity for intervention. That is, intervention studies may be able to achieve greater improvements in overall health and well-being when targeting physical activity and sleep in combination, rather than on their own using separate interventions [233,238-241]. This notion is supported by a study that showed an increased CVD-related mortality risk (RR = 1.27) for individuals with short sleep who were physically inactive (<1h MVPA/week), compared to those with short sleep who were more physically active; and an increased risk (RR = 1.18) for those with optimal sleep duration who were physically inactive, relative to those who were physically active  $(\geq 1h \text{ MVPA/week})$  [242]. A study examining CVD risk also found lower risks for those who reported high physical activity levels and sufficient sleep, relative to those who reported sufficient sleep, but only light levels of physical activity and high levels of sedentary time, regardless of gender [243]. Interestingly, a 15-year prospective data analysis of long sleep duration (>8h/night) and mortality showed an increased mortality risk was observed only for individuals who reported low levels of physical activity (HR = 1.24) [244]. Given this evidence, interventions should aim to target physical activity and sleep health concurrently to leverage the synergistic effects between these behaviours.

## 2.4 Interventions targeting physical activity and sleep in combination

A review of multiple risk behaviour interventions has shown the majority (46%) of multiple health behaviour interventions target two behaviours in combination, with the most frequently targeted combination being physical activity and diet (72%) [245]. Though there are small pilot interventions and commercially available apps that do target these behaviours in combination [77,246,247], it appears there have been no reports from studies, which have done this using an RCT design and an m-health approach that is characterised by features associated with potential for wide reach [248]. Reviews of multiple behaviour change interventions conclude that these interventions are efficacious and that based on the available evidence, there appears to be no difference between simultaneous and sequential targeting of behaviours [245,249].

Wang and researchers studied a sample of chronic insomniacs to compare the effect of a sleep restriction condition to a sleep restriction and physical activity intervention on insomnia severity and sleepiness [250]. The combined group showed significantly greater improvements on most of the outcomes, which included MVPA, pedometer-based step counts, insomnia severity, sleepiness, sleep efficiency and wake after sleep onset [250].

However, as stated in previous sections of this chapter, sleep restriction as a form of treatment for sleep problems may not be suitable for use in a non-clinical population. In addition, this study provided multiple face-to-face sessions including sleep hygiene education through a therapist and physical activity counselling to help participants increase their physical activity levels, which limits the scalability of the intervention.

Filion and researchers combined physical activity and sleep as part of an intervention targeting young adult smokers who were planning to quit smoking [251]. This study compared two groups who received either a smoking cessation intervention or a combined physical activity and sleep intervention for a duration of six weeks, which showed no simultaneous improvements in physical activity and sleep between groups. However, the subgroup of participants in the physical activity and sleep with short sleep duration at baseline reported a significantly greater increase in sleep duration on work/school days compared to the smoking cessation intervention [251]. It is important however, to acknowledge the primary motivation for participants to enrol in this study, which was to quit smoking and may have affected participants' outcome expectations and efforts relating to physical activity and sleep. Due to the nature of this intervention, participants were not specifically recruited based on being insufficiently active and having poor sleep health, which resulted in limited room for improvement for the majority of the sample. Moreover, the intervention relied solely on text-message based information (i.e., educational content and motivational prompts) and did not supply any additional strategies (e.g., action planning) to support participants with the implementation of the educational contents.

Atlantis and colleagues delivered a work-based exercise programme combined with sleep hygiene and health knowledge, which also promoted physical activity [252]. A number of behaviour change strategies (e.g., goal-setting, problem-solving, rewards) were implemented to engage participants in the programme. This study reported promising improvements in PSQI scores, which were reduced from an average of 6.0 ( $\pm$ 2.5), to 4.1 ( $\pm$ 1.8), which corresponds to participants who on average had poor sleep prior to the intervention classifying as having good sleep at the follow-up [252]. The findings of this study were limited in that between-group differences for sleep quality were statistically significant for shift workers only, which made up 73% of the sample, while the non-shift work subgroups (intervention vs. waitlist-control) showed no between-group difference. In addition to its low generalisability to the general population, this study did not assess changes in physical activity. Although a measure of compliance with the exercise component of the intervention was reported, it was not clear if participants in this study were already physically active prior to the study and still encouraged to increase their physical activity levels, and if they simply received a structured exercise programme at a fixed dose that aimed to improve sleep.

A small, unpublished randomised (n = 64) trial by Duncan and colleagues [77] that had the purpose of comparing two modes of self-monitoring (automated vs. manual data entry) demonstrated improvements in physical activity and sleep following nine-weeks of simultaneous intervention. However, this study did not include a control condition to allow for testing of intervention efficacy. Nonetheless, preliminary findings from this trial were promising and showed that using a theory-driven approach and a mode of delivery utilising a smartphone app was feasible and acceptable in an adult sample. In both intervention groups, there were no significant changes in self-reported minutes of MVPA, accelerometer-measured minutes of MVPA or sleep efficiency from baseline to nine weeks, and there were no between-group differences. There were however, significant improvements in PSQI scores from baseline to nine weeks in both the manual entry group (mean change -2.20, [95% CI] -3.10 to -1.31) and the automated data entry group (mean change -1.66, [95% CI] -2.55 to -0.76), with no differences between groups at nine weeks.

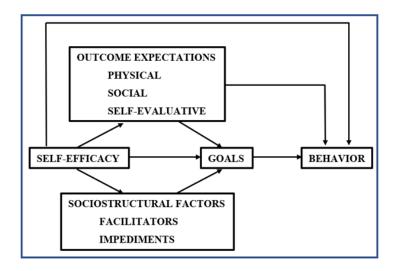
Taken together, the small amount of evidence that exists on the efficacy of interventions that combine physical activity and sleep with the objective to address two major public health issues is inconsistent. The available findings have several limitations, including small sample sizes, low fidelity and a lack of generalisability due to targeting very specific subgroups of the population [253]. Moreover, none of these studies have used an m-health mode of delivery and there is little indication regarding the use of theoretical frameworks and evidence-based strategies (BCTs) as part of intervention conceptualisation. This is surprising given the high prevalence of both behaviours in the general adult population and the growing evidence that supports the use of multibehaviour interventions [249,254].

## 2.5 Theories of behaviour change

Theoretical frameworks offer important guidance on how to predict and understand behaviour change and how to best conceptualise effective interventions that are thought to promote behaviour change [84]. They also facilitate proper alignment between intervention content (i.e., strategies) and the outcome to be measured. Studies that suggest a strong focus be placed on the use of appropriate behaviour change strategies also reinforce the importance of theory to guide this process [86]. This is particularly important when examining theory-based constructs and behaviour change strategies as mediators of intervention efficacy.

Social Cognitive Theory (SCT) [255] is one of the most widely cited models in the health behaviour literature [256]. SCT supports the notion that health and well-being depend on a range of self-regulatory processes [255,257]. Self-regulatory ability empowers a person to utilise facilitating factors in the best possible way and to pursue goals despite the presence of impediments or barriers [257]. Compared to major environmental modifications that are subject to policy-making or infrastructural development, an individual's perceptions of barriers and the capability needed to respond to environmental barriers can be influenced by way of successful self-regulation [257]. SCT distinguishes between factors at the individual level and those that characterise a person's social and physical environment and integrates these factors in a framework that acknowledges the complex and often bi-directional interplay between multiple constructs [258]. Furthermore, SCT acknowledges learning as a determinant of behavioural regulation [258,259], which is an important consideration for health behaviour interventions that may require participants to form new habits. Many of the other widely used psychosocial determinants theories (e.g., Self-Determination Theory [260], Theory of Planned Behaviour [261], Health Belief Model [262]) tend to have a strong focus on intrinsic factors and do not describe behaviour within the context of both, the social and physical environment.

Within SCT, the key constructs that influence health behaviour as described by Bandura (see Figure 2.3) are self-efficacy, outcome expectations, as well as socio-structural factors (e.g., social support and the environment) and goals [42]. Ancillary constructs of relevance to this thesis are described in Chapters 4 and 5.



*Figure 2.3* Structural paths of influence between constructs of SCT. Diagram reproduced based on A. Bandura, Health Promotion by Social Cognitive Means, *Health Education & Behavior*, *31*(2): 143–164 (April 2004).

Self-efficacy forms "the foundation of human motivation and action" [42]. Bandura defines self-efficacy as the belief to be able to take the actions needed to produce a desired effect or change [258]. Interventions that seek to enhance self-efficacy often implement strategies such as action planning, instructions on how to change behaviour, as well as feedback and positive reinforcement (contingent on progress toward the target behaviour) [87,263]. Self-efficacy as the single most widely studied construct of SCT may be measured as a treatment outcome but is also frequently assessed as a mechanism of behaviour change [264]. In the physical activity context, systematic reviews have shown the relationship between self-efficacy and physical activity is inconsistent [87]. Although a large proportion of the evidence shows that increased self-efficacy is associated with increased physical activity and explains approximately 30% of the variance in physical activity [265], there are some interventions that yield changes in self-efficacy, but not in physical activity, and vice versa [87]. As stated in Section 2.1.7, the evidence for selfefficacy as a mediator of physical activity is mixed [88]. This may emphasise the importance of other constructs as well the combined effect of multiple constructs on behaviour change.

Outcome expectations refer to the (desired) effect or consequence produced by the actions a person takes, which is either experienced as a benefit or as a loss [42]. That is, a person is thought to be more likely to take action (i.e., engage in a given behaviour) if the anticipated outcome is positive or perceived as valuable by the person [266]. Expectations

are often formed based on previous experience, ongoing self-evaluation and common beliefs that result in social approval or disapproval of an action [42]. Although primed through strategies that educate and foster awareness (i.e., information on the consequences of a behaviour), outcome expectations are largely influenced through positive reinforcement (including rewards) and environmental restructuring, which increases the likelihood of experiencing a benefit that is greater than the anticipated cost [266]. Studies of the direct link between outcome expectations and physical activity have reported mixed results and the same is true for studies that have examined outcome expectations as a mechanism (mediator) of behaviour change [88,266]. It is possible however, that outcome expectations have an indirect effect on behaviour by influencing other constructs such as intention [267].

Socio-structural determinants comprise factors within a person's social and physical environment that may act as facilitators or as impediments (barriers) of healthful behaviour [42]. Perceptions of self-efficacy are directly influenced by these factors, as is the relative ease of performing a given behaviour [42]. Thus, interventions may change levels of self-efficacy by changing perceptions of socio-structural factors. This can be achieved through a number of strategies, such as focussing on past performance, managing stress, setting realistic (achievable) goals, promoting gradual progress toward goals (i.e., graded tasks) and effective time management, as well as the proper utilisation of social support networks including partners, family members and/or friends [4,268]. In line with Bandura's theoretical model [42], it is generally assumed that socio-structural factors with impeding effects reduce engagement in the behaviour (e.g., physical activity), whereas factors that have a facilitating nature increase engagement in the behaviour. Due to the complexity of this construct, socio-structural factors are often assessed using proxy measures specific to a person's perceptions of their social support, or their physical environment [269]. Although social support has been identified as a consistent determinant of physical activity [38], there is mixed evidence from mediation studies that have assessed physical activity as the behavioural outcome [88]. The same is true for positive perceptions of the environment (i.e., good walkability and access to facilities, footpaths and trails) [38], which are known to be consistently associated with greater levels of physical activity. Nonetheless, there appears to be no clear consensus on whether the environment acts as a mediator of physical activity.

SCT further specifies goals as a key construct, which is directly influenced by outcome expectations and perceptions relating to socio-structural factors, and in turn determines health behaviour [42]. Intentions are often assessed to predict the impact of goals on behaviour and stronger intentions are thought to represent stronger, more ambitious goals, which also tend to predict higher levels of physical activity [269]. Although a number of studies have reported consistent positive associations between intentions and physical activity [38], very few have assessed the mediating role of intentions/goals as a mediator of behaviour change and findings remain inconclusive.

Relatively little is known about how psychosocial factors relate to sleep health [158,177,270]. The small number of studies that are available have either examined a single construct or did not acknowledge the full complexity sleep hygiene [271,272]. One study found that although intention and perceived behavioural control were significant predictors of sleep hygiene, there were other factors (i.e., response inhibition) that predicted the outcome more strongly. These studies underline the importance of selfregulation in the context of changing a given set of behaviour related to sleep (e.g., sleep hygiene) [271,272]. Even though there is some evidence suggesting that sleep-related self-efficacy levels tend to be lower in the insomniac population, it remains unclear which other psychosocial factors could help explain the severity of sleep problems [273], particularly in the sub-clinical population group. As a result, it is uncertain to what extent SCT has comparable utility when applied to the sleep health context, and if the same constructs play a role in changing the various indicators of sleep health. Further, the above sections have demonstrated the inconsistent and deficient evidence base with regards to the various psychosocial mediators of physical activity and sleep behaviours as proposed by SCT. To improve the understanding of psychosocial determinants and their role as mechanisms of changes in physical activity and sleep health, it is important to assess these theoretical constructs as part of a trial's evaluation. Finally, it is noteworthy the majority of studies that have examined SCT constructs either as determinants or as mediators of behaviour change have focussed on the initiation of behaviour change; however, as seen in a review of theoretical frameworks, it is likely the factors that influence the initiation of behaviour change (i.e., increased physical activity) are different to those that drive the maintenance of behaviour change over time [274]. Thus, it is important to align the conceptualisation of intervention content with its overarching objective.

## 2.6 Summary of Chapter 2

The purpose of Chapter 2 was to summarise the evidence that has informed this thesis. The literature shows that insufficient physical activity and poor sleep health are highly prevalent in the adult population and considered global public health concerns. Physical activity and sleep share a bi-directional relationship and may exert synergistic effects on health and well-being, but the evidence from trials that aim to improve physical activity and sleep in combination is limited. Thus, interventions targeting the two behaviours concurrently and also have the potential for wide reach are needed. Further knowledge gaps and research needs as identified in Chapter 2 are as follows:

- A considerable amount of evidence has been published on the efficacy of singlebehaviour interventions targeting increased physical activity and also for interventions that target improvements in sleep for clinical population groups (e.g., CBT-I). However, there is relatively little information on the efficacy of interventions targeting sleep in populations without a sleep disorder.
- The majority of studies that have examined determinants of sleep hygiene practices have focussed on demographic factors (i.e., age, gender). Hence, the psychosocial factors influencing sleep hygiene practices are poorly understood, which may be due to the lack of comprehensive instruments available to assess these factors. Studies that target behaviour change to improve sleep health would benefit from an enhanced understanding of psychosocial determinants, to enhance intervention design, delivery and evaluation.
- Efficacy trials are needed to confirm if physical activity and sleep health can be improved in combination using an m-health approach and whether it is possible to harness the synergistic effects between these behaviours.
- Resistance training is infrequently examined relative to aerobic exercise, despite it being recommended as part of physical activity guidelines. Therefore, interventions promoting physical activity should not only consist of aerobic exercises, but also integrate resistance training exercise.
- Due to the lack of previous studies specific to the above combination of health behaviours, little is known about how mechanisms of behaviour change (i.e., psychosocial determinants) operate in such a combined intervention, and if these differ between behaviours. This knowledge could help enhance the development of interventions that target multiple behaviours.

## **References – Chapter 2**

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# CHAPTER 3. A SYSTEMATIC REVIEW AND META-ANALYSIS OF COGNITIVE AND BEHAVIOURAL INTERVENTIONS TO IMPROVE SLEEP HEALTH IN ADULTS WITHOUT SLEEP DISORDERS

Chapter 3 presents the findings from a systematic review and meta-analysis, which addressed Secondary Aim 1 of this thesis. The contents of this chapter were peer-reviewed and published as a journal article in *Sleep Medicine Reviews*.

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## 3.1 Abstract

Many adults without a diagnosed sleep disorder report poor sleep health, which is defined by dissatisfactory levels of sleep duration, sleep quality, or the timing of sleep. No previous review has summarised and described interventions targeting poor sleep health in this population. This meta-analysis aimed to quantify the efficacy of behavioural and cognitive sleep interventions in adults with poor sleep health who do not have a sleep disorder. Electronic databases (MEDLINE, Embase, PsycINFO, CINAHL) were searched with restrictions for age (18-64 years) and English-language full-text, resulting in 18,009 records being screened and 592 full texts being assessed. Eleven studies met inclusion criteria, seven of which reported a measure of overall sleep health (PSQI). Following appraisal for risk of bias, extracted data were meta-analysed using randomeffects models. Meta-analyses showed interventions had a medium effect on sleep quality (Hedge's g = -0.54, [95% CI] -0.90 to -0.19, p < 0.01). Baseline sleep health was the only significant effect moderator (p = 0.01). The most frequently used intervention components were stress management and relaxation practice, stimulus control, sleep hygiene and exercise. Interventions targeting cognitive and behavioural self-regulation improve sleep quality in adults without clinical sleep disorder.

## **3.2 Introduction**

Healthy sleep plays a key role in the maintenance of good health and well-being and is recognised as an important behaviour to improve public health [1]. Good sleep health consists of multiple indicators, such as adequate duration, timing, efficiency and a level of satisfaction with sleep that leaves a person feeling alert and functional throughout the day [2]. Indicators of poor sleep health include a sleep duration of fewer or more hours than the recommended seven to nine hours per night [3] and dissatisfactory sleep quality. Sleep hygiene recommendations that are aimed at promoting sleep health [4] also frequently address inconsistencies in sleep timing (fluctuating bed and wake times). Although non-pharmacological treatment for clinical sleep disorders, such as Cognitive Behavioural Therapy for Insomnia (CBT-I) [5], recommends consistent wake times, some variability in bedtimes is encouraged based on prioritising feelings of tiredness as a requirement for sleep onset and maintenance [6,7], with overall timing consistency being more of a secondary or long-term goal. Nevertheless, in non-clinical populations the effect of regular bed and wake times on sleep health is unknown. These factors are associated with a host of non-communicable diseases including cardiovascular disease, type-2 diabetes, obesity and poor mental health [2]. Adults who report inadequate sleep duration and/or poor sleep quality hence are at high risk for morbidity and early mortality [8].

A large proportion of the global population does not meet guidelines for optimal sleep duration, sleeping either less than seven or more than nine hours per night [9,10]. The evidence regarding temporal changes in the prevalence of inadequate sleep duration is inconsistent [10]. However, it is possible there has been a concomitant increase in poor sleep health, due to reductions in the quality of sleep or shifts in the timing of sleep [11]. Indeed, poor quality sleep is reported by more than a quarter of the adult population [12]. This prevalence is greater than any of that associated with clinical sleep disorders such as chronic insomnia at 6–15% [13], restless legs syndrome at 2–8% [14], and sleep apnea at 3-7% [15]. To improve sleep health at the population level, it is important to promote sleep as a modifiable health behaviour and provide access to effective solutions [16].

Given that traditional practitioner-delivered treatments to improve sleep health cannot meet treatment demands for those with clinical sleep disorders [17], it is unlikely that resources are sufficient for those without diagnoses. Technology- or web-based interventions therefore may be useful in providing the necessary reach to effectively improve various indicators of sleep health [18,19].

Individuals who need to improve their sleep health may benefit from cognitive and behavioural interventions, as the underlying causes of poor sleep health often relate to factors at the cognitive or behavioural level [20]. These interventions include components such as mindfulness, relaxation training and *sleep hygiene* [4]<sup>1</sup>, all of which improve sleep quality and can be made accessible in ways (e.g., technology-based delivery) that do not require a trained facilitator [17]. Numerous systematic reviews have summarised the efficacy of non-pharmacological interventions in populations reporting a diagnosed sleep disorder or meeting diagnostic criteria for insomnia [21-24], with more recent publications also including web-based interventions [25,26]. Most of these reviews report a large pooled effect for sleep quality outcomes following treatment for insomnia. The authors are unaware of any prior reviews that have specifically examined the efficacy of sleep interventions in individuals who report poor sleep health but do not have a clinical sleep disorder, or that have compared treatment efficacy based on the presence or absence of a clinical sleep disorder. Pharmacological interventions including prescription medications have also demonstrated high levels of effectiveness but are not always superior to non-pharmacological treatment [27] and do not present a long-term solution [26]. Further, the evidence on use of over-the-counter sleep aids in non-clinical populations is limited and remains inconclusive [28]. Therefore, a synthesis with a focus on the efficacy of non-pharmacological interventions in populations that report poor sleep health but do not have a sleep disorder is much needed.

It is important to describe intervention features of interventions conducted in the nonclinical population, as prior reviews of clinical populations have identified that intervention efficacy varies by the type and number of intervention components used [25].

<sup>&</sup>lt;sup>1</sup> Sleep hygiene refers to a set of recommended behaviours a person can engage in throughout the day or before bedtime to promote good sleep. This includes abstinence from caffeine, alcohol and nicotine late in the day, the practice of relaxation, regular exercise, regular sleep/wake times, modifying the environment (e.g., reducing impact of noise/light), no daytime napping, and minimal use of light-emitting devices (e.g., smartphones). Sleep hygiene differs from sleep knowledge, in that it has an instructional nature whereas sleep knowledge, in this context, refers to any broader information highlighting the importance of good sleep health.

Furthermore, describing the different components of an intervention can advance the understanding of how intervention content is delivered to participants and why a component is effective in changing behaviour [29]. A useful way to describe these features is the use of behaviour change taxonomies [30]. However, no literature to date has described how BCTs are implemented in sleep interventions or to what extent they drive changes in sleep health; or whether the frequencies at which BCTs are implemented differ by intervention components. Furthermore, it is to be clarified whether the efficacy of sleep interventions differs by mode of delivery and study duration similar to that reported in other health behaviour trials [25,31].

The aims of this systematic review with meta-analysis were to (1) synthesise the evidence from peer-reviewed published studies on cognitive and/or behavioural sleep interventions in adults without a sleep disorder, (2) describe intervention components by use of behaviour change techniques, and (3) examine if intervention efficacy is moderated by number and type of intervention components, mode of delivery, study duration and participant characteristics (age and baseline sleep).

## **3.3 Methods**

The search strategy, selection criteria, data extraction, study quality assessment, and statistical analyses described below were defined *a priori*. The conduct and reporting of this review was guided by PRISMA guidelines [32] and prospectively registered (PROSPERO: CRD42015029642; Appendix A).

#### 3.3.1 Selection of Studies

Electronic database searches were conducted in December 2015 using comprehensive search strings (Table 3.S1) in MEDLINE, Embase, PsycINFO, and CINAHL. Search strings were devised from the following term sets: (i) *sleep*, (ii) *intervention*, and (iii) *study type*. Record retrieval was limited to age groups between 18 and 64 years, and English-language full-text. Searches covered the periods from database inception to December 2015 and weekly search alerts were set up to identify any records that were indexed while the review was underway (date of last search alert considered for review: 28/10/2016). The reviewers' existing libraries complemented the electronic database search. Any study protocols identified as part of the electronic database searches were retained and one reviewer (BM) then manually searched for any publications of related

study outcomes (BM). In addition, the WHO International Clinical Trials Registry Platform (ICTRP) and the Cochrane Central Registry of Controlled Trials (CENTRAL) were searched for potentially relevant records. One reviewer (BM) also screened the titles of all studies listed in relevant reviews that were either known to the authors or identified through electronic database searches. Abstracts of references were only screened if the eligibility criteria specified in the review were too ambiguous (i.e., if it was not clear whether the review included only studies conducted in an insomniac population).

#### 3.3.2 Inclusion Criteria

Studies were eligible if they were full reports of experimental studies that had a control condition (i.e., no-intervention/waitlist control group, treatment as usual) with both or all groups reporting poor sleep health at baseline. Interventions were limited to those aiming to improve sleep health using one or several cognitive and/or behavioural components. A cognitive/behavioural component included any of the following: sleep knowledge or education; single components usually found as part of CBT-I (stimulus control, sleep restriction, relaxation, cognitive restructuring and sleep hygiene); single components usually found as part of sleep hygiene education; stress management techniques; mindbody approaches (i.e., mindfulness-based practice, breathing), and sleep diaries or logs. Studies also had to state that it was their aim (or one of several study aims) to improve sleep health. Subjective and/or objective measurements of any parameter relating to sleep health had to be reported including baseline and immediate post-test or change scores (M, SD, SE etc.) for all groups. Table 3.S2 presents a detailed list of exclusion criteria and reasons for applying these criteria. Briefly, studies were excluded if participants were not aged 18–64 years, had a chronic disease, mental health condition, or sleep disorder, were institutionalised, were shift workers, had a BMI >35, were normal sleepers, or if all intervention arms received pharmacological treatment.

#### 3.3.3 Study Screening

Records were exported to EndNote X7 and de-duplicated using automated and manual procedures. Irrelevant records were screened out by two reviewers (BM, LW) based on titles and abstracts. Following full-text retrieval for those retained after screening, both reviewers (BM, LW) independently assessed each record against inclusion criteria and a third reviewer (MJD) provided mediation if no decision could be made.

## Data Extraction

Both reviewers (BM, LW) independently extracted and coded data of interest using a set of pilot-tested coding sheets. Data were extracted in five general categories: *study design* (study type, sample size, study duration, follow-ups, attrition), *sample characteristics* (age, BMI, gender, chronic disease, baseline sleep), *intervention components* (e.g., relaxation, sleep hygiene, immediate), *mode of delivery* (face-to-face or remote delivery, frequency and duration of contact), and *intervention outcomes* (sleep measures including M, SD/SE at all time points). Where necessary, authors of eligible studies were contacted to request missing information. Intervention components were identified based on a list of common components of CBT-I [17] and individual sleep hygiene behaviours [4]. Behaviour change techniques (BCTs) were extracted using a 40-item taxonomy of BCTs [33]. The presence or absence of a BCT was coded independently by each reviewer (BM, MJD) and specifically in relation to each intervention component. Coding outcomes were then compared, and discrepancies noted to determine a *kappa* statistic for inter-rater agreement, with greater *kappa* values corresponding to greater strength of agreement [34].

## **Risk of Bias**

Risk of bias was assessed by two reviewers (BM, MJD) using an adaptation of an existing checklist [35]. Item number 13 was omitted from the scoring procedure, as it lacks applicability in a non-clinical context (see Table 3.S3). Fewer scores across a total of 26 items indicate lower study quality due to poor reporting, low external validity, low internal validity relating to risk of bias, confounding, or insufficient power [35].

#### 3.3.4 Data Synthesis

Extracted data were analysed using *Comprehensive Meta-Analysis* (CMA, Version 3; Biostat, Englewood, NJ). Means and standard deviations from pre-test and immediate post-test measurements were used to calculate change scores per group in each study for subsequent analysis in the meta-analysis. Confidence intervals and standard errors were converted to standard deviations where necessary. If a study had more than one intervention arm that was to be included in the meta-analysis, the sample size of the shared control group was divided by the number of included intervention arms to avoid

participants being counted multiple times [36]. Due to the broad spectrum of intervention components, an analysis using random-effects models was deemed appropriate *a priori*.

Mean effects throughout are reported as Hedge's g as a result of including studies with small sample sizes. The magnitude of effects is interpreted using the criteria small (0.2), medium (0.5), and large (0.80) as defined by Cohen [37]. Pooled effect sizes were deemed statistically significant at p < 0.05. In addition to computed estimates of between-study variance (Tau<sup>2</sup>), *Q*-statistics and *I*-statistics are reported to determine the level of heterogeneity in the aggregate data.  $I^2$  values under 25% are interpreted as low heterogeneity; values of 50–75%, and above 75% indicate moderate and high study heterogeneity respectively [38].

Analyses for risk of publication bias were carried out using Rosenthal's *classic fail-safe* N [39], if mean effect estimates were statistically significant. Greater *fail-safe* N values are interpreted as lower concern for risk of publication bias and refer to the number of studies with a zero mean effect that is needed before the pooled effect would no longer be statistically significant (p > 0.05). A tolerance level (criterion value) for the robustness of results was calculated by multiplying the number of effects (m) pooled in the analysis by five and adding 10. In addition, funnel plots were inspected for symmetry, followed by Duval and Tweedie's Trim and Fill analyses [40], which re-calculate the pooled effect sizes).

Due to eligibility of only a small number of studies, the previously screened records (n = 7) reporting results from studies with an active comparator condition, which otherwise met inclusion criteria were considered for a separate meta-analysis of the PSQI total score. However, this was conducted merely to examine the potential superiority of cognitive and behavioural interventions relative to minimal interventions or other types of active control groups. Pooling effect sizes from these studies with the primary mean effect from studies with a no-intervention or waitlist control group would have caused substantial blurring of the mean effect [41] and increased heterogeneity, which in turn would have limited the conclusions to be drawn from these findings.

#### **3.3.5 Subgroup Analyses**

Subgroup analyses were performed to examine potential moderator effects on the overall sleep health outcome measure (PSQI only). Moderator analyses were only conducted for

the PSQI total score only if a minimum of two studies per subgroup were available. The a priori dichotomised moderators were (i) number and type of intervention components, (ii) intervention duration, (iii) mode of delivery, and (iv) sample characteristics (age, baseline sleep) and use of BCTs. A previous meta-analysis of comparable sleep interventions [25] showed that intervention effects can be influenced by the duration of an intervention and whether a relaxation component was included or not. The number of intervention components was initially specified as a moderator, because there is little consensus as to how the use of individual components of CBT-I impacts on treatment efficacy. In addition, although inconclusive, there is some evidence that indicates interventions to improve sleep are more effective if baseline sleep is worse [42]. Internetdelivered CBT-I and face-to-face CBT-I have been found to be equally effective in clinical populations [43,44]. It is unclear how mode of delivery influences intervention efficacy in non-clinical populations; thus, mode of delivery was examined as a moderator. Age was examined as a further moderator, since it is suggested that sleep problems are more frequent in older individuals [45] and previous meta-analyses have also reported a less pronounced intervention effect in older adults [46]. Although planned a priori, moderator analyses for use of BCTs were not performed due to inadequate reporting of use and extensive variation between studies.

For all moderator analyses, the results of mixed-effects models are reported and include effect size predictions per covariate, as well as Q-values and *p*-values. Moderator effects were deemed statistically significant at p < 0.05.

## 3.4 Results

#### **Record Selection**

The study selection and the reasons for exclusion of studies are detailed in Figure 3.S1. A total of 27,883 records were retrieved from database searches (MEDLINE: 12,443; Embase: 11,330; PsycINFO: 2,250; CINAHL: 1,860) and 13 studies that were known to the authors through previous studies or cited in closely related literature were also considered for screening. In four instances, additional data were requested from authors for the purpose of inclusion in meta-analyses. However, none of these requests were fulfilled in due time (six months from date of initial correspondence). In summary, eleven studies (m) were selected for synthesis and meta-analysed.

Inter-rater agreement for record screening procedures based on Cohen's *kappa* [47] was almost perfect ( $\kappa = 0.97$ , p < 0.01), corresponding to disagreement on 40 out of 18,009 screened titles and abstracts between the two reviewers (BM, LW), which was resolved by discussion. A substantial level of agreement was reached for the 592 records that were assessed for eligibility ( $\kappa = 0.78$ , p < 0.001), with discrepancies in judgment for six studies, which also were resolved by discussion.

## **Description of Included Studies**

The eleven studies [48–58] were conducted in seven different countries (China, Denmark, Germany, Japan, Taiwan, UK, USA) and full-text reports were published in English between 1984 [56] and 2017 [57]. There was a high degree of diversity in sample sizes, intervention components, study duration and mode of delivery (see Table 3.1).

#### **Description of Participants**

Results from a total of 1,082 participants were available for analyses and sample sizes ranged from n = 19 [49] to n = 391 [55] (M = 98; SD = 104; median = 84; IQR = 36–107). Participant mean age across studies ranged from 19.47 (SD = 2.73) [48] to 58.42 (SD = 2.75) [49] years with a weighted average of 33.98 (SD = 12.34). Table 3.1 provides further details of participant characteristics. Participants of all study arms identified as poor sleepers with a weighted mean PSQI score of 7.67 (SD = 2.26) at baseline. In line with cut-off values for self-report measures other than the PSQI, participants in the remaining studies were also classed as poor sleepers.

## **Description of Interventions**

The selected studies provided 24 study arms and 11 eligible intervention arms. One threearm RCT [50] provided only one eligible intervention arm and another three-arm RCT [53] collapsed its two intervention arms for analyses and therefore was treated as a twoarm trial.

Interventions had a mean duration of five weeks (range 2–10 weeks), with repeat contact once per week in four out of the nine face-to-face studies (all of which used mind–body approaches [51-53,55]), a one-off session in two studies (sleep hygiene used in both [48,54]), daily contact in one study (relaxation training [56]), twice-weekly contact in one study (comprehensive sleep management [52]), and three sessions per week in one study

(aerobic exercise [49]). Two studies (online cognitive behavioural programme and mindfulness course [57,58]) were delivered entirely remotely and therefore did not involve any face-to-face contact. Seven studies [48,50-55] provided additional materials (i.e., booklets, audiotapes). Instructor-led group practice was complemented by structured home-based practice using complementary materials in five studies [48,50,51,54,55], whereas two studies [52,53] advised optional home-based practice. Both online programmes [57,58] had a structured modular format, combining educational and instructional content.

The most frequently used cognitive and behavioural intervention components to target changes in sleep were *stress management/relaxation* (m = 7); *meditation* (m = 4); *controlled breathing* (m = 4); and *stimulus control* (m = 4). The frequencies at which other components were used are listed in Table 3.S4. With up to 13 components per trial, studies reported using an average of four intervention components.

Each intervention component was coded individually for use of behaviour change techniques (see Table 3.S4). Agreement between the two reviewers (BM, MJD) when coding each component against the 40 BCTs was almost perfect ( $\kappa = 0.93$ , p < 0.01). BCT use per component per study ranged from one to 16. The most frequently used BCTs across components were *providing instructions on how to perform the behaviour* (k = 41), *providing information on where and when to perform the behaviour* (k = 33), and *action planning* (k = 24).

#### 3.4.1 Study Outcomes

Eight studies [48-50,52-55,57] measured sleep quality using the Pittsburgh Sleep Quality Index (PSQI) [59]. Three of these [48,50,55] reported a total PSQI score and all seven component scores and one study [52] used a single-component PSQI measure (subjective sleep quality). Table 3.1 details the instruments used to assess sleep outcomes in all included studies. The change scores used for meta-analyses are presented in Table 3.S5.

## Table 3.1

# Summary of characteristics reported in the included studies

Study	n <sup>1</sup> (IG/CG)	Study design <sup>2</sup> Format		Study duration <sup>3</sup>	Participants	Outcome measure	
Brown et al. [48]	56/66	repeated-measures design	face-to-face; group-based education	6	US American students; $M_{age} = 19.47$ male and female (50:72)	PSQI (total and component scores)	
Cai et al. [49]	10/9	controlled pre-post design	face-to-face; group-based instruction	10	Taiwanese postmenopausal women; $M_{age} = 58.42$	PSQI (total score)	
Gao et al. [50]	42/42	2-arm RCT	face-to-face, brochure; group-based education	4	Chinese University students; $M_{age} = 20.49$ ; male and female (27:57)	PSQI (total and component scores)	
Greeson et al. [51]	45/45	2-arm RCT with a waitlist CG	face-to-face; group-based instruction; home-based practice	4	US American students; $M_{age} = 25.4$ ; male and female (31:59)	MOS-SLP9	
Hahn et al. [52]	48/47	2-group trial with a waitlist CG	face-to-face; group-based workshops	2	German employees (from various organisations); M <sub>age</sub> = 44.6; male and female (42:53)	PSQI single-item score (sleep quality)	
Jensen et al. [53]	48/24	3-arm RCT with a TAU CG <sup>4</sup>	face-to-face; group-based instruction plus materials (print, web, audiotape)	9	Danish volunteers of the general public recruited through GP practices; $M_{age} = 42.24$ ; male and female (25/47)	PSQI (total score)	
Kakinuma et al. [54]	214/177	2-arm CT with a waitlist CG	face-to-face and E-mail; group-based education	4	Japanese IT company workers; $M_{age} = 33.8$ ; male and female (316:75)	PSQI (total score)	
Klatt et al. [55]	22/20	2-arm RCT with a waitlist CG	face-to-face; group-based instruction	6	US American working adults; $M_{age} = 43.41$ ; male and female (11:34)	PSQI (total and component scores)	
Murphy [56]	11/8	3-arm RCT with a waitlist CG⁵	face-to-face; group-based instruction	2	US American highway maintenance workers; $M_{age} = 42^6$	Sleep Quality (Sleep Behaviour Scale)	
Querstret et al. [57] <sup>7</sup>	60/58	2-arm RCT with a waitlist CG	online course (incl. video instructions)	6	British employees from various organisations; $M_{age} = 40.68$ ; male and female (23:95)	PSQI (total score)	

Study	n <sup>1</sup> (IG/CG)	Study design <sup>2</sup>	Format	Study duration <sup>3</sup>	Participants	Outcome measure
Suzuki et al. [58]	12/18	2-arm RCT with a waitlist CG	online programme (incl. website, E-mail, SMS)	2	Japanese workers; $M_{age} = 39.6$ ; male and female (25:16)	CSQI (total score)

*Note.* <sup>1</sup> n analysed per group, where IG = Intervention group and CG = Control group; <sup>2</sup> as reported by the authors, where RCT = randomised controlled trial, CT = controlled trial and TAU = treatment as usual; <sup>3</sup> study duration in weeks; <sup>4</sup> the two intervention groups in this study were collapsed for analyses; <sup>5</sup> this study provided only one eligible study arm; <sup>6</sup> gender not reported; <sup>7</sup> this study was available online in full-text at the time of screening; however, it was not indexed within any of the electronic databases until 2017.

#### Attrition, Adherence, and Acceptability

Three studies [49-51] reported no loss to follow-up in either of their groups. Average loss to follow-up was 16% in intervention groups and 12% in control groups. Five studies that required home-based practice of intervention components reported programme compliance using either participant diaries or website logs. However, it was generally unclear which components and what proportion of instructed contents were taken up in the home setting. None of the studies (m = 11) reported any adverse events.

## Post-treatment Efficacy

The PSQI total score (overall sleep quality) was based on pooled data from seven studies [48-50,53-55,57], and the multi-component score was based on pooled data from the nine studies [48-51,53-55,57,58] that reported scores from the PSQI total, the CSQI and the MOS SLP-9 scale (Table 3.2).

Sensitivity analyses were conducted on both of the above listed primary outcomes by removing those studies that had the main aim of reducing stress [51,53,55,57] and a moderator analysis was used to test differences between studies that had the primary aim of improving sleep [48–50,54,58] and those that aimed to improve sleep and other secondary health indicators through reductions in stress [51,53,55,57].

Secondary outcomes included all PSQI component scores. One analysis was conducted using outcome data (m = 4) for *subjective sleep quality* from the three studies [48,50,55] reporting all PSQI component scores and from one study [52] that used this item as a single measure to assess changes in sleep. Six separate analyses were carried out on the remaining PSQI component scores (m = 3 per analysis) for (1) *sleep onset latency*, (2) *sleep duration*, (3) *sleep efficiency*, (4) *sleep disturbance*, (5) *sleep medication use*, and (6) *daytime dysfunction*. Lastly, another meta-analysis of combined outcome measures was used to pool all single-component sleep quality scores (m = 5; using the subjective sleep quality score from the PSQI from four studies and the sleep quality rating used by Murphy [56]). Analyses of both pooled effects and moderator effects were standardised by change scores. Effect directions were kept negative, due to a reduction in PSQI scores corresponding to improved sleep quality [59].

Changes in PSQI total scores (m = 7) following intervention (see Table 3.2, Figure 3.S2) resulted in a medium effect for changes in overall sleep quality (g = -0.54, [95% CI] -0.89 to -0.19, p < 0.01) and a high level of heterogeneity (Q = 30.1, I<sup>2</sup> = 80.0, p < 0.01). Sensitivity analysis removing the three stress management studies increased the effect size (g = -0.70, [95% CI] -1.31 to -0.09, p = 0.02), but a moderator analysis confirmed that there was no statistically significant difference (Q = 0.68, [95% CI] -0.72 to -0.22, p = 0.41) between studies with the primary aim of improving sleep and those that measured changes in sleep following a stress reduction programme.

The seven studies [60-66] with active comparator conditions provided a total of ten effect sizes, with control groups receiving a range of reduced or minimal intervention content (e.g., sleep diaries, sleep hygiene education or basic health education). A summary table describing these studies and a forest plot showing the pooled effect are provided as supplementary material (Table 3.36, Figure 3.S6). The pooled effect from this meta-analysis based on a random-effects model was small, yet in favour of the intervention groups relative to the active control groups (g = -0.25, [-0.39 to -0.10], p < 0.01).

#### Table 3.2

Summary of effect sizes, study heterogeneity, and publication bias per outcome	
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		Effect sizes			Heterogeneity			<b>Publication Bias</b>		
	m	Hedge's g	CI	р	Q (df)	р	$I^2$	Tau <sup>2</sup>	$N^{l}$	Criterion
Primary outcomes										
Overall sleep quality										
PSQI total	7	-0.54	-0.90; -0.19	< 0.01	30.1 (6)	< 0.01	80.0	0.17	65	45
Overall sleep quality										
Combined measures	9	-0.52	-0.80; -0.24	< 0.01	30.4 (8)	< 0.01	73.7	0.12	100	65
Secondary outcomes										
Subjective sleep quality										
PSQI component	4	-0.21	-0.43; -0.02	0.05	3.1 (3)	0.37	3.8	< 0.01	0	30
Subjective sleep quality										
Combined measures	5	-0.22	-0.42; -0.01	0.04	3.4 (4)	0.49	0.0	< 0.01	0	35
Sleep duration										
PSQI component	3	-0.32	-0.57; -0.07	0.01	0.9 (2)	0.65	0.0	< 0.01	2	25
Sleep onset latency										
PSQI component	3	-0.44	-0.94; 0.05	0.08	7.1 (2)	0.03	71.7	0.14		
Sleep efficiency										
PSQI component	3	-0.28	-0.62; 0.06	0.11	3.5 (2)	0.18	42.1	0.04		
Sleep disturbance										
PSQI component	3	-0.22	-0.47; 0.03	0.09	0.8 (2)	0.67	0.0	< 0.01		
Sleep medication use										
PSQI component	3	-0.15	-0.40; 0.10	0.25	1.1 (2)	0.59	0.0	< 0.01		
Daytime dysfunction										
PSQI component	3	-0.67	-1.85; 0.51	0.27	36.4 (2)	< 0.01	94.5	1.03		

*Note.* <sup>1</sup> *N* refers to the number of studies with a zero mean effect needed for *p* to be >0.05, based on Rosenthal's *fail-safe N* test (computed for statistically significant mean effects only). Standard deviations for change scores were imputed where necessary [36] and conservative pre-post correlations of r = 0.5 were used throughout. Effect directions for scores based on the CSQI, the MOS SLP-9 and the single-item sleep quality rating were reversed for consistency.

Baseline sleep health was the only pre-specified moderator that was significant (Q = 30.1, p = 0.01) (Table 3.3). Those reporting poorer sleep health at baseline (PSQI total score  $\geq$ 8) resulted in larger point estimates (-1.03, [95% CI] -1.65 to -0.41, p < 0.01) compared with studies reporting better sleep health (PSQI <8: -0.20, 95% -0.36 to -0.04, p = 0.01).

Table 3.3

Summary of outcomes	testing moderator	r effects on ove	erall sleep	quality (PSQ)	<i>I total score</i> )

Subgroups	т	Point estimates	Q	95% CI	<b>P</b> <sup>1</sup>
Number of components					
Overall	7	-0.49	0.18	-0.77; -0.22	0.67
Less than four	4	-0.47		-0.76; -0.17	< 0.01
Four or more	3	-0.63		-1.31; 0.06	0.07
Mean participant age					
Overall	7	-0.50	0.18	-0.77; -0.22	0.67
18–35	3	-0.63		-1.31; 0.06	0.07
36–64	4	-0.47		-0.76; -0.17	< 0.01
Baseline sleep quality					
Overall	7	-0.25	6.57	-0.40; -0.10	0.01
Less than eight	4	-0.20		-0.36; -0.04	0.01
Eight or more	3	-1.03		-1.65; -0.41	< 0.01
Primary study aim					
Overall	7	-0.47	0.68	-0.72; -0.22	0.41
To improve sleep	4	-0.70		-1.31; -0.09	0.02
To reduce stress	3	-0.42		-0.70; -0.15	< 0.01

*Note.* <sup>1</sup> Testing the hypothesis of a difference between subgroups using mixed-effects models (significant at p < .05).

Analysis of overall sleep quality from nine studies (see Table 3.2, Figure 3.S3) revealed a high level of study heterogeneity (Q = 32.2, I<sup>2</sup> = 75.1, p < 0.01). Pooling the effects of these sleep interventions yielded a medium-sized effect (g = -0.52, [95% CI] -0.80 to -0.24, p < 0.01). Removing the four studies that focused on stress management in this analysis also resulted in a slightly larger effect size (g = -0.65, [95% CI] -1.18 to -0.13, p = 0.01), but a moderator analysis that stratified effect sizes by primary study aims confirmed there was no statistically significant difference (Q = 0.46, [95% CI] -0.69 to -0.28, p = 0.50) between the two subgroups (sleep improvement versus stress management). Pooling data from the four studies reporting subjective sleep quality resulted in low heterogeneity (Q = 3.1; I<sup>2</sup> = 3.8, p = 0.37) and a small effect size (g = -0.21, [95% CI] - 0.43 to -0.002, p = 0.05). The addition of an additional study with a single-component sleep quality measure reduced study heterogeneity to zero (Q = 3.4, I<sup>2</sup> = 0.0 p = 0.49) and also resulted in a small yet statistically significant effect (g = -0.22, [95% CI] -0.42 to - 0.01, p = 0.04).

Changes in the PSQI component score for sleep duration (m=3) showed a small to medium pooled effect (g = -0.32, [95% CI] -0.57 to -0.07, p = 0.01) and low heterogeneity (Q = 0.8; I = 0.0, p = 0.66). None of the meta-analyses conducted on the remaining outcomes (sleep onset latency, sleep efficiency, sleep disturbance, sleep med use, and daytime dysfunction) showed statistically significant changes (see Table 3.2).

## Efficacy at Follow-up

Only three of the included studies reported results from follow-up assessments, which took place after three weeks [58], 12 weeks [53] and after 12 and 24 weeks [57]. Group means for sleep quality continued to improve following discontinuation of the intervention in all of these studies, but follow-up data were not pooled due to insufficient numbers of studies per outcome measure.

#### **3.4.2 Clinical Significance**

In the context of chronic insomnia, cut-off criteria for treatment response and remission of sleep problems specify a 3-point change in PSQI total scores and a post-test score of less than five respectively [67]. None of the studies that were meta-analysed, however, yielded a post-test PSQI total score under five. Only one study [53] reported a mean score below five in favour of the intervention group (IG  $4.96 \pm 2.93$  compared with CG  $6.63 \pm 3.16$ ), but this was measured at the 12-week follow-up. Although the majority of samples had a mean baseline sleep duration 'between 6 and 7 hours', which shifted towards '7 hours or more' after the intervention (reduced scores indicate longer sleep duration), a longer than recommended sleep duration cannot be determined based on the scoring of this PSQI sub-component [3]. Measuring change in any of the PSQI component scores, in fact, is problematic, as response scores range only from zero to three.

#### 3.4.3 Risk of Bias

Following independent full-text assessment for risk of bias, the two reviewers agreed on 240 out of 260 scores ( $\kappa = 0.86$ , p < 0.01). Disagreements were resolved through discussion under consideration of the *a priori* consolidated criteria for each item. Table 3.S7 shows that study quality varied substantially.

#### **Publication Bias**

For both primary outcomes (PSQI total and PSQI total combined with other sleep health measures), the Rosenthal's *classic fail-safe* N was high, with 65 and 100 studies needed to bring the *p*-value above 0.05 (see Table 3.2). A Trim and Fill analysis of the pooled effect for the PSQI total score did not identify any outliers and the reported effect size therefore remained unchanged. Trim and Fill analysis of the combined PSQI total score resulted in one study being imputed to the left of the mean, which caused the pooled estimate to increase (g = -0.59 [95% CI] -0.90, -0.28). Funnel plots illustrating these findings are provided in Figures 3.S4 and 3.S5.

# 3.5 Discussion

This systematic review with meta-analysis is the first to quantify the efficacy of cognitive and behavioural interventions to improve sleep health in adults without a clinical sleep disorder. Meta-analyses showed that cognitive and behavioural interventions have small effects on subjective sleep quality and sleep duration as individual parameters of sleep health. Improvements in overall sleep health were of medium size and appeared robust when comparing results based on PSQI total scores only (g = -0.54) and those on combined multi-component sleep health scores (g = -0.52). Moderator effects revealed that larger effects are observed in studies where sleep health baseline sleep health was worse. The moderator analysis comparing studies that had the primary aim of improving sleep relative to studies that sought to improve sleep as an outcome secondary to stress reduction was not significant. This may be due to studies with the primary aim of improving sleep also including a stress reduction component, despite not detailing that as a main aim.

Subjective sleep quality and sleep duration were the only two parameters of sleep health that improved significantly following cognitive and/or behavioural intervention. This

may have been a function of the objectives most studies had and the extent to which changes in the various parameters of sleep health were tangible for participants. A small effect (g = -0.32) associated with improved sleep duration observed in this synthesis is similar to the magnitude of change (d = 0.22) observed in interventions targeting insomnia patients [46,68]. A direct comparison between these estimates is difficult, since CBT-I interventions in insomnia populations [18] commonly include sleep restriction. Sleep restriction is an intervention component that was not identified in any of the included studies, which may be due to the relatively short duration of studies in the current review.

Larger effects have been observed in systematic reviews of cognitive and behavioural sleep interventions for the treatment of clinical insomnia [46,69]. This may be due to a larger potential magnitude of change for populations with a clinical sleep disorder relative to non-clinical populations, which was reflected in the moderator analysis on baseline sleep.

Similarly, the lack of change observed for other components of sleep health (e.g., sleep onset latency) may have been due to assessment issues, as the use of self-report measures for these parameters is known to be subject to recall bias [70]. No study used an objective measure of sleep (e.g., polysomnography, accelerometers) despite the growing use of accelerometers for the assessment of sleep in epidemiology research and interventions research [71]. Using a combination of both accelerometer and continuous self-report measures (e.g., sleep diaries) may assist in overcoming this, while still catering for the issue that accelerometer-based methods are not capable of assessing the perceived restorative effects of sleep.

The small effect that was found for studies with an active control group again did not lend itself to comparison or incorporation with the primary effect estimate for studies that did not have active control groups. Particular caution should be applied when interpreting the pooled estimate for these studies; although all of the studies in this meta-analysis employed an active control group, they varied greatly in what was included as the active control, which introduced an undesirable level of heterogeneity. Overcoming this would have required moderator analyses to be conducted by type of comparator (e.g., non-sleep specific, minimal sleep intervention), for which too few studies were available. This finding, however, does provide some support for the superiority of the cognitive and behavioural interventions that were tested in these studies.

#### **3.5.1 Effect Moderators**

Due to the low number of studies that were available for synthesis, any subgroup analyses conducted in this review are exploratory in nature and therefore warrant cautious interpretation. The only statistically significant effect moderator for PSQI score was baseline sleep health. Although mean changes were significant in both subgroups, a greater effect was seen in those with poorer sleep health at baseline (PSQI >8). While likely a result of the low number of studies per subgroup, this observation is partially explained by the smaller margin of improvement that can be achieved with individuals who have less severe sleep difficulties [42] (i.e., ceiling effects).

Although hypothesised *a priori*, mode of delivery, study duration and the inclusion of a relaxation component were not assessed as effect moderators, due to insufficient effect sizes available per subgroup. In a clinical context, however, there is some evidence for the comparable efficacy of face-to-face versus remote modes of delivery [43]; thus, future studies using remote intervention delivery in non-clinical populations are warranted. Furthermore, examining the efficacy of longer interventions in non-clinical populations may be worthwhile, given prior reviews of CBT-I in insomniac populations demonstrated that longer-lasting studies yielded larger effects [25].

#### **3.5.2** The Use of Behaviour Change Techniques

The overall reporting of BCTs was generally inadequate, which made it impossible to incorporate this factor in the quantitative synthesis. Patterns for reported use of BCTs were relatively consistent between studies and many were based on utilising information and instructions relating to the behaviour (e.g., sleep hygiene). A greater number of BCTs were used in studies with cognitive and mind–body components (e.g., mindfulness), whereas fewer BCTs were reported in studies using mainly behavioural components. This was particularly true for exercise and food intake in relation to sleep, where generic advice on the importance of these behaviours was provided, but no further implementation plans were given to participants. This may reduce the likelihood that participants change physical activity behaviours and obtain the benefits that physical activity has on sleep [46,62].

The behaviour change techniques most commonly used in interventions for other health behaviours – for example, goal-setting, self-monitoring and feedback [72] – were less prominent in the sleep interventions examined in this review. A certain degree of concern when implementing strategies that have the potential to exacerbate sleep problems may exist, if not delivered appropriately and with due guidance. Self-monitoring, for example, involves a strong observational focus on practising the behaviour in question and encourages individuals to build a sense of enhanced self-efficacy when evaluating behavioural progress against goals or expectations over time [73]. In some participants, this may lead to unintended outcomes (i.e., delayed sleep onset due to feelings of frustration), caused by undue effort assigned to trying to sleep, which is a common driver of chronic insomnia. Given the evidence that goal-setting, self-monitoring, and feedback are consistently associated with improvements in other health behaviours, it would be useful to examine the efficacy of these techniques to improve sleep health. This needs to be implemented in a way that is cognisant of these issues.

#### **3.5.3 Implications of Findings from this Review**

This review focused on populations reporting poor sleep in the absence of a diagnosed sleep disorder and demonstrated that cognitive and behavioural interventions are effective at improving sleep quality and duration. This has important implications given the large number of adults who report poor quality sleep but do not have a sleep disorder. It was beyond the scope the review to comment on how these improvements influence the risk of developing future sleep disorders. Despite the magnitude of observed effects, intervention efficacy needs to be enhanced, given no study reported PSQI scores under 5 at post-treatment. Reported attrition was low; however, study durations were relatively short and it is unknown if dropout would increase in studies of longer duration, given the evidence from other health behaviour interventions [74]. The majority of participants were full-time students or employees, who were in relatively good health; hence, the efficacy of similar interventions in other populations is unknown.

#### Limitations

It remains unclear to what extent individuals with poor sleep health are truly distinct from those who would meet diagnostic criteria for insomnia. It may be that included participants simply had an undiagnosed sleep disorder. However, PSQI mean scores in chronic insomniacs are usually much higher (>10 [75]) compared with those observed in the included studies and may be indicative of a different population group. The coding of BCTs was constrained by a lack of detailed reporting in the studies; thus, future reports are encouraged to improve reporting of intervention strategies used to operationalise the intervention.

In studies including multiple sleep hygiene recommendations, it was not possible to determine adherence to different recommendations and the difficulty in assessing adherence is exacerbated by the fact that not all sleep hygiene recommendations apply to all participants. It is undetermined whether the exclusion of studies where effect sizes could not be calculated (due to missing data) affected the overall findings in this review; however, all of these studies reported improvements in one or several parameters of sleep following intervention. Some level of bias may have been introduced by only including published studies and studies published in English; however, the impact of this is likely to be minor [76]. Statistical tests for publication bias showed the findings in this review are robust for the primary outcomes. This potential limitation was further reduced by searching trial registries for studies that were yet to be published.

#### **Directions for Future Research**

Future interventions are encouraged to combine educational approaches with BCTs to help provide participants with the tools necessary to drive behaviour change. There is a need for future studies to better utilise the potential of individual intervention components and extend the choice of self-regulation strategies beyond the ones fostering implementation intentions (i.e., action planning) [77]. Some components identified in this review are components commonly found in CBT-I interventions, suggesting these components are also effective in non-clinical populations. However, there is a need to test the efficacy of these interventions in more diverse populations to better understand the mechanisms that drive changes in sleep health. Further, given many of the included trials still included some face-to-face aspect, it will be useful to further examine the efficacy of interventions that use a mode of delivery capable of broad reach to address the high prevalence of poor sleep health.

#### **3.6 Conclusion**

This systematic review with meta-analysis showed that interventions involving activities that de-stress mind and body significantly improve sleep quality in adults without clinical sleep disorders. Although producing robust effects of medium magnitude on overall sleep health, interventions using cognitive and behavioural components show room for improvement, as the exact mechanisms by which sleep health is restored to normal (PSQI <5) remain to be investigated. Additional investigations into broad-reaching interventions that promote self-regulatory strategies with the aim of improving sleep health are much needed and the present review supports the efficacy thereof.

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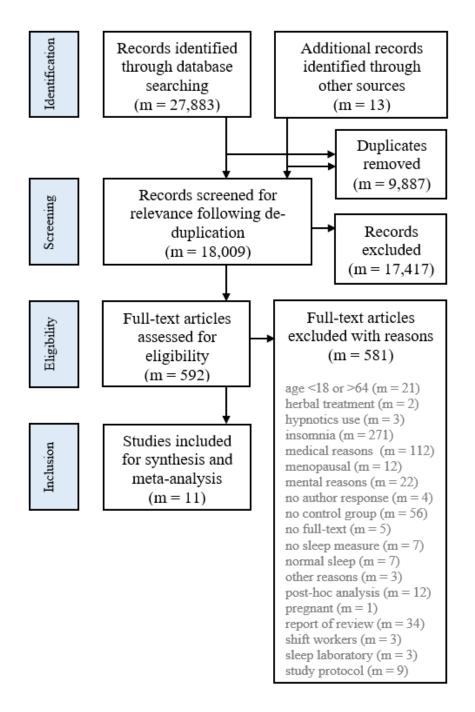
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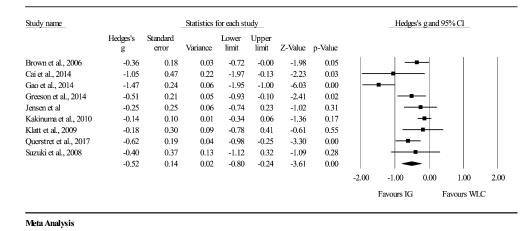
# **Supplementary Material – Chapter 3**



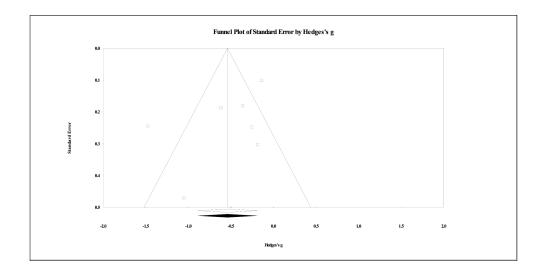
*Figure 3.S1*: Flow diagram of records

Study name			Statistics i	for each st	udy				Hedge	s's gand 9	5% CI	
	Hedges's g	Standard error	Variance	Lower limit	Upper limit	Z-Value	p-Value					
Brown et al., 2006	-0.36	0.18	0.03	-0.72	-0.00	-1.98	0.05		-	-		
Cai et al., 2014	-1.05	0.47	0.22	-1.97	-0.13	-2.23	0.03		-			
Gao et al., 2014	-1.47	0.24	0.06	-1.95	-1.00	-6.03	0.00	<u> </u>	-			
Jensen et al., 2015	-0.25	0.25	0.06	-0.74	0.23	-1.02	0.31		_	-		
Kakinuma et al., 2010	-0.14	0.10	0.01	-0.34	0.06	-1.36	0.17					
Klatt et al., 2009	-0.18	0.30	0.09	-0.78	0.41	-0.61	0.55		—			
Querstret et al., 2017	-0.62	0.19	0.04	-0.98	-0.25	-3.30	0.00			-		
	-0.54	0.18	0.03	-0.89	-0.19	-3.02	0.00					
								-2.00	-1.00	0.00	1.00	2.00
									Favours IG	F	avours WL	С

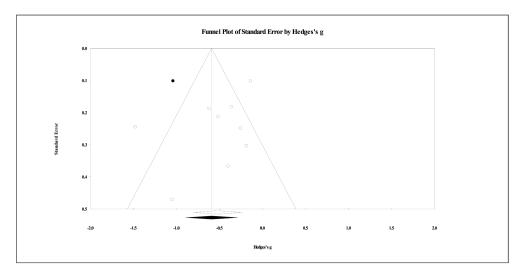
*Figure 3.S2:* Forest plot illustrating bias-corrected effect estimates (*g*) for sleep quality based on the PSQI total score (where lower scores indicate improvements in sleep quality)



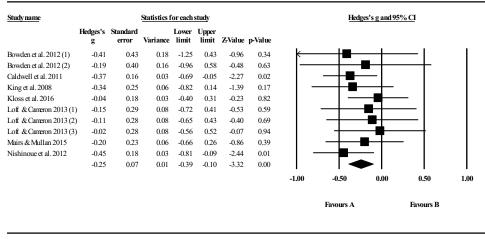
*Figure 3.S3:* Forest plot illustrating bias-corrected effect estimates (g) for overall sleep quality based on combined multi-component measures (where lower scores indicate improvements in sleep quality)



*Figure 3.S4:* Unadjusted and adjusted effect size estimates for the PSQI total score based on Duval and Tweedie's Trim and Fill analysis for publication bias under the random effects model (where  $\diamond$ = unadjusted ES and  $\blacklozenge$  = adjusted ES



*Figure 3.S5:* Unadjusted and adjusted effect size estimates for the PSQI score combined with other sleep health measures based on Duval and Tweedie's Trim and Fill analysis for publication bias under the random effects model (where  $\bullet$  = imputed studies,  $\diamondsuit$ = unadjusted ES and  $\blacklozenge$  = adjusted ES).



Meta Analysis

*Figure 3.S6.* Forest plot for the effect estimate (g) based on studies (n = 7) using active comparator conditions.

Table 3.S1

Search strings by database

# Medline

001	Sleep/
002	sleep*.tw.
003	1 or 2
004	Intervention Studies/
005	intervention*.tw.
006	program*.tw.
007	treatment*.tw.
008	therap*.tw.
009	4 or 5 or 6 or 7 or 8
010	exp Randomized Controlled Trials as Topic/
011	randomized controlled trial/
012	randomized controlled trial.pt.
013	Random Allocation/
014	(allocated adj2 random*).tw.
015	Double Blind Method/
016	Single Blind Method/
017	((singl* or doubl* or treb* or tripl*) adj (blind*3 or
	mask* 3)).tw.
018	exp Clinical Trials as topic/
019	clinical trial/
020	(clinical adj trial*).tw.
021	Multicenter Study/
022	exp Multicenter Studies as Topic/
023	Cross-Over Studies/
024	(crossover adj2 (design or study)).tw.
025	PLACEBOS/
026	placebo*.tw.
027	control*.tw.
028	(compar* adj2 stud*).tw.
029	(experiment* adj2 design*).tw
030	(experiment* adj2 stud*).tw.
031	(followup* or follow-up*).tw.
032	10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23
	or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31
033	3 and 9 and 32
034	limit 33 to (english language and ("young adult (19 to 24 years)" or "adult (19 to
	44 years)" or "young adult and adult (19-24 and 19-44)" or "middle age (45 to 64 years)"))

Table 3.S1Search strings by database

\_

Embas	e
001	sleep/
002	sleep*.tw.
003	1 or 2
004	intervention study/
005	intervention*.tw.
006	program*.tw.
007	treatment*.tw.
008	therapy/
009	therap*.tw.
010	4 or 5 or 6 or 7 or 8 or 9
011	Randomization/
012	Randomi?ed controlled trial?.tw.
013	Random allocation.tw.
014	randomly allocated.tw.
015	Allocated randomly.tw.
016	(allocat* adj2 random*).tw.
017	Rct.tw.
018	Single blind procedure/
019	Double blind procedure/
020	Single blind*.tw.
021	Double blind*.tw.
022	((singl* or doubl* or treb* or tripl*) adj (blind*3 or mask*3)).tw.
023	Clinical trial/
024	exp Clinical Trials as Topic/
025	Crossover procedure/
026	(crossover adj2 (design or study)).tw.
027	Placebo/
028	placebo*.tw.
029	control*.tw.
030	"multicenter study (topic)"/
031	(multicent* adj2 stud*).tw.
032	(compar* adj2 stud*).tw.
033	(experiment* adj2 design*).tw.
034	(experiment* adj2 stud*).tw.
035	(followup* or follow-up*).tw.
036	Randomized controlled trial/
037	11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or
	27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36
038	3 and 10 and 37
039	limit 38 to (english language and adult <18 to 64 years>)

Table 3.S1Search strings by database

PsycI	PsycInfo		
001	Sleep/		
002	sleep*.tw.		
003	1 or 2		
004	Intervention/		
005	intervention*.tw.		
006	program*.tw.		
007	Treatment/		
008	treatment*.tw.		
009	therap*.tw.		
010	4 or 5 or 6 or 7 or 8 or 9		
011	((randomi?ed adj7 trial*) or ((single or doubl* ot tripl* or treb*) and (blind* or		
	mask*))).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]		
012	(random* adj3 assign*).tw.		
013	random*.tw.		
014	control*.tw.		
015	(controlled adj3 trial*).tw.		
016	exp Clinical Trials/		
017	(clinical adj3 trial*).tw.		
018	Treatment Effectiveness Evaluation/		
019	treatment outcomes/		
020	(evaluat* adj3 stud*).tw.		
021	(compar* adj3 stud*).tw.		
022	Experimental Design/		
023	(experiment* adj3 stud*).tw.		
024	crossover*.tw.		
025	(multicent* adj2 stud*).tw.		
026	Followup Studies/		
027	(followup* or follow-up*).tw.		
028	Placebo/		
029	placebo*.tw.		
030	11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29		
031	3 and 10 and 30		
032	limit 31 to (english language and (320 young adulthood <age 18="" 29="" to="" yrs=""> or</age>		
340	thirties <age 30="" 39="" to="" yrs=""> or 360 middle age <age 40="" 64="" to="" yrs="">))</age></age>		
Cinah	nl		

Table 3.S1
Search strings by database

S33	S31 NOT S32 Limiters - English Language; Age Groups: Adult: 19-44 years, Middle Aged: 45-
	64 years
S32	(MH "Animals")
S31	S3 AND S9 AND S30
S30	S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28 OR S29
S29	TI experiment* W2 stud* AND AB experiment* W2 stud*
S28	TI experiment* W2 design* OR AB experiment* W2 design*
S27	TI multicent* W2 stud* OR AB multicent* W2 stud*
S26	TI followup W2 stud* OR AB followup W2 stud*
S25	TI follow-up W2 stud* OR AB follow-up W2 stud*
S24	(MH "Evaluation Research+")
S23	TI compar* W2 stud* OR AB compar* W2 stud*
S22	(MH "Comparative Studies")
S21	TI placebo* OR AB placebo*
S20	(MH "Placebos")
S19	(MH "Placebo Effect")
S18	TI treb*-blind* OR AB treb*-blind*
S17	TI triple-blind* OR AB triple-blind*
S16	TI double-blind* OR AB double-blind*
S15	TI single-blind* OR AB single-blind*
S14	"random?ed controlled trial*"
S13	TI random* OR AB random*
S12	(MH "Random Sample")
S11	TI clinical W3 trial* OR AB clinical W3 trial*
S10	(MH "Clinical Trials+")
S9	S4 OR S5 OR S6 OR S7 OR S8
<b>S</b> 8	TI therap* OR AB therap*
<b>S</b> 7	TI treatment* OR AB treatment*
<b>S</b> 6	TI program* OR AB program*
S5	TI intervention* OR AB intervention*
S4	(MH "Intervention Trials")
S3	S1 OR S2
S2	TI sleep* OR AB sleep*
<b>S</b> 1	(MH "Sleep")

Exclusion criteria

	Criteria for exclusion	Reasons for exclusion		
Participants	Participant mean age <18 years or >64 years.	Sleep needs as well as the prevalence and aetiology of sleep problems differ for children and adolescents as well as for the elderly. The population group of interest in this review were working age adults, defined as 18–64 years old [1].		
	Studies that specifically recruited pregnant women or parents of newborns (<12 months old).	Reason A: Nursing a newborn throughout the night, combined with substantial hormonal changes that affect sleep [2].		
	Perimenopausal or menopausal women (reporting being without menses for <12 months).	Reason A: Substantial hormonal changes causing symptoms such as night sweats that affect sleep; development of clinical sleep disorders during menopause is common [3].		
	jetlagged individuals and airline workers (travelling across at least three time zones once a month).	Reason A: Significant disruptions in chronobiology (circadian rhythm) are a common consequence of jetlag [4].		
	Any study populations reporting acute or chronic medical or mental illness (e.g., cancer, renal failure, fibromyalgia, depression, schizophrenia, clinical anxiety, Alzheimer's, Parkinson's, post- traumatic stress disorder, etc.) and those who still received treatment at the time of recruitment.	Reasons A & B: Moderate to severe sleep problems are reported for most co- morbidities [5]; thus, a more comprehensive treatment than that available by an intervention only targeting sleep may be necessary. Further, the use of medication for the primary condition may have effects on sleep or cause fatigue [6].		
	Samples where baseline means for mental illness exceeded established diagnostic cut-offs for mental illness (e.g., Beck depression inventory-II [7]).	Reasons A & B: Moderate to severe sleep problems are reported for most mental illnesses [5]; this may be a confounder of any intervention targeting sleep. The use of medication for the primary condition may have effects on sleep or cause fatigue [6].		
	Studies that recruited participants with addictions to and/or abuse of alcohol or drugs, ongoing rehabilitation attendance and self-reported abstinence from drugs or alcohol for <12 months (pre-recruitment).	Reason A: Significant disruptions in chronobiology (circadian rhythm) related to withdrawal may confound the intervention [8].		
	Samples with >25% shift workers	Reason A: Significant disruptions in chronobiology (circadian rhythm) and low levels of sleep quality, sleep latency and sleep efficiency [9].		

### Exclusion criteria

Participants	Samples with a mean body mass index (BMI) that exceeded a score of 35 (severe obesity) due to its strong associations with insomnia and other sleep disorders.	Sleep apnea as well as indicators of sleep health (e.g., total sleep time) are more common in those with a higher BMI [10,11].
	Studies conducted in normal sleepers (defined as mean baseline values on the total PSQI score of <5, or a subjective sleep quality rating of 'fair' or better (as per PSQI component score for subjective sleep quality). Note: wherever it was not possible to utilise cut-off criteria for good sleep/poor sleep, and if the study used single-item scores or not validated items, a conservative approach was adopted to exclude studies, provided that mean scores at baseline exceeded the mid-point value (50%) of the maximal score (for scales where higher scores indicated better sleep and vice versa).	The population of interest was defined as individuals who have not been diagnosed with sleep disorders such as insomnia, yet report poor sleep health and these criteria were selected to help eliminate irrelevant studies.
	Studies that were conducted in or specifically recruited participants who met diagnostic criteria for insomnia as per DSM-5, ICD-10, ICSD-3, or equivalent diagnostic criteria (consistent with Edinger et al. [12], or alternatively reporting an Insomnia severity index score of >10 [13]), and those in which participants self-reported having a diagnosed condition such as nocturia, restless legs syndrome, narcolepsy, cataplexy, obstructive sleep apnea (OSA), or sleepwalking.	The population of interest was defined as individuals who have not been diagnosed with sleep disorders such as insomnia, yet report poor sleep health and these criteria were selected to help eliminate irrelevant studies.
Interventions	Samples with >25% of the sample using sleep medication (or reporting a baseline PSQI component score of $\geq 1$ for use of sleep medications).	Reason B: It would have made it very difficult to determine if the observed effect was due to the intervention or due to some people also taking sleep medications.
	Samples with >25% of the sample receiving or reporting using any type of medication or treatment that is known to interfere with natural sleep (antidepressants, hemodialysis, hormone therapy, etc.).	Reason B: It would have made it very difficult to determine if the observed effect was due to the intervention or to some people also taking medications for primary conditions. The treatments excluded may also cause levels of fatigue that cannot be counteracted with good sleep alone [6].

# Exclusion criteria

Interventions	Interventions involving manual treatments that cannot be self- administered (e.g., acupuncture, massage, neuro- and biofeedback), or cannot be described as a self-regulatory strategy (e.g., façade insulation of housing) as well as interventions that required the ingestion or inhalation of herbal or alternative remedies (e.g., lavender, valerian, homoeopathic medicines, etc.).	The scope of this review was framed around self-regulatory strategies that are suitable for independent administration/practice and reflect the maximum of accessibility, affordability and acceptability.
	Interventions involving the disruption or radical deprivation of sleep (e.g., skipping a full night's sleep).	This type of intervention is not feasible as a recommendation that can be given out without personalised guidance and ongoing monitoring.
Comparator conditions	Studies, where all intervention arms received pharmacological treatment, as either an adjunct to behavioural treatment or as the main treatment.	The inclusion of study arms that received pharmacological treatment would have made it difficult to compare effects between groups for the purpose of examining intervention efficacy.
	Studies, during which all intervention arms received some form of cognitive or behavioural treatment that impacts sleep (e.g., education only).	The inclusion of comparator arms that also received an intervention would have made it difficult to determine the effect of the intervention in question.
	Any comparator conditions that cannot be described as a no-intervention control group or where significant contamination was reported.	The inclusion of control groups that received an intervention would have made it difficult to compare effects between groups for the purpose of examining intervention efficacy.
Outcomes	Assessments that were conducted in an unfamiliar sleep environment such as a sleep laboratory.	Reason A: Unfamiliar sleep environments may inadvertently have adverse effects on sleep [14].
Study types	Studies that did not have an experimental design comparing an intervention against at least one control condition.	Since the meta-analysis intended to pool data for the purpose of examining intervention efficacy, a control condition was required.
	Studies that did not report assessment data from pre- and immediate post- intervention tests.	Since the meta-analysis intended to pool data to examine intervention efficacy, immediate post-test data were required.
	Studies that reported data from post-hoc analyses where the main study did not have the aim to improve sleep (for example, the main study aimed to reduce	Since it had to be one of the main aims of the study to improve sleep, any post-hoc analyses based on studies that did not have

	work-family conflict and secondary outcomes incl. a sleep parameter are presented in a separate report).	the main aim to improve sleep were not selected.
Settings	Hospitalised or institutionalised subjects (e.g., intensive care, care home, psychiatry, etc.).	Reason A: High likelihood of other health conditions that are the driver of poor sleep [15].

*Notes.* Reason A = This exclusion criterion was nominated, because the condition/circumstances in question do not allow natural sleep to occur or introduce sleep problems at a level that would require other forms and content of intervention; Reason B = This exclusion criterion was nominated due to its high potential to introduce a bias (confounding) affecting intervention effects.

#### **References for supplementary information file Table S2**

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Table 3.S3

Criteria		Yes No		Unable to determine	
Re	porting				
1.	Is the hypothesis/aim/ objective of the study clearly described?	The description of study hypotheses/aims/ objectives was clear.	The description of study hypotheses/aims/ objectives was unclear.	N/A	
2.	Are the main outcomes to be measured clearly described in the Introduction or Methods section?	Outcomes to be measured were clearly described prior to the results section.	Outcomes to be measured were not clearly described or only described in the results section.	N/A	
3.	Are the characteristics of the participants included in the study clearly described?	The characteristics of participants to be studied were clearly described and the report stated inclusion/exclusion criteria.	The characteristics of participants to be studied were not clearly described or the report did not state included inclusion/exclusion criteria.	N/A	
4.	Are the interventions of interest clearly de- scribed?	The intervention of interest and the comparator condition were clearly described.	The intervention of interest and the comparator condition were not clearly described.	N/A	
5.	Are the distributions of principal confounders in each group of participants to be compared clearly described?	Yes (2), if the distribution of principal confounders as well as baseline scores of the study outcomes in each group was clearly described. Yes (1), if only the distribution of principal confounders was clearly described.	The distribution of principal confounders as well as baseline scores of the study outcomes in each group was not clearly described.	N/A	
6.	Are the main findings of the study clearly described?	The report included simple outcome data for all major findings.	The report did not include simple outcome data for all major findings.	N/A	

Scoring criteria used to assess risk of bias – adapted from Downs & Black, 1998 [35]

Scoring criteria used to assess risk of bias

	Criteria	Yes	No	Unable to determine
7.	Does the study provide estimates of the random variability in the data for the main outcomes?	The report provides estimates of random variability such as standard errors, standard deviations or confidence intervals (or inter- quartile ranges in the case of non-normally distributed data).	The report did not provide estimates of random variability.	N/A
8.	Have all important adverse events that may be a consequence of the intervention been reported?	The report stated that there was a comprehensive attempt to measure adverse events and either states the occurrence of adverse events or clearly states that no adverse events were observed.	The report did not state that there was a comprehensive attempt to measure adverse events or did not state if any adverse events were observed.	
9.	Have the characteristics of participants lost to follow-up been described?	There were no losses to follow-up or losses to follow-up were so small that findings would be unaffected by their inclusion.	The study did not report the number of patients lost to follow-up or the losses to follow-up were large enough to affect the findings.	
10.	Have actual probability values been reported (e.g. 0.035 rather than <0.05) for the main outcomes except where the probability value is less than 0.001?	The report provided precise probability values for the main outcome measures.	The report did not provide precise probability values (e.g., used <0.05).	
Ex	ternal validity			
11.	Were those participants who were asked to participate in the study representative of the entire population	The report identified the source population for participants, described how participants were selected and provided a statement that determined the proportion of those	The report did not identify the source population for participants or did not describe how the participants were	The report did not state the proportion of the source population from which the participants were derived.

selected.

the proportion of those

who were asked in

from which they were

recruited?

Table 3.S3

Scoring criteria used to assess risk of bias

Cri	teria	Yes	No	Unable to determine
		relation to the population from which they were recruited (or the sample comprised the entire population, an unselected sample or a random sample).		
12.	Were those participants who were prepared to participate representative of the entire population from which they were recruited?	The report stated the proportion of those asked who agreed and the distribution of the main confounding factors was the same in the study sample and the source population.	The report did not state the proportion of those asked who agreed or the distribution of the main confounding factors was not the same in the study sample and the source population.	The report stated the proportion of those asked who agreed but did not state if the distribution of the main confounding factors wa the same in the study sample and the source population.
13.	Were the staff, places, and facilities where the patients were treated, representative of the treatment the majority of patients receive?	Item omitted		
Int	ernal validity – bias			
14.	Was an attempt made to blind participants to the intervention they have received?	Participants would have had no way of knowing which intervention they received.	No attempt was made to blind study participants or it was not possible to blind participants due to the nature of the intervention or an attempt to blind participants failed.	It was unclear if any attempt was made to blind participants or it was unclear whether an attempt was successful.
15.	Was an attempt made to blind those measuring the main outcomes of the intervention?	Those measuring study outcomes would have had no way of knowing which intervention they received.	No attempt was made to blind those measuring study outcomes or it was not possible to blind those due to the nature of the intervention or an attempt to blind staff failed.	It was unclear if any attempt was made to blind those measuring study outcomes or it wa unclear whether any attempt was successful.

Table 3.S3

Scoring criteria used to assess risk of bias

Criteria	Yes	No	Unable to determine
16. If any of the resu of the study were based on "data dredging", was made clear?	been planned at the outset of the study were	Analyses that had not been planned at the outset of the study were not indicated. Study aims and reported outcomes did not align.	Analyses that had not been planned at the outset of the study were not clearly indicated or it was unclear whether any of the reported subgroup analyses were unplanned. This included reports that did not state clear study aims.
17. Do the analyses adjust for differe lengths of follow of patients?		Differences in follow-up were not taken into account.	It was unclear if length of follow-up was the same for all participants or it was unclear if any differences in follow-up were taken into account.
18. Were the statistic tests used to asso the main outcom appropriate?	used were appropriate to	The statistical techniques used were not appropriate to the data or little statistical analysis has been undertaken but there was evidence of bias.	It was unclear if the statistical techniques used were not appropriate.
19. Was compliance with the intervention/s reliable?	There was compliance with the allocated treatment and there was no contamination of one group.	There was non- compliance with the allocated treatment or there was contamination of one group.	It was unclear if there was compliance with the allocated treatment or if there was contamination of one group.
20. Were the main outcome measur used accurate (v and reliable)?	5	The outcome measures were not accurate.	The outcome measures were described, but the study did not refer to other work or demonstrate that the outcome measures were accurate.
Internal validity – c	onfounding (selection bias)		
21. Were the	Participants for all	Participants were not	There was no

21.	Were the	Participants for all	Participants were not	There was no
	participants in	comparison groups were	selected from the same	information concerning
	different	selected from the same	organization, workplace,	the source of participants
	intervention groups	organization, workplace,	etc.	included in the study.
	recruited from the	etc.		

same population?

Table 3.S3

Scoring criteria used to assess risk of bias

	Criteria	Yes	No	Unable to determine
22.	Were the participants in different intervention groups recruited over the same period of time?	Participants for all comparison groups were selected over the same period of time.	Participants were not selected over the same period of time.	The report did not specify the time period over which participants were recruited.
23.	Were participants randomised to intervention groups?	The report stated that subjects were ran- demised.	The method of randomisation used did not ensure random allocation.	The report did not describe clearly how subjects were assigned to different groups.
24.	Was the randomised intervention assignment concealed from both participants and staff?	Assignment was concealed from both participants and staff.	Assignment was concealed from participants, but not from staff (or vice versa) or the study was non-randomised.	It was unclear if assignment was concealed from both participants and staff.
25.	Was there adequate adjustment for confounding in the analyses from which the main findings were drawn?	The study reported adequate adjustment for confounding.	The main conclusions of the study were based on analyses of treatment rather than intention-to- treat or the distribution of known confounders in the different treatment groups was not described or the distribution of known confounders differed between the treatment groups, but was not taken into account in the analyses.	It was unclear if there was adequate adjustment for confounding.
26.	Were losses of participants to follow-up taken into account?	Loss to follow-up was taken into account or the proportion lost to follow-up was too small to affect the main findings.	The proportion lost to follow-up was enough to affect the main findings, but this was not taken into account.	The numbers of patient lost to follow-up were not reported.

Table 3.S3

Scoring criteria used to assess risk of bias

Criteria	Yes	No	Unable to determine
Power			
27. Did the study have sufficient power to detect a clinically important effect?	The report described clearly how sample sizes were calculated to detect a difference and the sample size used for analysis was sufficient.	The report did not describe sample size calculations or the sample size used for analysis was insufficient.	

*Note.* As per the original checklist by Downs & Black [35], items of study quality are subdivided into five broader categories: reporting (10 items), external validity (3 items), internal validity - bias (7 items), internal validity - confounding (6 items), and power (1 item); to independently scoring each study, the two reviewers consolidated their conceptual understanding of the checklist items and made amendments where necessary.

вст	L Information on consequences of behaviour in general	$\boldsymbol{\omega}$ Information on consequences of behaviour to individual	► Normative information (others)	u Goal-setting (behaviour)	• Goal-setting (outcome)	<ul> <li>Action Planning</li> </ul>	æ Barrier identification/problem solving	<b>6</b> Setting graded tasks	<b>1</b> Review of behavioural goals	11 Review of outcome goals	<b>1</b> Rewards contingent on progress towards behaviour	<b>1</b> Rewards contingent on successful behaviour	<b>15</b> Generalisation of target behaviour	91 Self-monitoring of behaviour	<b>1</b> Self-monitoring of outcome	<b>8</b> Prompting focus on past success	61 Feedback on performance	<b>1</b> Information on where $\&$ when to perform behaviour	<b>1</b> Instructions on how to perform behaviour	<b>2</b> Modelling/demonstrating behaviour	<b>5</b> Environmental restructuring	<b>5</b> Prompting practice	<b>Z</b> Using follow-up prompts	<b>8</b> Facilitating social comparison	<b>1</b> Prompting anticipated regret	<b>B</b> Prompting use of imagery	<b>5</b> Relapse prevention/coping planning	<b>36</b> Stress management	<b>88</b> Time management	<b>6</b> Anticipation of future rewards
Brown [32]																														
Sleep knowledge	x	x																x	х		х									
Caffeine intake	x	x				x												х												
Alcohol intake	x	x				x												х												
Exercise			х																											
Sleep timing	х	x				х												х	Х										х	
Environment																		х	Х		х									
Napping	х	X				х												Х	Х											
Stimulus control	x					Х	Х											х	Х											
Light exposure																		Х	Х		х									

	Information on consequences of behaviour in general	Information on consequences of behaviour to	Goal-setting (behaviour)	Goal-setting (outcome)	Action Planning	Barrier identification/problem solving	Setting graded tasks	Review of behavioural goals	Review of outcome goals	Rewards contingent on progress towards behaviour	Rewards contingent on successful behaviour	Generalisation of target behaviour	Self-monitoring of behaviour	Self-monitoring of outcome	Prompting focus on past success	Feedback on performance	Information on where $\&$ when to perform behaviour	Instructions on how to perform behaviour	Modelling/demonstrating behaviour	Environmental restructuring	Prompting practice	Using follow-up prompts	Facilitating social comparison	Prompting anticipated regret	Prompting use of imagery	Relapse prevention/coping planning	Stress management	Time management	Anticipation of future rewards
BCT	1	2 4	5	6	7	8	9	10	11	12	13	15	16	17	18	19	20	21	22	24	26	27	28	31	34	35	36	38	40
Cai [33]																													
Relaxation					х													Х	Х								Х		
Exercise					х													Х	Х										
Gao [34]																													
Sleep hygiene					х												х	х			Х								
Relaxation					х												х	х			х						Х		
Stimulus control					x												х	х			х								
Music listening					x												х	х			х						х		
Greeson [35]																													
Relaxation	x				x													х	х								х		

BCT	L Information on consequences of behaviour in general	<b>c</b> Information on consequences of behaviour to individual	▶ Normative information (others)	Jon Goal-setting (behaviour)	• Goal-setting (outcome)	Justice Action Planning	& Barrier identification/problem solving	<b>6</b> Setting graded tasks	<b>1</b> Review of behavioural goals	<b>1</b> Review of outcome goals	<b>1</b> Rewards contingent on progress towards behaviour	<b>1</b> Rewards contingent on successful behaviour	Generalisation of target behaviour	<b>9</b> Self-monitoring of behaviour	<b>1</b> Self-monitoring of outcome	<b>R</b> Prompting focus on past success	6 Feedback on performance	<b>6</b> Information on where & when to perform behaviour	<b>1</b> Instructions on how to perform behaviour	<b>2</b> Modelling/demonstrating behaviour	<b>5</b> Environmental restructuring	<b>5</b> Prompting practice	<b>22</b> Using follow-up prompts	8 Facilitating social comparison	<b>1</b> Prompting anticipated regret	<b>R</b> Prompting use of imagery	<b>3</b> Relapse prevention/coping planning	<b>36</b> Stress management	<b>8</b> Time management	<b>b</b> Anticipation of future rewards
Imagery						х													х	х						х		х		
Mindfulness						х									х				х	х								х		
Meditation						х								х					х	x		х						x		
Breathing						x													х	х								x		
Hahn [36]																														
Relaxation	x																								х			x		
Self-management <sup>a</sup>			x	x			x	x		x						х			х					х				x		
Jensen [37]																														
Meditation							x											х	х											

# BCT coding per intervention component

Table 3.S4

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BCTª	<ul> <li>Information on consequences of behaviour in general</li> </ul>	<ul> <li>Information on consequences of behaviour to individual</li> </ul>	<b>A</b> Normative information (others)	Goal-setting (behaviour)	• Goal-setting (outcome)	L Action Planning	<ul> <li>Barrier identification/problem solving</li> </ul>	<b>6</b> Setting graded tasks	<b>1</b> Review of behavioural goals	T Review of outcome goals	<b>1</b> Rewards contingent on progress towards behaviour	<b>1</b> Rewards contingent on successful behaviour	Generalisation of target behaviour	9 Self-monitoring of behaviour	<b>1</b> Self-monitoring of outcome	<b>R</b> Prompting focus on past success	<b>6</b> Feedback on performance	<b>1</b> Information on where & when to perform behaviour	<b>17</b> Instructions on how to perform behaviour	<b>25</b> Modelling/demonstrating behaviour	<b>5</b> Environmental restructuring	<b>5</b> Prompting practice	22 Using follow-up prompts	<b>8</b> Facilitating social comparison	<b>12</b> Prompting anticipated regret	<b>R</b> Prompting use of imagery	<b>S</b> Relapse prevention/coping planning	<b>96</b> Stress management	<b>8</b> Time management	<b>b</b> Anticipation of future rewards
Kakinuma [38]																														
Sleep knowledge	х	х																												
Sleep hygiene	х			х		х			х									х	х		х	х	х					x		
Caffeine intake																		х	х											
Alcohol intake																		х	х											
Relaxation																		Х	х									х		
Exercise																		х	х											
Sleep timing																		х	х										х	
Environment																		Х	х		х									
Food intake																			Х											

BCTª	<ul> <li>Information on consequences of behaviour in general</li> </ul>	2 Information on consequences of behaviour to individual	<ul> <li>Normative information (others)</li> </ul>	• Goal-setting (behaviour)	• Goal-setting (outcome)	<ul> <li>Action Planning</li> </ul>	<ul> <li>Barrier identification/problem solving</li> </ul>	<b>6</b> Setting graded tasks	<b>0</b> Review of behavioural goals	<b>1</b> Review of outcome goals	<b>1</b> Rewards contingent on progress towards behaviour	5 Rewards contingent on successful behaviour	G Generalisation of target behaviour	<b>9</b> Self-monitoring of behaviour	<b>L</b> Self-monitoring of outcome	8 Prompting focus on past success	<b>61</b> Feedback on performance	<b>0</b> Information on where $\&$ when to perform behaviour	<b>1</b> Instructions on how to perform behaviour	<b>2</b> Modelling/demonstrating behaviour	<b>5</b> Environmental restructuring	<b>5</b> Prompting practice	<b>Z</b> Using follow-up prompts	85 Facilitating social comparison	<b>1</b> Prompting anticipated regret	<b>R</b> Prompting use of imagery	<b>3</b> Relapse prevention/coping planning	<b>36</b> Stress management	<b>8</b> Time management	
Stimulus control	_	_		-	-		-	-											x											
Light exposure																		х	x											
Breathing																		х	x									x		
Klatt [39]																														
Mindfulness						x								х					x			x						х		
Meditation						x								х				х				x						х		
Breathing																		х	х									x		
Murphy [40]																														
Relaxation	х	х				х												х	х			х					х	х		

BCTa	1 Information on consequences of behaviour in general	2 Information on consequences of behaviour to individual	<ul> <li>Normative information (others)</li> </ul>	• Goal-setting (behaviour)	• Goal-setting (outcome)	J Action Planning	8 Barrier identification/problem solving	<b>6</b> Setting graded tasks	<b>1</b> Review of behavioural goals	<b>1</b> Review of outcome goals	<b>7</b> Rewards contingent on progress towards behaviour	<b>U</b> Rewards contingent on successful behaviour	G Generalisation of target behaviour	9 Self-monitoring of behaviour	<b>1</b> Self-monitoring of outcome	<b>B</b> Prompting focus on past success	<b>1</b> Feedback on performance	<b>0</b> Information on where & when to perform behaviour	<b>1</b> Instructions on how to perform behaviour	<b>25</b> Modelling/demonstrating behaviour	5 Environmental restructuring	<b>5</b> Prompting practice	22 Using follow-up prompts	<b>8</b> Facilitating social comparison	<b>1</b> Prompting anticipated regret	<b>R</b> Prompting use of imagery	<b>3</b> Relapse prevention/coping planning	<b>36</b> Stress management	<b>8</b> Time management	<b>b</b> Anticipation of future rewards
Querstret [41]																														
Relaxation																		х	x			x						x		
Mindfulness							х											х	х			х						x		
Meditation							х											х	x			x						x		
Breathing							х											х	х			х						x		
Suzuki [42]																														
Sleep knowledge	х	x									x	x		x	х		x		x			x								х
Sleep hygiene	х	x				x		x	х	x	x	x		x	х		x	х	x			x						x		х
Cog restructuring	х	x				х		х	х	х	x	х		х	х		х	х	х			х								х
Stimulus control	x	X		X	X	X			X	X		x		X	Х		Х	Х	х			x								Х

*Note.* This table excludes the BCT that were not present in any of the 11 studies; <sup>a</sup>comprehensive self-management consisted of recovery experiences, psychological detachment and relaxation mastery; frequencies of implementation per study component: *stress management/relaxation* (m = 7); *meditation* (m = 4); *controlled breathing* (m = 4); *stimulus control* (m = 4); *sleep knowledge* (m = 3); *mindfulness* (m = 3); *sleep hygiene practice* – either unspecified and administered as a set of components (m = 3), or specified as individual components including the following: *regular exercise* (m = 3), *avoiding/reducing caffeine intake* (m = 2), *avoiding/reducing alcohol intake* (m = 2), *keeping consistent sleep timing* (m = 2), *modifications to the sleep environment* (m = 2), *bright light exposure* (m = 2), *avoiding daytime napping* (m = 1), *avoiding use of light-emitting devices in bed* (m = 1), *regular food intake* (m = 1); *imagery* (m = 1), *comprehensive self-management* (m = 1), and *cognitive restructuring* (m = 1). None of the studies reported using sleep restriction or sleep diaries as intervention components.

Changes	in s	leep	outcome	measures	per	group

	-		Careford and				
	I	ntervention g	-		Control gro	-	
	n	Mean	SD	n	Mean	SD	
Overall sleep health (PSQI t	otal score	<sup>1</sup> )					
Brown et al $(n = 122)$	56	-1.10	2.77	66	-0.03	3.10	
Cai et al $(n = 19)$	10	-2.00	2.22	9	0.22	1.77	
Gao et al $(n = 84)$	42	-2.48	1.43	42	-0.16	1.68	
Jensen et al $(n = 72)$	48	-1.54	3.22	24	-0.75	2.77	
Kakinuma et al (n = 391)	214	-0.67	1.90	177	-0.41	1.86	
Klatt et al $(n = 42)$	22	-1.73	2.86	20	-1.18	3.02	
Querstret et al $(n = 118)$	60	-3.5	5.10	58	-0.34	5.07	
Subjective sleep quality (PSC	QI compo	nent score)					
Brown et al $(n = 122)$	56	-0.08	0.58	66	-0.15	0.69	
Gao et al $(n = 84)$	42	-0.39	0.69	42	-0.03	0.62	
Hahn et al $(n = 95)$	48	0.47	0.76	47	0.35	0.81	
Klatt et al $(n = 42)$	22	-0.32	0.66	20	-0.33	0.66	
Sleep onset latency (PSQI co	mponent	score)					
Brown et al $(n = 122)$	56	-0.25	0.86	66	-0.14	0.96	
Gao et al $(n = 84)$	42	-0.62	0.79	42	0.04	0.69	
Klatt et al $(n = 42)$	22	-0.41	0.92	20	-0.10	0.85	
Sleep duration (PSQI compo	onent scor	·e)					
Brown et al $(n = 122)$	56	-0.30	0.99	66	0.12	0.95	
Gao et al $(n = 84)$	42	-0.29	0.62	42	-0.12	0.66	
Klatt et al $(n = 42)$	22	-0.90	0.57	20	0.00	0.83	
Sleep efficiency (PSQI comp	onent sco	re)					
Brown et al $(n = 122)$	56	-0.26	0.92	66	0.23	0.93	
Gao et al $(n = 84)$	42	0.07	0.46	42	0.07	0.58	
Klatt et al $(n = 42)$	22	0.04	0.46	20	-0.10	0.62	
Sleep disturbance (PSQI con	nponent s	core)					
Brown et al $(n = 122)$	56	-0.12	0.49	66	-0.02	0.57	
Gao et al $(n = 84)$	42	0.16	0.55	42	-0.04	0.56	
Klatt et al $(n = 42)$	22	-0.32	0.58	20	-0.30	0.51	

	I	ntervention	group		Control gro	oup		
	n	Mean	SD	n	Mean	SD		
Sleep medication use (PSQ	I compone	nt score)						
Brown et al $(n = 122)$	56	-0.14	0.58	66	-0.13	0.81		
Gao et al $(n = 84)$	42	-0.12	0.51	42	-0.02	0.15		
Klatt et al $(n = 42)$	22	-0.23	0.78	20	-0.05	1.06		
Daytime dysfunction (PSQI component score)								
Brown et al $(n = 122)$	56	0.09	0.69	66	0.05	0.70		
Gao et al $(n = 84)$	42	-1.31	0.61	42	-0.07	0.69		
Klatt et al $(n = 42)$	22	-0.40	0.85	20	-0.35	0.78		
Other multi-component me	easures of o	overall sleep	health					
Greeson et al $(n = 90)^2$	45	-8.84	17.21	45	-0.07	16.74		
Suzuki et al $(n = 30)^3$	12	69.16	174.47	18	7.78	132.05		
Other single-component m	easures of s	subjective slo	eep quality					
Murphy $(n = 19)^3$	11	1.1	1.30	8	1.25	1.73		

## Changes in sleep outcome measures per group

*Note.* <sup>1</sup> PSQI total scoring: 0-21 (lower scores indicate better sleep health for the total score and all composite scores); Scores for composite measures range from 0-3; <sup>2</sup> for the MOS-SLP9, lower scores indicate better sleep health; <sup>3</sup> for these measures, greater scores indicate better sleep health

Study	Intervention	description	Samp	le characteristi	ics	Duration	Format	Change score	es (PSQI total)
	IG	CG	Total sample	IG	CG			IG (M, SD)	CG (M, SD)
Bowden, 2012 [60]	Rhythmic yoga- like meditative exercises (brain wave vibration training) n = 12	Iyengar yoga n = 9	Healthy adults (n = 33) Age range = 18-50 years 21 females, 12 males	not reported	not reported	16 weeks	Two 75-min group-based face-to-face sessions per week (10 in total) plus home-based practice (10 min per practice)	-1.36 ± 3.55	-0.10 ± 1.81
Bowden, 2012 [60]	Rhythmic yoga- like meditation (brain wave vibration training) n = 12	Mindfulness n = 12	see above	not reported	not reported	16 weeks	see above	-1.36 ± 3.55	$-0.67 \pm 3.48$
Caldwell, 2011 [61] <sup>‡</sup>	Taijiquan training (mind- body exercises)	Special recreation (exercise session)	Undergraduate students (n = 208)	M <sub>Age</sub> = 21.56 (SD = 3.65); Age Range = 18-48	M <sub>Age</sub> = 21.11 (SD = 2.47); Age Range = 19-39	15 weeks	Two 50-min sessions/week face-to- face, group-based practice for Taijiquan group and either a 2.5h session/week or two 75- min sessions/week for the special recreation group	-0.92 ± 3.02	0.3 ± 3.43

Summary table of studies with an active control group

Study	Intervention	description	Samp	ole characterist	ics	Duration	Format	Change score	es (PSQI total)
	IG	CG	Total sample	IG	CG			IG (M, SD)	CG (M, SD)
King, 2008 [62]	Moderate- intensity endurance exercise n = 36	Health education control programme n = 30	Underactive US adults (n = 66) 44 females, 22 males	M <sub>Age</sub> = 61.86 (SD = 6.33) 24 females, 12 males	M <sub>Age</sub> = 60.90 (SD = 7.19) 20 females, 10 males	52 weeks	2 days/week face-to-face 60-min aerobic exercise classes and 3d/week home- based aerobic exercise	-2.11 ± 3.51	-1.00 ± 2.81
Kloss, 2016 [63]	Sleep 101 workshop (sleep education, sleep hygiene instructions, sleep logs, CBT-I) n = 63	Sleep monitoring only (logs) n = 57	US undergraduate students $M_{Age} = 21.11$ (SD = 2.43); 60.8% females, 39.2% males	not reported	not reported	3 weeks	2 x 90-min face-to-face workshops and home-based practice incl. daily logs	$-0.80 \pm 3.36$	-0.94 ± 3.30
Loft, 2013 [64]	Arousal reduction n = 26	Control imagery n = 25	Malaysian business employees (n = 99) $M_{Age} = 37$ (SD = 10.56); Range = 21-61 years 64% females, 36% males	81.5% females, 18.5 % males	64% females, 36% males	3 weeks	face-to-face training (1 x 30 min) and home-based practice (approx. 2 min per practice)	-1.77 ± 3.37	-1.83 ± 2.45

# Summary table of studies with an active control group

Study	Intervention	description	Samp	le characteristi	cs	Duration	Format	Change score	es (PSQI total)
	IG CG Total sample IG		IG	CG			IG (M, SD)	CG (M, SD)	
Loft, 2013 [64]	Sleep hygiene implementation intentions n = 26	Control imagery n = 25	see above	38.5% females, 61.5% males	see above	3 weeks	see above	-1.54 ± 2.70	-1.83 ± 2.45
Loft, 2013 [64]	Combined arousal reduction and sleep hygiene implementation intentions n = 22	Control imagery n = 25	see above	68.2% females, 31.8% males	see above	3 weeks	see above	-2.27 ± 3.20	-1.83 ± 2.45
Mairs & Mullan, 2015 [65]	Sleep hygiene implementation intentions n = 43	Self- monitoring (sleep diary) n = 47	Australian undergraduate students $M_{Age} = 20.7$ (SD = 5.8); Range = 17- 49 years 53 females, 19 males (at baseline)	not reported	not reported	2 weeks	online (remote)	-1.76 ± 2.74	-1.21 ± 2.68

# Summary table of studies with an active control group

Study	Intervention description		Samp	ole characterist	ics	Duration	Format	Change scores (PSQI total)				
	IG	CG	Total sample	IG	CG			IG (M, SD)	CG (M, SD)			
Nishinoue, 2012 [66]	Sleep behaviour training (CBT- I) n = 60	Sleep hygiene education n = 61	18 females, 109 males (at baseline)	M <sub>Age</sub> = 31.3 (SD = 7)	M <sub>Age</sub> = 31.3 (SD = 7.2)	12 weeks	Five 40-min face-to-face workshops (lecture plus Q&A), followed by individual sleep hygiene education based on personal preferences for 30 min	-1.70 ± 3.10	-0.30 ± 3.12			

#### Summary table of studies with an active control group

**Bias-adjusted pooled estimate based on a random-effects model**\*: g = -0.25, [-0.39 to -0.10], p < 0.01

*Note.* IG = Intervention group; CG = Control/comparator group; \* a forest plot for this estimate is provided below;  $\ddagger$  = summary statistics (pre- and post-test data) for the PSQI total were requested from the authors for the purpose of this analysis and were kindly provided for synthesis.

Table 3.S7

Risk of	<sup>c</sup> bias	scores	per	study
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Study Name	1	2	3	4	5*	6	7	8	9	10	11	12	14	15	16	17	18	19	20	21	22	23	24	25	26	27	Total score
Brown et al. [48]	1	1	1	1	1	1	1	1	0	1	?	?	?	1	1	1	1	?	1	1	1	1	?	0	0	0	17
Cai et al. [49]	1	1	1	1	1	1	1	0	1	0	?	?	0	0	1	1	1	?	1	1	?	0	0	1	1	0	15
Gao et al. [50]	1	1	1	1	2	1	1	0	1	1	1	?	0	0	1	1	1	?	1	1	?	1	0	1	1	0	19
Greeson et al. [51]	1	1	1	1	2	1	1	1	1	1	?	0	0	1	1	1	1	1	1	1	?	1	1	1	1	1	23
Hahn et al. [52]	1	1	0	1	1	1	1	0	0	1	?	?	0	0	1	1	1	1	1	1	?	0	0	0	1	0	14
Jensen et al. [53]	1	1	1	1	2	1	1	?	1	1	1	0	0	1	1	1	1	1	1	1	?	1	1	1	1	1	23
Kakinuma et al. [54]	1	1	1	1	2	1	1	0	1	1	1	?	0	0	1	1	1	?	1	1	?	0	0	0	1	0	17
Klatt et al. [55]	1	1	1	1	2	1	1	0	1	1	?	0	0	0	1	1	1	1	1	1	?	1	?	0	1	1	19
Murphy [56]	1	1	0	1	1	1	1	0	0	0	?	?	0	0	1	1	1	1	?	1	?	1	?	0	0	0	12
Querstret et al. [57]	1	1	1	1	2	1	1	1	0	1	?	1	1	0	1	1	1	1	1	1	0	1	?	1	1	0	21
Suzuki et al. [58]	1	1	1	1	2	1	1	0	1	1	?	?	0	0	1	1	1	?	?	1	1	1	1	0	1	0	18

*Note.* Item 13 was omitted due to being inapplicable; Scoring criteria were 1 = yes; 0 = no; ? = unable to determine and \*(only applicable to item # 5) <math>2 = yes; 1 = yes, partially; 0 = no; ? = unable to determine.

# CHAPTER 4. DEVELOPMENT AND PSYCHOMETRIC TESTING OF AN INSTRUMENT TO ASSESS PSYCHOSOCIAL DETERMINANTS OF SLEEP HYGIENE PRACTICE

Secondary Aim 2 of the thesis was addressed in a study that focused on the development and psychometric qualities of a set of scales that measure psychosocial factors related to sleep hygiene practice. Chapter 4 presents the revised version of the paper that is currently under review at a peer-reviewed journal.

### 4.1 Abstract

This study aimed to develop a set of scales to assess the psychosocial determinants of sleep hygiene and examine the scales' psychometric properties. Baseline data (n = 160) from an m-health physical activity and sleep intervention were analysed to examine relationships between the psychosocial scales and actual sleep hygiene practices (pairwise correlations, ANOVAs and Tukey's post-hoc test), unidimensionality (Principal Component Analysis) and internal consistency (Cronbach's alpha). A separate sample (n = 20) was recruited to compute test-retest reliability (Intra-class correlation (ICC)). Four of the constructs showed significant correlations (r = -0.17 to -0.36) with actual sleep hygiene practice, indicated by lower sleep hygiene scores (i.e., more desirable practices) for participants with better psychosocial disposition (e.g., greater self-efficacy). This was consistent for different levels of psychosocial disposition (e.g., low, average, high self-efficacy). The seven scales generally displayed unidimensional component structures. Internal consistency was good to excellent ( $\alpha = 0.76-0.92$ ). Test-retest reliability was good to excellent (ICC = 0.61-0.84). Though satisfactory, these findings warrant to be replicated in larger samples.

## 4.2 Introduction

Sleep health consists of multiple indicators including the quality, duration and timing of sleep, but also comprises feelings of sufficiency (satisfaction with sleep) and the ability to sustain daytime alertness [1-3]. Many adults without a diagnosed clinical sleep condition such as insomnia or sleep apnoea still report poor sleep health [4]. Indicators of poor sleep health (i.e., inadequate sleep duration, poor quality sleep) are associated with greater chronic disease risk and immense costs for healthcare providers and employers [3,5,6]. Sleep health relies on adequate self-regulation (i.e., maintenance of

consistent sleep and wake times [7]; thus, wide-reaching behaviour change interventions are needed to reduce the prevalence of poor sleep health [5].

The practice of *sleep hygiene* is known to predict sleep quality [8]. Behaviours pertaining to good sleep hygiene are commonly recommended as part of sleep interventions [9,10] and considered one of several effective strategies to improve indicators of sleep health such as sleep quality or sleep onset latency [11]. Sleep hygiene consists of a set of actions during hours of wakefulness and pre-bedtime to avoid sleep-impeding factors and stimulants (e.g., caffeine, blue-light emitting devices) and to engage in sleep-promoting factors (e.g., regular exercise, relaxation) [12]. However, there is very little empirical knowledge of factors that facilitate or impede the practice of sleep hygiene and potentially drive changes in sleep hygiene practices is limited.

Psychosocial mechanisms of behaviour (and behaviour change) have been assessed extensively in the context of other health behaviours (e.g., physical, diet) [13,14] by way of mediation analysis, which facilitates a more in-depth examination of intervention efficacy. In contrast, there is a paucity of evidence for the psychosocial determinants of sleep health, and sleep hygiene in particular. Previous studies have either examined a limited range of psychosocial constructs (e.g., self-efficacy, intention) in relation to obtaining good sleep in general, or addressed sleep hygiene as an entity or only included a selected subset of behaviours [15,16]. A measure that reflects the complex interplay of behaviours that make up sleep hygiene currently does not exist, though is essential for investigations concerning the psychosocial mechanisms affecting sleep hygiene, as this can help improve intervention design and delivery. Therefore, the present study aimed to test the reliability and validity of a new set of scales developed to assess potential psychosocial determinants of sleep hygiene practice.

## 4.3 Methods

The psychometric evaluation of the scales followed a three-phase approach. The scales were developed in Phase One. Construct validity and internal consistency were tested as part of Phase Two using data from a randomised waitlist-controlled trial that targeted adults' physical activity and sleep health (referred to as *Sample One*) [17]. Test-retest reliability was examined in Phase Three using data from a separate sample recruited specifically for the purpose of testing the scales' reproducibility (referred to as *Sample Two*). The University of Newcastle Human Research Ethics Committee (HREC) granted

full ethical approval for this study: H-2016–0181 (Sample One, Appendix B); H-2018-0012 (Sample Two, Appendix C).

#### 4.3.1 Phase One

A qualitative review of the behaviour change literature was conducted to collate content from psychosocial determinants items previously used in broadly related health behaviour studies [18-24]. The seven a priori specified constructs were: *self-efficacy*, *behavioural capability*, *outcome expectations* and *expectancies*, *social support*, *goals* and *action planning*. As the concept of sleep hygiene builds on the regulation of personal and environmental factors, the search for relevant items was limited to those aligning with theoretical frameworks that also incorporate both intrapersonal correlates of behaviour and those relating to a person's social or physical environment [25].

Item stems and wording of previous questionnaire items used in the context of physical activity and diet [18-24] were aggregated separately for each construct. The objective of this process was to create parsimonious scales for the assessment of psychosocial determinants of sleep hygiene using a single item per sleep hygiene domain. The content validity of the scales was addressed by the authors (BM, RCP, MJD) comparing source items (psychosocial determinants items for physical activity and diet) against the new items, the wording of which was adapted specifically for sleep hygiene. For example, the social support source item "Most people who are important to me would encourage me to engage in regular physical activity" [24] was contextually adapted to "Most people who are important to me would encourage me to reduce the impact of noise and nuisance in my bedroom." The aim of this procedure was to reduce deviation from the original wording beyond the minimum necessary, while retaining logic, unambiguity and comprehensiveness. In summary, item wordings were modified to reflect the evidence-based sleep hygiene domains of interest [12] while retaining the stems of the original items identified through the literature review.

#### 4.3.2 Phase Two

**Participant recruitment and data collection.** Sample One consisted of 160 adults recruited Australia-wide through Facebook (Appendices D and E) in June–July 2017 to take part in the Synergy Study, a six-month randomised waitlist-controlled trial to improve physical activity and sleep quality using a mobile app and personalised support. Full details for the study rationale, design and methods are reported elsewhere [17].

Eligible participants were those who: resided in Australia; were 18–55 years of age with a BMI of 18.5–35; self-reported insufficient physical activity (<90 min of moderate–vigorous intensity physical activity/week); and were dissatisfied with their sleep quality (rating their sleep quality over the past month as *fairly bad* or *very bad*). Criteria for exclusion, group allocation and data collection procedures are listed in the study protocol [17]. Informed consent was obtained from all participants (Appendices F and G), and all baseline data were collected via online survey prior to randomisation. The sample descriptive is presented in Table 4.1.

**Measures.** In addition to the psychosocial determinants items (see Phase One results), participants' sleep quality, sleep hygiene and sociodemographic characteristics were assessed (Appendix H). The Pittsburgh Sleep Quality Index (PSQI) is a validated and widely used self-report measure of sleep quality [26] comprising seven composite scores (subjective sleep quality, sleep onset latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleep medication and daytime dysfunction). Global scores greater than five indicate difficulties with sleep. Sleep hygiene was assessed using the Sleep Hygiene Index [27]. The Sleep Hygiene Index assesses behaviours that align with those assessed in the psychosocial determinants scales and provides a measure of an individual's current sleep hygiene practices. This measure has demonstrated acceptable psychometric qualities including convergent validity with the PSQI [27].

**Analyses.** Only a small proportion of the sample identified as smokers (7.38%). Thus, to avoid violation of content validity, all items relating to nicotine use were dropped from the analyses and the following findings therefore refer to the remaining eight items per scale. All items were treated as continuous variables for analysis.

Floor and ceiling effects were examined to determine potential issues with the scales' content validity, reliability and responsiveness to change [28,29], which are likely to occur if more than 15–20% of the sample answer at the highest or lowest point of a given scale [30,31].

Correlations between the psychosocial scales and sleep hygiene scores (measured by the Sleep Hygiene Index (SHI)) were calculated to examine the relationship between participants' psychosocial dispositions and actual practice (NB. higher scores on the SHI

## Table 4.1

Procedures			
Study Phase	Participants	Objective	Analyses
Phase One	N/A	Scale development via adaptation of existing items	N/A
Phase Two	Sample One (n = 160)	Assessment of floor/ceiling effects	Calculation of proportions
		Assessment of the relationship between the psychosocial scales and actual sleep hygiene practices (Sleep Hygiene Index)	Pairwise correlations, ANOVAs and Tukey's post-hoc tests
		Assessment of scale unidimensionality	Kaiser-Meyer- Olkin (KMO) tests, principal component analysis (PCA) and scree plots
		Assessment of internal consistency	Cronbach's alphas
Phase Three	Sample Two (n = 20)	Assessment of test- retest reliability	Intraclass correlation coefficients

## Overview of study procedures, objectives, analyses and participant characteristics

## Sociodemographic and behavioural characteristics

	Sample (n = 160	Sample Two (n = 20)				
Age, M (SD)	41.5 (		31.8	(6.91)		
Gender n (%)						
Males	32.0	(20.00)	8.0	(60.00)		
Females	128.0	(80.00)	12.0	(40.00)		
Ethnicity n (%)						
Caucasian	146.0	(91.25)				
Asian	10.0	(6.25)				

Not stated	4.0	(2.50)		
Body mass index, M (SD)	27.9	(4.38)	23.8	(3.12)
Chronic condition/s n (%)				
None	54.0	(33.75)		
One	41.0	(25.62)		
Two	41.0	(25.62)		
Three or more	24.0	(15.00)		
Smoking n (%)				
Yes	11.0	(7.38)		
No	138.0	(92.62)		
DASS-21 Symptom severity, M (SD)				
Depression	11.9	(8.37)		
Anxiety	7.0	(6.38)		
Stress	15.3	(6.76)		
Insomnia severity, M (SD)	12.6	(4.23)		
Sleep hygiene, M (SD)	32.3	(6.65)		
PSQI total score, M (SD)	9.2	(2.96)		
PSQI Subjective sleep quality n (%)				
Very good	0.0	(00.00)	5.0	(25.00)
Fairly good	30.0	(18.75)	7.0	(35.00)
Fairly bad	109.0	(68.12)	7.0	(35.00)
Very bad	21.0	(13.12)	1.0	(5.00)
Sleep duration in minutes, M (SD)	370.6	(64.30)	403.3	(61.14)

*Note.* Depression anxiety stress scale (DASS-21): Depression cut-offs 0–9 (normal), 10–13 (mild), 14–20 (moderate), 21–27 (severe), 29+ (extremely severe); Anxiety cut-offs 0–7 (normal), 8–9 (mild), 10–14 (moderate), 15–19 (severe), 20+ (extremely severe); Stress cut-offs 0–14 (normal), 15–18 (mild), 19–25 (moderate), 26–33 (severe), 34+ (extremely severe); Insomnia severity (ISI): 0–7 (no clinically significant insomnia), 8–14 (subthreshold insomnia), 15–21 (moderate clinical insomnia), 22–28 (severe clinical insomnia); Sleep hygiene index (SHI): Scores range from 13–65 with higher scores indicating better sleep hygiene practices; Pittsburgh sleep quality index (PSQI): Scores range from 0–21 with scores >5 indicating poor quality sleep; Chronic conditions, mental health symptom severity (DASS-21), insomnia severity (ISI), sleep hygiene (SHI) and overall sleep quality (PSQI total score) were only administered in Sample One.

indicate less desirable sleep hygiene practices). Additionally, one-way ANOVAs and Tukey's post-hoc tests [32] were used to test differences in sleep hygiene scores for different levels of psychosocial disposition. Participants were categorized into three approximately equal sized groups per construct, i.e., low self-efficacy (0-22), average self-efficacy (23-26) and high self-efficacy (27-36). The purpose of these analyses was

to examine if the scales were sufficiently capable of discriminating between different levels of a construct, as it was anticipated that groups with better psychosocial disposition (e.g., higher self-efficacy) would report better sleep hygiene practices. Subgroups per construct and respective score ranges are provided in Table 4.2.

Principal component analysis (PCA) was used for the purpose of determining unidimensionality of the scales, rather than to reduce the scales. The appropriateness of using PCA to examine scale unidimensionality was assessed using Kaiser-Meyer-Olkin (KMO) tests [33]. Values greater than 0.80 are considered *meritorious* for the assessment of between-variable variance and indicate PCA analyses are a pertinent method [34]. KMO tests were conducted per scale and values ranged from 0.82–0.90. Eigenvalues greater than one were used to identify the number of components extracted by way of PCA [35]. In addition, Cattell's scree plots were examined to confirm unidimensionality [36]. Component loadings of at least 0.3 were deemed as *minimally significant*, those above 0.4 as *more important* and those above 0.5 *practically significant* [37].

Internal consistency of the scales was assessed using Cronbach's alpha [38], with values between 0.8 and 0.9 indicating good internal consistency and values greater than 0.9 considered excellent [39]. All analyses were conducted using Stata Version 14.2 (StataCorp, College Station, Texas, USA).

#### 4.3.3 Phase Three

**Participant recruitment and data collection.** The test-retest reliability of the scales was determined using data from a separate sample including 20 participants (Sample Two; see Table 4.1), who completed their surveys on two occasions one week apart. Eligibility criteria that were relevant to the current study (i.e., age; living in Australia; not being pregnant; no diagnosed sleep disorder; not taking sleep medication; no regular jetlag-inducing travel; and no shift work) were kept aligned with those for Sample One (Appendix I). Sociodemographic and behavioural items used to assess participant eligibility included age, height, weight, gender, maternal status, postcode, country of residence, years of education, work hours and days, frequent travel, use of sleep medication, chronic sleep condition, and current use of activity/health tracking systems. Additionally, participants were asked to indicate at the second assessment whether they had made changes to their sleep hygiene practices over the past week. Sample characteristics are presented in Table 4.1.

Participants in this study were recruited via Facebook (Appendix J) and by way of convenience sampling. Those who completed both surveys were randomly selected to receive one of five shopping vouchers (AU\$ 50). Online surveys were hosted on the Qualtrics platform (Provo, Utah) and all participants provided informed consent (Appendices K and L).

**Measures.** At each time point, participants were asked to answer the psychosocial determinants scales described above in addition to items (Appendix M) that assessed physical activity levels ("*As a rule, do you do at least half an hour per day (30 min/day) of moderate or vigorous exercise (such as walking or a sport) on three or more days a week?*"); subjective sleep quality ("*During the past month, how would you rate your sleep quality overall?*"); sleep duration ("*During the past month, how many hours of actual sleep did you get at night? (This may be different than the number of hours you spend in bed*)"); current sleep hygiene practice as measured by the Sleep Hygiene Index [27]; and other health behaviours (i.e., smoking, alcohol consumption, caffeine intake).

**Power and Sample Size.** Based on established guidelines [40], to detect a minimal intraclass correlation of 0.7 between n = 2 measurement occasions, with an alpha = 0.05, and power = 0.80, at least 10 participants were required. Allowing for an anticipated dropout of 30% between the two time points resulted in a minimum target sample size of n = 15.

Analysis. The seven-day test-retest reliability per scale was examined using two-way random effects intraclass correlation (ICC), which considers both the correlation and level of agreement between measures [41]. Magnitudes of intraclass correlation estimates were interpreted as:  $\geq 0.75$  excellent reliability; 0.60–0.74 good; 0.40–0.59 fair; and <0.40 poor [42].

## 4.4 Results<sup>2</sup>

#### 4.4.1 Phase One

For each construct, one item for each of the following nine a priori determined sleep hygiene domains was developed: (1) *avoiding caffeinated beverages (coffee, tea, energy* 

<sup>&</sup>lt;sup>2</sup> At the end of the study participants received a plain English summary report (Appendix N).

drinks) in the late afternoon or right before bedtime; (2) avoiding nicotine at bedtime; (3) avoiding alcohol at bedtime; (4) exercising regularly; (5) reducing stress levels; (6) reducing the impact of noise and nuisance in the bedroom; (7) keeping sleep and wake times consistent; (8) avoiding daytime naps; and (9) avoiding the use of technological devices (e.g., phone, TV, laptop) at bedtime or in bed. Therefore, the seven psychosocial determinants scales included a total of 63 items, measuring nine domains of sleep hygiene per construct (full instrument provided in Table 4.S1). To provide a referent, participants were told "The following questions relate to some general daytime routines and what you do before going to bed".

**Self-efficacy.** Self-efficacy ("I can [...]") relating to sleep hygiene practice was assessed on a 5-point Likert-type scale (from *not at all confident* (0) to *extremely confident* (4)) with one item per sleep hygiene domain (e.g., "[...] reduce the impact of noise and nuisance in my bedroom") [43].

**Behavioural capability.** This construct assessed the frequency with which participants make conscious choices in favour of good sleep health when they have the opportunity to do so, using a 5-point Likert-type scale (from *never* (0) to *always* (4)). For example, "Whenever I have the opportunity to use technological devices right before bedtime or in bed, I know how to avoid or remove them." In line with the source scales, these items focused on situations that challenge commitment to healthy choices [18], which is integral to the understanding of health behaviour [25].

**Outcome expectations and expectancies.** Participants' expectations and expectancies pertaining to personal gains from engaging in regular physical activity were assessed separately. Participants were first asked to indicate their level of agreement (outcome expectations) with a range of statements (adapted from Plotnikoff et al. [44] and Dewar et al. [18]) relating to the benefits of regular sleep hygiene practice (e.g., "For me, [keeping consistent sleep and wake times] would help me sleep better") and then rate the value (outcome expectancies) associated with these benefits (e.g., "How important is it to [e.g., keep sleep and wake times consistent] to sleep well?"). All outcome expectations items were answered on a 7-point Likert scale and outcome expectancies items were answered on a 4-point Likert-type scale ranging from *not at all important* (0) to *extremely important* (3). Separate sum scores were calculated for each construct.

**Social support.** Social support is another key determinant that may have a facilitating effect on sleep hygiene practice, while also shaping expectations and attitudes toward sleep hygiene practice [25]. Using a fixed stem, (e.g., "Most people who are important to me would encourage me to [e.g., reduce my stress levels.]" participants rated their level of agreement on nine difference statements on a 5-point Likert scale (from *strongly disagree* (0) to *strongly agree* (4)) [16,24].

**Intention.** Participants were asked to what extent they "intend to [...]" practice sleep hygiene behaviours by rating the strength of their intention using a 7-point Likert scale (from *no, not really* (0) to strongly *intend* (6)) where higher scores indicate stronger intention. This item was used previously in a sleep hygiene context [16].

**Planning.** Plans regarding the implementation of sleep hygiene practice were assessed by asking if a participant had planned "where, when and how" to avoid caffeine, avoid nicotine, avoid alcohol, exercise regularly, reduce stress levels, minimise the impact of noise and nuisance in the bedroom, keep sleep and wake times consistent, avoid daytime naps, and avoid the use of technological devices right before bedtime or in bed. Previous studies have used separate items to assess planning to engage in the behaviour ("when", "where" and "how") [23]. However, in the current study, these denominators were collapsed to have one item per sleep hygiene domain to reduce response burden since the when, where and how of practicing sleep hygiene are likely to co-occur and be interdependent. Higher scores correspond to more detailed planning (from *no plans* (0) to *detailed plans* (6)).

#### 4.4.2 Phase Two

No floor effects were observed (all seven scales had <15% participants scoring lowest), and, except for outcome expectancies (19%) and intention (17%), there was no evidence of potential ceiling effects.

With an average score of 32.3 (SD = 6.65), participants reported reasonable sleep hygiene practices (out of a maximum SHI score of 65, which corresponds to worst sleep hygiene practices). Self-efficacy (p < 0.001), perceived behavioral capability (p < 0.001), intention (p = 0.003) and planning (p = 0.031) were moderately correlated with the SHI (see Table 3). The remaining scales did not show statistically significant correlations with the SHI. As shown in Table 4.2, SHI scores were significantly different by levels of self-efficacy

(p<0.001), perceived behavioral capability (p<0.001), social support (p = 0.019), and intention (p = 0.008), but not by levels of outcome expectations and expectancies, and planning (all p >0.05). SHI scores were typically higher (i.e., indicating less desirable sleep hygiene practices) among participants with lower dispositions (e.g., lower self-efficacy) on the psychosocial scales.

Principal component analyses for the seven constructs resulted in three one-component solutions and four two-component solutions based on including eight items per scale. The scales measuring self-efficacy, intention and planning demonstrated a single component and those of behavioural capability, outcome expectations, outcome expectancies and social support demonstrated two components. However, appraisal of the scree plots (Appendix O) indicated a single underlying component per scale (distinct elbow and levelling), consistent with unidimensionality [45]. Table 4.4 presents the eigenvalues and proportion of variance, as well as component loadings for each of the items. A sum score per scale was calculated from the respective nine items, with higher scores indicating stronger psychosocial dispositions towards sleep hygiene (e.g., greater confidence, stronger intentions). Means and median values, and levels of skewness per scale are shown in Table 4.S2 (NB. medians are presented due to mild skewness in some of the data, i.e., intention and planning). All seven scales demonstrated acceptable reliability, with Cronbach's alphas ranging from  $\alpha = 0.76$  to 0.92 (Table 4.4).

For the four scales that showed a two-component solution based on empirical testing, the items that loaded most strongly onto each component were reviewed for conceptual alignment, consistency between items, cross-loading and number of items per subcomponent. However, due a lack of conceptual alignment and because internal consistency per subscale (Cronbach's alphas) was not noticeably improved relative to the alphas calculated for the full scales, it was decided that the full scales should be retained.

#### 4.4.3 Phase Three

Four of the scales demonstrated excellent test-retest reliability (planning: ICC = 0.84; self-efficacy: ICC = 0.84; capability: ICC = 0.81; intention: ICC = 0.80), while the remaining three scales demonstrated good reliability (outcome expectations: ICC = 0.68; social support: ICC = 0.63; outcome expectancies: ICC = 0.61). Intra-class correlation coefficients were calculated based on complete data from n = 20 participants (see Table 4.4).

## Table 4.2.

		nge of cores		Subgroups*					
Construct/scale	Per item	Per scale	Subgroup	Score range	n	SHI score M (SD)**	F	Prob >F***	
Self-efficacy	0–4	0–36	Low	0–22	55	35.3 (7.06)	9.51	<0.001	
			Average	23–26	46	31.6 (6.01)			
			High	27–36	59	30.2 (5.81)			
Behavioural	0–4	0–36	Low	0–23	48	35.5 (7.16)	9.94	<0.001	
capability			Average	24–27	51	32.0 (5.90)			
			High	28–36	61	30.1 (5.90)			
Outcome	0–6	0–54	Low	0–36	50	33.2 (6.99)	1.20	0.303	
expectations			Average	37–45	52	32.7 (6.49)			
			High	46–54	58	31.3 (6.47)			
Outcome	0–3	0–27	Low	0–18	51	32.7 (6.98)	0.12	0.889	
expectancies			Average	19–22	54	32.3 (6.32)			
			High	23–27	55	32.0 (6.77)			
Social support	0–5	0–45	Low	0–24	55	32.7 (6.05)	4.05	0.019	
			Average	25–29	52	33.9 (6.76)			
			High	30–45	53	30.4 (6.77)			
Intention	0–6	0–54	Low	0-41	47	34.5 (6.33)	4.94	0.008	
			Average	42–49	56	32.4 (6.23)			
			High	50–54	57	30.5 (6.87)			
Planning	0–6	0–54	Low	0–19	49	33.6 (6.47)	1.83	0.164	
			Average	20–35	54	32.5 (7.43)			
			High	36–54	57	31.1 (7.43)			

Range of scores per construct and results of one-way ANOVAs testing the difference in sleep hygiene practices by subgroups

*Note.* Subgroups were created based on achieving approximately equal group size, rather than equal size ranges (NB. no clinical cut-offs were available to subdivide the constructs); \*\* Tukey's post-hoc tests revealed that sleep hygiene practices were better in subgroups with stronger/higher psychosocial disposition for all constructs; \*\*\* statistically significant at p<0.05, indicated in bold font.

#### Table 4.3.

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Test of the relationship between psychosocial determinants of sleep hygiene and actual sleep
hygiene practice (Sleep Hygiene Index scores)

Scale	Correlation coefficient (r)*	<i>p</i> -value**	
Self-efficacy	-0.36	<0.001	
Behavioral capability	-0.28	<0.001	
Outcome expectations	-0.08	0.336	
Outcome expectancies	0.01	0.878	
Social support	-0.07	0.359	
Intention	-0.24	0.003	
Planning	-0.17	0.031	

Note. \*negative coefficients indicate lower scores on the Sleep Hygiene Index (SHI), which corresponds to more desirable sleep hygiene practices; \*\* statistically significant at p < 0.05, indicated in bold font.

### Table 4.4

<b>n</b>	1 1		· 1	•	1.	• •	. 1		1 1.
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		j					.,	r o n p o n o n o n	· · · · · · · · · · · · · · · · · · ·

Scale	<b>EV</b> ( <b>VE</b> ) <sup>1</sup>	Component l	oadings for t	he extracted	componen	t/s				Alphas <sup>2</sup>	ICC <sup>3</sup>
		Caffeine	Alcohol	Exercise	Stress	Noise	Timing	Napping	Technology		
Self-efficacy	3.03 (38%)	0.28	0.21	0.40	0.40	0.38	0.40	0.32	0.39	0.76	0.84
Behavioural	3.16 (40%)	0.31	0.21	0.42	0.36	0.34	0.42	0.34	0.38	0.77	0.81
capability	1.11 (14%)	0.49	0.69	-0.13	-0.38	-0.33	0.03	-0.10	0.08		
Outcome	3.84 (48%)	0.41	0.37	0.30	0.32	0.40	0.33	0.37	0.30	0.84	0.68
expectations	1.06 (24%)	-0.37	-0.44	0.43	0.36	-0.14	0.35	-0.28	0.36		
Outcome	3.66 (46%)	0.33	0.37	0.35	0.34	0.40	0.36	0.31	0.36	0.82	0.61
expectancies	1.17 (15%)	0.51	0.45	-0.38	-0.28	0.09	-0.39	0.29	-0.27		
Social	4.13 (52%)	0.34	0.33	0.35	0.30	0.39	0.37	0.38	0.34	0.86	0.63
support	1.29 (16%)	-0.45	-0.47	0.37	0.42	-0.02	0.23	-0.33	0.31		
Intention	4.02 (50%)	0.28	0.28	0.36	0.38	0.34	0.43	0.35	0.39	0.85	0.80
Plans	5.21 (65%)	0.35	0.35	0.34	0.36	0.36	0.37	0.34	0.36	0.92	0.84

*Note.* <sup>1</sup> Principal components were extracted if they had an Eigenvalue (EV) of >1; VE = percentage of variance explained; <sup>2</sup> Cronbach's alphas presented in this table are based on one-component solutions for all seven scales; <sup>3</sup> ICC = Intraclass correlation coefficients

### 4.5 Discussion

This study aimed to describe the development of an instrument that measures the psychosocial determinants of sleep hygiene practice and to evaluate its psychometric properties. The scales assessed self-efficacy, behavioural capability, outcome expectancies, outcome expectations, social support, intention, and planning specific to the practice of sleep hygiene. All seven scales demonstrated acceptable levels of construct validity, good internal consistency and good to excellent test-retest reliability. On average, participants completed the survey in less than 10 minutes (M = 9.7, SD = 4.77), which corresponds to a low response burden.

Mild ceiling effects were observed for outcome expectancies and intention with 19% and 17%, respectively reporting the lowest scores for these scales, and this may have had a slight effect on the scales' content validity and reliability, and it is possible this limits the responsiveness of these scales to change (i.e., pre- to post-test) [28]. However, the fact that participants scored high on these particular scales was not surprising, considering they were assessed at the outset of an intervention, which recruited participants who were seeking to increase their physical activity and improve their sleep [17], as is commonly observed in baseline measurements [46,47]. Sample Two however, was too small to rule out that these ceiling effects also occur in a non-intervention context.

The statistically significant correlations between four of the psychosocial scales and sleep hygiene practices were of small to moderate magnitude (r = -0.17 to -0.36), which is typical of the relationship between psychosocial factors and health behaviours [48-50]. The limited correlation between the remaining constructs (i.e., outcome expectations and expectancies and social support) was not surprising, given their conceptual relationship with sleep hygiene, where perceived benefits might be subject to previous education and awareness, and the social context may not be applicable or relevant. The observed differences in actual sleep hygiene practices provide some evidence of validity of the scales where participants who reported poorer self-efficacy, perceived behavioural capability, social support and intention, also reported poorer sleep hygiene practices. It will be useful to examine these issues in a more diverse population including those with a broader range of scores. A previous study tested the predictive utility of the Theory of Planned Behaviour in the context of sleep hygiene among university students (n = 257) [16]. The study assessed three sleep hygiene domains (i.e., those of greatest perceived importance to participants) in relation to attitude, subjective norm, perceived behavioral control, intention, current/actual behavior and past behavior, as well as perceived autonomy support. The study used elicitation interviews to identify the three sleep hygiene domains of the greatest perceived importance to participants and assessed those in relation to attitude, subjective norm, perceived behavioural control, intention, current/actual behaviour and past behaviour, as well as perceived autonomy support. Cronbach's alphas for the scales used in that study ranged from 0.75 to 0.92 [16], which is a similar range to that observed for internal consistency in the present study ( $\alpha = 0.76-0.92$ ); however, no further psychometric characteristics were reported. Further, the concept of sleep hygiene was limited to "keeping a restful sleep environment", "not going to sleep when thirsty/hungry" and "avoiding stress-inducing activities before bedtime" [16], which does not consider other components that may impact on sleep quality (e.g., regular exercise, avoiding lightemitting devices at bedtime). Acceptable to good levels of internal consistency are frequently reported for instruments examining the psychosocial determinants of health behaviours such as physical activity and diet [18,23]. A study assessing barrier selfefficacy and outcome expectancies specific to sleep apnoea treatment adherence reported Cronbach's alphas of 0.89 and 0.85 respectively [51]. These values were slightly higher than those reported in the current study; this may be due to the greater number of items per construct used in the earlier study, which inherently leads to larger estimates of internal consistency [52].

The scales in the present study were developed to provide an instrument assessing the psychosocial determinants of sleep hygiene, a key requirement of which is to have acceptable levels of test-reliability. Measurement consistency reported in the present study was good to excellent (ICC = 0.61-0.84), which is comparable with that reported for scales assessing similar constructs [51]. The overall psychometric qualities of the developed scales suggest they may be useful to understand psychosocial determinants of changes in sleep hygiene behaviour. The scales may be used to assess levels of self-regulatory readiness in individuals with poor sleep quality in need of intervention. However, the scales' utility to be used as a pre-intervention screening tool requires to be evaluated in larger samples, as sleep hygiene is only one set of several useful strategies

to improve sleep health and has demonstrated weaknesses compared to other interventions (e.g., relaxation training, full CBT-I) [53].

#### 4.5.1 Limitations

Rather than using a set of reflective scales, where multiple items share one underlying latent construct [54], a single item per sleep hygiene domain was used for each of the seven scales herein (e.g., one item assessing self-efficacy to engage in regular exercise). This may have limited the ability to fully capture what constitutes a given construct. However, this approach is widely used for the assessment of situational or environmental determinants of behaviour (e.g., barrier self-efficacy), and is known to be of multi-faceted nature and may apply to varying degrees from one person to another [55]. Mainly for pragmatic reasons (e.g., response burden), some of the most frequently studied psychosocial determinants have been assessed using single-item measures and there is evidence that single-item and multi-item scales have similar ability to predict behaviour [54]. Moreover, although the scales developed in this study aligned with the key constructs from theories that acknowledge both intrapersonal and environmental determinants (e.g., Social Cognitive Theory) [25], it is possible that other constructs with potential influence on sleep hygiene practices were overlooked. Systematic reviews of the literature may be useful to identify these broader determinants.

Seven respondents (Sample Two) reported having made minor changes to their sleep hygiene practices between the two measurement points, which may have had an impact on test-retest reliability. Despite this, the scales still demonstrated good to excellent stability, indicating robustness. Participants were mostly Caucasian (91%), which is slightly higher compared to the general Australian population. Both samples consisted predominantly of female participants, which may have reduced generalizability. However, this is a commonly observed limitation [56] that may require different recruitment strategies. Finally, Sample One respondents were assessed prior to commencing an intervention to improve physical activity and sleep health and may, as a consequence, have differed in their intentions and expectations toward sleep hygiene (e.g., improved self-regulation) in comparison with Sample Two respondents. For the same reason, it was deemed unsuitable to use these data to determine the scales' divergent validity. Instruments of similar nature were not available to allow for comparison with the newly developed scales. However, once these become available, any future studies

shall be expanded to examine domains such as convergent and discriminant validity. Although both samples reported similar sum scores per scale (see supplemental material S2), it was not possible to establish scale reliability in Sample Two, due to the small number of participants recruited. Further, the sample size used in the current study is acknowledged as a potential limitation. Thus, it is recommended that future studies confirm the factor structure per scale as well as other aspects of scale validity and reliability using larger samples.

There are limited measures to assess the psychosocial determinants of sleep hygiene. This may have several reasons, including the inter-individual variability of sleep hygiene practices [53], and differences in how relevant certain sleep hygiene practices are to a person. For instance, avoiding caffeine, nicotine and alcohol close to bed time is consistently recommended, although individuals vary in how sensitive they are to caffeine, while not everybody smokes or consumes alcohol. Also, there is inconsistency in the sleep hygiene practices recommended. For example, regular exercise is recommended as it promotes good sleep health [12], however, some recommendations do not promote regular exercise per se, but advise to avoid exercise right before bedtime [57]. For participants, this may provoke feelings of cautiousness towards exercise, rather than motivate a person and for researchers, it hinders the development of streamlined scales. A consolidated set of recommendations with minimal ambiguity and amenableness is required to inform intervention design and delivery. The current study aimed to treat sleep hygiene as a comprehensive set of practices, each of which should be taken into account when assessing the psychosocial factors driving these practices. Once sleep hygiene recommendations are refined and improved to an extent that enhances intervention effectiveness, it is important to review the scales developed in this study for optimal alignment.

## 4.6 Conclusion

This appears to be the first study to report on the development of a new instrument to assess a broad set of psychosocial determinants specific to sleep hygiene and its psychometric qualities. Analyses confirmed levels of validity and reliability that make the scales suitable for use by researchers and practitioners in the context of sleep hygiene, including studies examining how changes in these determinants relate to a range of outcomes (e.g., sleep quality). A greater understanding of the mechanisms associated with changes in sleep hygiene behaviours may ultimately assist in improving sleep health.

## **References – Chapter 4**

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# **Supplementary Material – Chapter 4**

## Table 4.S1

Psychosocial determinants of sleep hygiene scales

The following questions relate to some general daytime routines and what you do before going to bed.

	í	Please indicate your level of confidence in engaging in the followin	g behaviours fo	r the general p	ourpose of keep	ing your sleep	healthy.
	Item	I can	Not at all confident (0)	A little confident (1)	Moderately confident (2)	Very confident (3)	Extremely confident (4)
	sef_1	avoid caffeinated beverages (coffee, tea, energy drinks, etc.) right before bedtime.					
X	sef_2	avoid nicotine right before bedtime.					
CAC	sef_3	avoid alcohol right before bedtime.					
EFF	sef_4	exercise on a regular basis.					
BLF-	sef_5	reduce my stress levels.					
С́О́	sef_6	reduce the impact of noise and nuisance in my bedroom.					
	sef_7	keep my sleep/wake times consistent.					
	sef_8	avoid taking daytime naps.					
	sef_9	avoid using technological devices (e.g., phone, TV, laptop, etc.) right before bedtime or in bed.					

	(i)	The following sections ask how confident you are about making specific	choices.				
	U	Rate how confident you are that you can make the following choices over	er the next 3	months.			
	Item	Whenever I have the opportunity to	Never (0)	Rarely (1)	Sometimes (2)	Often (3)	Always (4)
ł	bcp_1	drink coffee/tea/energy drinks right before bedtime, I know how to avoid them.					
ł	bcp_2	smoke a cigarette right before bedtime, I know how to avoid it.					
ł	bcp_3	drink alcohol right before bedtime, I know how to avoid it.					
ł	bcp_4	do some exercise, I know how to make it happen.					
ł	bcp_5	reduce my stress levels, I know how to relax and unwind.					
ł	bcp_6	<ul><li> minimise the impact of noise and nuisance in my bedroom,</li><li>I know how to remove all sources of noise and nuisance</li><li>or block them out.</li></ul>					
ł	bcp_7	set my own sleep and wake times, I know how to keep them consistent.					
ł	bcp_8	take a daytime nap, I know how to avoid it.					
ł	bcp_9	use technological devices right before bedtime or in bed, I know how to avoid or remove them.					

#### The following questions relate to some general daytime routines and what you do before going to bed.

í	The following questions list a number of things, w question, please indicate how much you agree with			impact your s	sleep-related h	abits over t	he next 3 mo	nths. For each
Item	For me	Strongly disagree (0)	Disagree (1)	Slightly disagree (2)	Neither disagree nor agree (3)	Slightly agree (4)	Agree (5)	Strongly agree (6)
oeo_1	avoiding caffeine/tea or energy drinks would help me sleep better.							
oeo_2	avoiding nicotine would help me sleep better.							
oeo_3	avoiding alcohol would help me sleep better.							
oeo_4	exercising regularly would help me sleep better.							A
 oeo_5	reducing my stress levels would help me sleep better.							
 oeo_6	reducing the impact of noise and nuisance in my bedroom would help me sleep better.							
oeo_7	keeping consistent sleep/wake times would help me sleep better.							
oeo_8	avoiding daytime naps would help me sleep better.							
 oeo_9	avoiding the use of technological devices right before bedtime or in bed would help me sleep better.							

**OUTCOME EXPECTATIONS** 

The following questions relate to some general daytime routines and what you do before going to bed.

	í	The following questions list a number of things, which may or may not impact you question, please rate how important each statement is to you.	r sleep-relate	d habits over t	he next 3 moi	nths. For each
	Item	How important is it to	Not at all important (0)	Only slightly important (1)	Important (2)	Extremely important (3)
S	oei_1	avoid caffeine/tea or energy drinks to sleep well?				
NCIE	oei_2	avoid nicotine to sleep well?				
ECTA	oei_3	avoid alcohol to sleep well?				
EXP	oei_4	exercise regularly to sleep well?				
OME	oei_5	reduce stress to sleep well?				
DUTC	oei_6	reduce bedroom noise and nuisance to sleep well?				
0	oei_7	keep sleep/wake times consistent to sleep well?				
	oei_8	avoid daytime naps to sleep well?				
	oei_9	avoid technological devices right before bedtime or in bed to sleep well?				

The following questions relate to some general daytime routines and what you do before going to bed.

Item	Most people who are important to me would encourage me to	Strongly disagree (0)	Disagree (1)	Neither agree nor disagree (2)	Agree (3)	Strongly agree (4)	Strongly disagree (5)
soc_1	avoid caffeine.						
soc_2	avoid nicotine.						
soc_3	avoid alcohol.						
soc_4	exercise regularly.						
soc_5	reduce my stress levels.						
soc_6	reduce the impact of noise and nuisance in my bedroom.						
soc_7	keep my sleep and wake times consistent or keep the same schedule as me.						
soc_8	avoid taking daytime naps.						
soc_9	avoid the use of technological devices right before bedtime or in bed and not use them either when they are in the same bedroom/bed.						

SOCIAL SUPPORT

(i) Now, referring to your friends, family members, partner or your housemates, please indicate your level of agreement with the following statements.

Item	I intend to	No, not really (0)	(1)	(2)	Somewhat intend (3)	(4)	(5)	Strongly intend (6)
int_1	avoid caffeine, especially right before bedtime.							
int_2	avoid nicotine, especially right before bedtime.							
int_3	avoid alcohol, especially right before bedtime.							
int_4	be more physically active.							
int_5	reduce my stress levels.							
int_6	keep my bedroom free of noise and nuisance.							
int_7	keep my sleep and wake times more consistent.							
int_8	take fewer daytime naps.							
int_9	avoid using technological devices, especially right before bedtime or in bed.							

# (1) Please indicate to what extent you intend to engage in the following behaviours over the next 3 months.

INTENTION

Sum score:

Item	I have planned where, when and how I will	No plans (0)	(1)	(2)	(3)	(4)	(5)	Detailed plans (6)
pln_1	avoid caffeine.							
pln_2	avoid nicotine.							
pln_3	avoid alcohol.							
pln_4	exercise regularly.							
pln_5	reduce my stress levels.							
pln_6	minimise the impact of noise and nuisance in my bedroom.							
pln_7	keep my sleep and wake times consistent.							
pln_8	avoid daytime naps.							
pln_9	avoid using technological devices right before bedtime or in bed.							

(i) Next, we are going to ask you about your planning related to sleep over the next 3 months.

PLANNING

Sum score:

## SCORING INSTRUCTIONS

For each of the seven scales, add up the scores from all nine items to calculate a sum score. For scales with response choices ranging from 0-3 (oei), the range of sum scores is 0-27. For scales with response choices ranging from 0-4 (sef, bcp), the range of sum scores is 0-36. For scales with response choices ranging from 0-5 (soc), the range of sum scores is 0-45. For scales with response choices ranging from 0-6 (oeo, int, pln), the range of sum scores is 0-54.

Interpretation: Higher scores indicate stronger psychosocial dispositions for sleep hygiene.

(i	D	Please indicate your level of confidence in engaging in the fol healthy.	llowing behaviou	rs for the gene	ral purpose of	keeping you	r sleep
lte	em	l can	Not at all confident (0)	A little confident (1)	Moderately confident (2)	Very confident (3)	Extremel confiden (4)
sef	f_1	avoid caffeinated beverages (coffee, tea, energy drinks, etc.) right before bedtime.					X
sef	f_2	avoid nicotine right before bedtime.				X	
sef	f_3	avoid alcohol right before bedtime.				X	
sef	f_4	exercise on a regular basis.			×		
sef	f_5	reduce my stress levels.		X			
sef	f_6	reduce the impact of noise and nuisance in my bedroom.				X	
sef	f_7	keep my sleep/wake times consistent.				X	
sef	f_8	avoid taking daytime naps.				X	
sef	f_9	avoid using technological devices (e.g., phone, TV, laptop, etc.) right before bedtime or in bed.			×		

**EXAMPLE SCORING:**  $sef_1 = 4$ ;  $sef_2 = 3$ ;  $sef_3 = 3$ ;  $sef_4 = 2$ ;  $sef_5 = 1$ ;  $sef_6 = 3$ ;  $sef_7 = 3$ ;  $sef_8 = 3$ ;  $sef_9 = 2$ **EXAMPLE SUM SCORE:**  $sef_1 + sef_2 + sef_3 + sef_4 + sef_5 + sef_6 + sef_7 + sef_8 + sef_9 = 24$ 

### Table 4.S2

Sum scores and skewness per scale for both study samples
----------------------------------------------------------

	San	nple One (n = 160)		S	Sample Two (n = 20)		
Scale	M (SD)	Median	Skewness	M (SD)	Median	Skewness	
Self-efficacy	24.4 (5.49)	24.0	-0.24	24.3 (4.97)	24.5	-0.61	
Behavioral capability	25.6 (5.40)	26.0	-0.57	26.8 (4.73)	26 0	-0.22	
Outcome expectations	41.0 (9.91)	42.0	-0.41	39.5 (9.03)	41.0	-0.38	
Outcome expectancies	20.4 (4.97)	20.5	-0.53	20.0 (4.81)	20.5	-0.30	
Social support	26.9 (6.22)	27.0	-0.32	26.8 (6.09)	26.5	-0.44	
Intention	44.8 (7.99)	47.0	-0.92	37.3 (10.81)	41.5	-0.69	
Planning	27.3 (16.02)	28.5	-0.26	25.9 (14.15)	26.0	-0.13	

*Note.* Values of skewness between -0.5 and 0.5 indicate an approximately symmetrical distribution, values between -1 and -0.5 or between 0.5 and 1 indicate moderate skewness and values less than -1 or greater than 1 indicate high levels of skewness; means (SD), medians and levels of skewness reported for Sample Two were assessed at the first of two time points (test-retest phase).

# CHAPTER 5. A RANDOMISED CONTROLLED TRIAL USING A THEORY-BASED M-HEALTH INTERVENTION TO IMPROVE PHYSICAL ACTIVITY AND SLEEP HEALTH IN ADULTS: THE SYNERGY STUDY PROTOCOL

Chapter 5 presents a study protocol including the rationale, development and methods of the Synergy Study. The contents of this chapter were peer-reviewed and published as a journal article in BMJ Open.

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# 5.1 Abstract

There is a need to reduce physical inactivity and poor sleep health in the adult population to decrease chronic disease rates and the associated burden. Given the high prevalence of these risk behaviours, effective interventions with potential for wide reach are warranted. The aim of this two-arm RCT will be to test the effect of a three-month personalised mobile app intervention on two main outcomes: minutes of moderate to vigorous physical activity and overall sleep quality. In addition, between-group changes in health-related quality of life and mental health status will be assessed as secondary outcomes. The prespecified mediators and moderators include social cognitive factors, the neighbourhood environment, health (BMI, depression, anxiety, stress), sociodemographic factors (age, gender, education) and app usage. Assessments will be conducted after three months (primary endpoint) and six months (follow-up). The intervention will provide access to a specifically developed mobile app, through which participants can set goals for active minutes, daily step counts, resistance training, sleep times and sleep hygiene practice. The app also allows participants to log their behaviours daily and view progress bars as well as instant feedback in relation to goals. The personalised support system will consist of weekly summary reports, educational and instructional materials, prompts upon disengagement and weekly facts.

# 5.2 Background

Engaging in sufficient physical activity and maintaining good sleep health are two lifestyle behaviours that significantly reduce the risk of all-cause mortality [1,2], cardiovascular disease [3,4] and type-2 diabetes [5,6]. *Sufficient physical activity* is the accumulation of at least 150 minutes of moderate-intensity or 75 minutes of vigorous-intensity physical activity per week [7]. *Good sleep health* is characterised by duration, quality and timing of sleep that leaves a person satisfied with their sleep and alert during the day [8]. Internationally, up to 32% of adults are insufficiently physically active [9], up to 29% report sleeping <6 hours [10], 24% report poor quality sleep [11] and >50% report inconsistent bed and wake times, the latter two of which are indicators of poor sleep health [12]. There is no global estimate of the percentage of adults who report both insufficient physical activity and poor sleep health. However, evidence suggests that individuals with poor sleep health also report lower levels of physical activity [13,14]. Thus, interventions that target both behaviours have the potential to make meaningful contributions to public health.

Multiple lifestyle behaviour interventions produce greater reductions in the risk of poor health than interventions that target a single behaviour [15]. Moreover, physical activity and sleep have a bi-directional relationship [16] in which physical activity improves indicators of sleep health (e.g., sleep quality) and good sleep health is associated with greater levels of physical activity [17]. Interventions targeting both behaviours simultaneously may capitalise on this reciprocal relationship to produce larger increases in both behaviours [18]. Previous reviews of multiple behaviour interventions, however, have not identified any studies that specifically targeted changes in both physical activity and sleep health and tested the efficacy of this approach in a randomised controlled trial [19–21].

Non-pharmacological sleep interventions (e.g., Cognitive Behavioural Therapy for Insomnia) frequently promote sleep hygiene [22] using a set of self-regulatory strategies that help to promote good sleep health, but details of behaviour change techniques (BCTs) to support changes in sleep hygiene behaviours, such as regular physical activity or stress management, are usually not reported [23,24]. Without providing the necessary guidance to promote behaviour change, such education-only interventions are unlikely to change behaviour, as education-only interventions are known to be less effective than those that

are combined with additional self-regulation strategies [25]. Furthermore, multiple health behaviour change interventions need to implement BCTs that are specific to each behaviour to produce greater changes in targeted behaviours [26]. Interventions targeting physical activity and sleep in combination therefore need to provide behaviour-specific intervention strategies to maximise change and harness the potentially synergistic effects between physical activity and sleep.

Reviews of the evidence suggest theory-based interventions are more effective in changing behaviour than interventions that do not use a theoretical approach [27]. Theoretical models provide important guidance for the development of behaviour change interventions, aiming for the uniform operationalisation of cognitive and behavioural determinants. Social Cognitive Theory (SCT) is one of the most widely used theories in health behaviour research [28]. SCT aids the conceptual understanding of behaviour change, as it accounts for the interactions between individual and environmental processes that either facilitate or impede behaviour change [29]. This is particularly relevant when targeting both physical activity and sleep health, since individual as well as environmental factors are known to influence both behaviours [30,31]. SCT has guided the development of numerous physical activity interventions and its constructs are strongly associated with physical activity [31,32], but there is only limited understanding of social cognitive factors in relation to sleep health [30]. However, it may be useful to apply social cognitive frameworks to better understand mechanisms of adult sleep health, since sleep is affected by factors at both the individual (e.g., self-efficacy to change sleep hygiene behaviours) and environmental (e.g., sleep environment, neighbourhood factors) level.

Due to the high prevalence of people who report either being insufficiently active or meeting indicators of poor sleep health, there is a need for broad-reaching interventions. Because smartphone ownership is growing steadily, with approximately 80% of the population owning a device [33], intervention delivery entailing this medium is likely to be accessible, affordable and conveniently integrated into daily life.

This study aims to test: (1) the efficacy of an app-based intervention to improve physical activity and sleep quality (as primary outcomes) and health-related quality of life and mental health status (as secondary study outcomes), relative to a waitlist control; (2) the mediating role of social cognitive factors and app usage in behaviour change; and (3)

health (BMI, depression, anxiety, stress), sociodemographic factors (age, gender, education) and the neighbourhood environment as potential moderators of intervention efficacy.

# 5.3 Methods

This trial was registered prospectively (pre-results) on the Australian New Zealand Clinical Trials Registry (ANZCTR Registration Number: ACTRN12617000376347; Universal Trial Number: U1111-1186-6588 (Appendix P)). The conduct and reporting of the trial will follow CONSORT guidelines [34] and the CONSORT-EHEALTH checklist [35]. Full ethical approval was obtained from the Human Research Ethics Committee of The University of Newcastle, Australia (Approval Number: H-2016-0181 (Appendix B)).

# 5.3.1 Study design

A two-arm randomised controlled (superiority) trial with a combined physical activity and sleep intervention and a waitlist control group, with assessments conducted at zero months (baseline), three months (primary endpoint) and six months (follow-up).

# 5.3.2 Recruitment

Digital and print-based advertising will be used to recruit nationwide in Australia. Recruitment for both intervention arms commenced in May 2017 and will conclude once sample size requirements are achieved (n = 160, refer to power and sample size section). Social media advertising will be used to recruit in social media networks (e.g., Twitter, Facebook) using target audiences that match inclusion criteria (i.e., age, living in Australia). Electronic and print-based advertising will include magazines and newspapers with state-wide reach. All recruitment materials will provide contact details and a link to the consent form and eligibility survey. Due to the remote delivery of the intervention in combination with self-report based assessments, participants will not be required to visit the research centre.

# 5.3.3 Exclusion criteria

Individuals who meet any of the following criteria will not be eligible to participate (see Appendix Q for Eligibility Screening Items).

• Not residing in Australia.

- Not being between 18 and 55 years old.
- Reporting a height and weight that is not consistent with a BMI between 18.5 and 35.
- Accumulating more than 90 minutes of moderate/vigorous physical activity per week.
- Rating their sleep-quality (over the past month) as *fairly good* or *very good*.
- Currently pregnant or having given birth in the past 12 months.
- Having a condition that would make it unsafe or limit their ability to increase activity levels or change sleep behaviours.
- Having a diagnosed sleep disorder (chronic insomnia, sleep apnoea, sleepwalking, narcolepsy, restless legs syndrome, etc.).
- Currently consuming hypnotics (sleep-inducing medication).
- Being employed in any night-shift work.
- Planning frequent travel (once a month or more often) to a destination with a shift in time zone by more than three hours during the intervention period.
- Currently using a self-monitoring system or device to track or log physical activity or sleep (this includes non-device assisted applications).
- Not having access to an internet-enabled iOS (Apple) or Android smartphone or tablet.

Interested participants who indicated they already used a self-monitoring system or tracking device were excluded to avoid the potentially confounding effect that the use of a self-monitoring system or device may have on behaviour, as most popular health apps or the trackers themselves frequently implement a variety of behaviour change strategies [36,37].

# 5.3.4 Study procedure

Eligible participants will be contacted via email and welcomed into the study. Participants will be asked to complete online surveys assessing primary and secondary outcomes, potential mediators/moderators and sociodemographics at three time points (see Appendix H for Baseline Survey Items). Figure 5.1 illustrates the flow of participants throughout the trial.

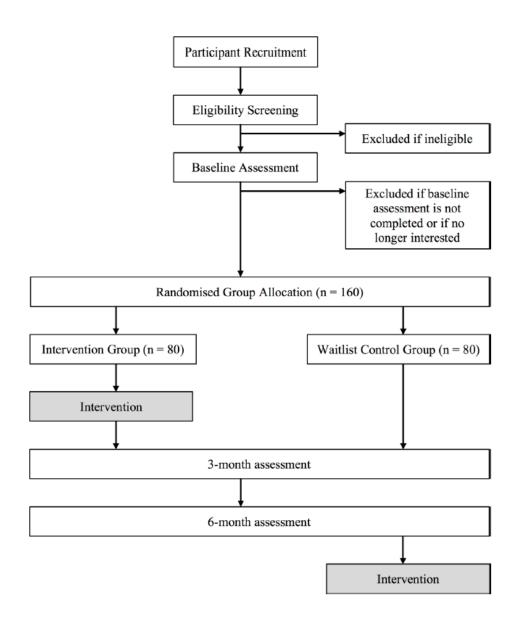


Figure 5.1 Flow of participants in the Synergy Study

All online surveys will be administered using Qualtrics (Provo, Utah). If specified screening criteria are not met, participants will be advised via text displayed at the end of their survey and further contact will only be made where ambiguous responses require clarification. Ineligible participants will also receive a link providing free and unlimited access to the public version of the Balanced app [38].

Participants will receive an email with a unique password-protected link to their survey at each assessment point. Each person who has completed their baseline survey will be randomly allocated to one of two groups. Participants allocated to the intervention group will be mailed a pedometer, tool sheets, login details and instructions for download and installation of the "*Balanced*" smartphone app in the form of a participant handbook (Appendices R and S). The initial Balanced app was specifically developed for scientific purposes and is described in more detail elsewhere [38]. It originally consisted of three separate categories, one for physical activity (active minutes), one for inactivity (hours and minutes of sitting) and one for sleep (bed and wake times and sleep quality rating). As part of the modifications to the previous app, the physical activity component of the app was revised to include daily steps and resistance training in addition to minutes of moderate to vigorous intensity physical activity; and the sleep component was revised to include sleep hygiene in addition to sleep times and sleep quality. The sitting behaviour category was removed for use in the Synergy Study, as no specific strategies to reduce sitting time will be provided in this study and because the objective will be to promote improvements in moderate to vigorous intensity physical activity and sleep health. App content was modified based on participant feedback (process evaluation and semistructured interviews) as part of the Balanced study [38], while design and aesthetics from the original version were retained. The main advance of the modified version lies in its increased level of tailoring using personal as opposed to the previously standardised goals, which makes feedback on progress towards goals and goal achievement more personalised and meaningful for those needing to get engaged in healthy behaviour [39].

Regular app use will be supported by an email and text message-based support system (see Table 5.1), which is initiated as soon as a participant has gained access to the app. All messaging will follow a standardised protocol that was designed under consideration of the specificity, timeliness and relevance of contents (see Table 5.1), as those are valued components in mobile apps designed to change health behaviours [40]. Following completion of their three-month assessment, participants may continue to use the app as much or as little as they like, but the message-based support will no longer be provided.

Table 5.1

		_	Frequenc	У
Delivery	Content	weekly	monthly	as required
Email	General communication, survey reminders, notifications (eligibility, group allocation)			X
	Personalised weekly summary (Appendix T)	х		
	Tool sheets (sent separately at weeks 3, 6 and 9)		х	
	App usage reminder (Condition: if 3 consecutive SMS prompts were unsuccessful in motivating participants to re-engage), only if applicable	x		
SMS	Fact of the week (Appendix U)	Х		
	Usage prompt (Condition: if non-usage occurred on at least 4/7 days per week)	x		
App-based Prompts	If enabled, a daily on-screen notification prompts participants to log data, if app has not been used to self-monitor behaviour in >24h			х

Overview and content of message-based support service

Note. The message-based support system will be delivered for the first 12 weeks of the intervention only.

### 5.3.5 Intervention

The intervention is composed of app and non-app components, with non-app components referring to any content of the intervention that is delivered via participant handbook, text message or email. App components consist of educational resources, self-monitoring, goal-setting and feedback. Participants will have continuous access to the app throughout the intervention period. For the first three months, which is the period between baseline and the primary endpoint, these components will be complemented by a messaging system providing personalised feedback on progress towards goals, prompting goal review and prompting practice of the target behaviours. The messaging component will cease at the three-month assessment, but participants will have continued access to the app. Following completion of the study, participants will be able to continue to access and use the app for an indefinite period, but will not be required to complete any further assessments as part of this study. The app will be available on both Android- and Applebased operating systems. Table 5.2 provides an overview of intervention strategies used to operationalise the social cognitive constructs in the intervention. In brief, the key constructs included relate to a person's confidence (self-efficacy) in their capacity to

define and follow a specific plan, the purpose of which is to experience a desired result in the face of situational or environmental (sociostructural) factors that either impede or facilitate progress, while the motivation to pursue results is regulated by perceptions regarding the personal benefit of the result in question and its importance (outcome expectations and expectancies) [29].

### Educational resources

App resources will consist of educational information about the importance of the two behaviours, basic instructions on how to change each behaviour and guidance for app use (e.g., how to interpret traffic lights and progress graphs). This content will provide participants with knowledge on the health benefits of each behaviour, the current national guidelines for physical activity and sleep and the importance of resistance training and incidental physical activity in addition to aerobic exercise, as well as the importance of all dimensions of sleep health (i.e., sleep duration, sleep quality, sleep timing). Resources will consist of a comprehensive range of stimulus control and sleep hygiene recommendations based on summaries of the evidence [22]. In addition to app content, participants will receive a total of three tool sheets (enclosed in the handbook): one tool sheet including goal-setting strategies [41] for each behaviour, one that emphasises action planning (again, one for each behaviour) and one tool sheet with information and instructions adapted from publicly available resources for the practice of stress management techniques (i.e., progressive muscle relaxation, deep breathing and mindfulness) [42-44]. All tool sheets (Appendix R) will be distributed at outset along with the participant handbook (Appendix S), which includes a brief study summary, a personalised timeline including assessment dates as well as a comprehensive troubleshooting guide covering the most common problems that may occur when installing and using the app. Participants in the intervention group will receive their materials following completion of their baseline assessment and waitlist controls will receive an identical package following their six-month assessment. In addition, during each month of the intervention, one tool will be promoted via email to encourage utilisation of these resources. Goal-setting tool sheets will be sent in week three, followed by the action planning tool sheet in week six and the stress management tool sheet in week nine for each participant. The examples given within the tool sheets are framed in a way that encourages participants to tailor any strategies to their own situation and priorities (for example: Once I get fitter, I will finally be able to...). Individuals are instructed to set goals that are personally relevant and meaningful to promote initial

engagement, but the goal-setting information provided will provide reference to the recommended minimum of 150 minutes of moderate-intensity physical activity per week [7] and a sleep duration of 7–9 hours per night [45] as overarching goals one should gradually work towards. Weekly summary reports (Appendix T), however, will focus on individual progress in relation to the individual goals set by the participant. Each report will detail progress in the form of totals and averages for both behaviours (i.e., active minutes, step count, resistance training sessions, bed and wake times, sleep hygiene, sleep quality), which will help participants understand how changes in the two behaviours are interrelated. Furthermore, participants will receive a weekly text message containing one of 12 educational and motivational facts relating to physical activity and sleep for better health (i.e., the consequences of poor sleep health). Each fact message will also refer to the resources section available in the app and encourage people to use it (Appendix U).

#### Table 5.2

Operationalisation of	f social cognitive	factors and behaviou	r change strategies

Constructs	BCT <sup>1</sup>	Components	Description of intervention components
Self-efficacy	<ul> <li>Graded tasks</li> <li>Self- monitoring</li> <li>Goal review</li> <li>Feedback on</li> <li>performance</li> <li>Praise/rewards</li> <li>Relapse</li> </ul>	App log	Participants will be asked to recall and enter their activity and sleep behaviours. The daily log will allow entries for active minutes, daily steps, resistance training sessions, sleep and wake times, a sleep quality rating, as well a checklist of 10 sleep hygiene goals. Participants will be asked to tick off those sleep hygiene goals they implemented the previous day.
	<ul> <li>prevention/</li> <li>coping</li> <li>Barrier identification/</li> <li>problem solving</li> <li>Stress management</li> </ul>	App progress charts App dashboard traffic light	Bar charts will provide a history for daily, weekly and 3-month progress in relation to goals per behaviour (for each of the items data logged for). The activity dashboard produces a traffic light colour relating to total active minutes, while the colour of the sleep dashboard relates to total sleep duration. Goals can be adjusted at any time, which will determine the colours on the dashboard traffic light. This is dynamically updated as soon as a self- monitoring entry is made: a green light indicates a participant is meeting, exceeding or close to their goal; an orange light indicates they are progressing toward their goal although are not close; and a red light indicates they are markedly below their goal.

# Table 5.2

SCT constructs	$BCT^1$	Components	Description of intervention components
Self-efficacy		Tool sheets	A series of tool sheets delivered at weeks three, six, and nine will promote goal-setting and action planning and give detailed guidance on how to set SMART goals and follow through with an action plan in the face of barriers (i.e., by being prepared).
		Weekly summary (Email)	This support feature will provide an overview of weekly totals and averages per behaviour (if sufficient data are available) and prompt participants to review goals, if needed.
		Prompts (SMS)	If participants fail to log any data on more than 4 days per week, they will receive a message prompting them to resume logging.
Perceived behavioural capability	• Information on where and when to be active/engage in in sleep promoting behaviours	App resources	The resources section will provide the current national guidelines on how much physical activity per week and how much sleep (hours) per night adults need. This section also includes brief content on the when, the where, who with and how of being active and sleeping well (e.g., sleep hygiene practices).
	• Instructions on how to be active and engage in sleep	Weekly facts (SMS)	Each week, participants will receive a short text message with educational content on activity and/o sleep and health to reinforce the importance of both behaviours.
	promoting behaviours	Tool sheets	Tool sheets provide more detailed information that enable a person to make positive changes to their physical activity and sleep levels and include action plan templates and examples of exercises. These materials will also include stress management techniques, such as Progressive Muscle Relaxation (PMR) and controlled breathing.
Outcome expectations/ expectancies	• Information about the behaviour in relation to health	Tool sheets	As part of the goal-setting tool sheet, participants will be asked to think about the reasons for wishing to improve their health behaviours and what they anticipate as personal benefits, following improved levels of activity and sleep (examples will be provided).

Operationalisation of social cognitive factors and behaviour change strategies

# Table 5.2

SCT constructs	BCT <sup>1</sup>	Components	Description of intervention components
Outcome expectations/ expectancies		App resources	This section will include information on why activity and sleep are important and how they contribute to health and well-being.
		App log personal goals	Participants will be asked to personalise their goals, but work towards recommended minima (150 MVPA/week; 7-9h sleep/night); goals are carried forward from previous entries unless adjusted
Goals	<ul> <li>Goal-setting</li> <li>Action Planning</li> <li>Self- monitoring</li> <li>Prompt practice</li> <li>Time Management</li> </ul>	App dashboard traffic light Tool sheets	Participants will be encouraged to put equal effort into improving both PA and sleep. This means two amber lights are better than one green and one red light. Participants will receive goal-setting strategies and example action plans for guidance (per behaviour) as part of the tool sheets described above. One of three tools will be promoted specifically via Email at week three, six and nine, respectively.
	<ul> <li>Teach use of prompts</li> <li>Time management</li> </ul>	Reminders	Participants are advised to set a daily bedtime reminder (optional) on their phone, which is intended to prompt a person's bedtime routine and will promote regular bedtimes.
	C	App resources	Environmental restructuring as part of good sleep hygiene will be highlighted in the resource section and include details on <i>how to</i> manage the bedroom environment.
			Also includes information on activity and sleep in the social context and seeking support from those in the same household (housemates, partner, family members).
Sociostructural factors (social support & environment)	<ul><li>prompts</li><li>Environmental</li><li>restructuring</li></ul>	Tool sheets	This will include short examples on how to identify and manage barriers around being active and getting good sleep and how to utilise one's social support and environment in favour of activity and sleep.

Operationalisation of social cognitive factors and behaviour change strategies

*Note.* <sup>1</sup>Behaviour change techniques were specified in accordance with the 40-item taxonomy of behaviour change techniques by Michie et al. [46]; MVPA = moderate to vigorous intensity physical activity; PA = physical activity.

## Self-monitoring

Participants will be asked to recall minutes of moderate to vigorous physical activity, and participation in resistance training, and manually enter this into the app every day. Daily steps will be objectively measured using the pedometer (Yamax SW200, Eagle Farm, QLD) provided and manually entered by participants into the app. Participants will not be asked to return their pedometer. Self-monitoring of sleep in the app will also be manually entered by participants. The sleep log consists of: bedtime (time of going to sleep), wake time (time of waking) and sleep quality (rating scale from zero to five where five indicates high sleep quality). As an additional feature, this section of the app allows participants to log which sleep hygiene behaviours they practised the previous day (Figure 5.2). These include consumption of caffeine, alcohol, nicotine, excessive intake of fluids or heavy meals before bedtime, regulation of the impact of light, noise and temperature in the bedroom, use of light-emitting devices, regular exercise, maintenance of consistent sleep and wake times, having and following a bedtime routine, creating comfort (e.g., proper pyjamas and bedding) and managing stress [22]. Participants can self-monitor these behaviours at any time of the day and update this information as many times per day as they prefer. The current study uses a manual data entry method based on selfmonitoring. This method was selected for use in the current trial due to financial restrictions and because the Balanced study did not observe any between-group differences (i.e., manual entry vs. device-entered method (via Fitbit)) in physical activity or sleep outcomes, or in time to non-usage attrition [38].



Figure 5.2 Sleep hygiene log items

# Self-regulation

App feedback on behaviour will be provided using graphical displays of logged behaviour in relation to the goals set by the participant (Figure 5.3). Two types of graphical feedback are provided. There will be separate graphs for moderate to vigorous intensity physical activity, steps, resistance training, sleep duration, sleep quality, sleep timing and sleep hygiene. This information will provide a breakdown in the form of daily, one-week and three-month bar charts. The second graphical feedback to participants is via the dashboard which changes to one of three colours – green, orange and red in a traffic light system – to provide immediate feedback on participants' behaviour to in relation their goals on a

daily basis (Figure 5.3). The comparison of actual behaviour to goals based on a percentage of the goal achieved allows the use of consistent criteria across behaviours. This differs from the traffic light system originally used in Balanced, since process data from that study alluded to participants preferring to see this feedback based on goals rather than guidelines for each behaviour [38].

As part of the goal review strategies, participants will be encouraged to evaluate their achievements in relation to goals and adjust their goals whenever needed. This will be facilitated by a personalised weekly summary of the previous week, delivered via email, so that any reviews and adjustments of goals align with the most recent progress and foster self-efficacy. If a participant has logged data on less than four days per week (per behaviour), a text message will be sent to prompt practice. Likewise, once per week, if a participant logs data for one behaviour but not the other, a prompt will encourage him or her to engage in both behaviours equally.

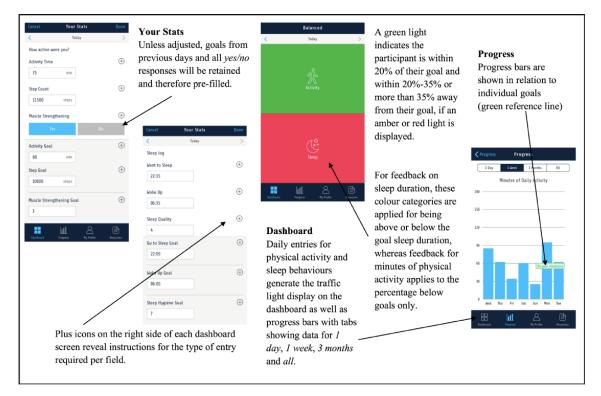


Figure 5.3 Screenshots of app screens for self-monitoring and feedback relative to goals

# 5.3.6 Waitlist control group

Upon enrolment and allocation, the waitlist control group will not receive any intervention materials and only be required to complete their baseline, three-month and

six-month assessments. After the six-month assessment is completed, participants in this group will receive full access to the intervention.

### 5.3.7 Randomisation

Participants will be randomly allocated to one of two groups (intervention or control) after having completed their baseline assessment. Opaque sealed envelopes (n = 80 per group) will be prepared by BM using permuted block randomisation with block sizes of four and eight, following the procedures suggested by Doig et al. [47] Once a participant has completed their baseline assessment, a researcher not associated with the study who is responsible for group allocation will open the envelope that is next in sequence and inform the project leader of the allocation outcome. Participants will be informed by the project leader and be sent a package containing study materials (i.e., handbook and pedometer), if they have been allocated to the intervention group (participants in the waitlist control group will receive their study materials after completing their six-month assessment). The only exception for contravention with the allocation sequence will be made if family members or couples living in the same household enrol in the study, which would pose a high risk of contamination, especially between groups. For this reason, all individuals who are identified as members of the same household will be allocated to the same group. Neither the trial participants nor the project lead (BM) will be blinded to group assignment.

#### 5.3.8 Outcome measures

All measures will be assessed via online survey at baseline, three months and six months except for sociodemographics, which will only be collected at baseline. The three-month survey will further include process evaluation items that measure system usability and participant satisfaction (intervention group only). The two primary outcomes will be total minutes of moderate to vigorous physical activity and sleep quality. To increase adherence to scheduled assessments, participants who complete their survey will be entered into a draw for one of five A\$50 shopping vouchers. This information will not be provided prior to enrolment and is not intended to function as an incentive for individuals to sign up to participate, but merely to promote adherence to assessment requirements. Table 5.3 provides a summary of outcome measures and assessment time points. All online surveys will be pilot-tested and locked prior to study commencement to prevent

any changes from being made once the study is underway. All survey forms will be hosted on Qualtrics.

Table 5.3

Overview of outcome measures and assessment time points

	Measure		Time point of assessment			
Variables		Instrument	Baseline	Three months	Six months	
Primary outcomes	Minutes of moderate- and vigorous intensity physical activity (last week)	The Active Australia Questionnaire (AAQ)	X	X	Х	
	Overall sleep quality (past 30 days)	The Pittsburgh Sleep Quality Index (PSQI)	Х	х	Х	
Secondary outcomes	Health- related quality of life	The RAND-12 plus 3 items assessing energy/fatigue (RAND-36)	X	х	Х	
	Depression, Anxiety, Stress	The DASS-21	Х	х	Х	
	Resistance training	Number of sessions per week and duration per session	х	х	х	
	Sitting behaviour	The Workforce Sitting Questionnaire	Х	х	х	
	Sleep timing	The Sleep Timing Questionnaire	х	х	х	
	Insomnia symptom severity	The Insomnia Severity Index (ISI)	Х	Х	х	
	Daytime sleepiness	The Epworth Sleepiness Scale (ESS)	х	х	х	
Process evaluation items	Self-efficacy using a mobile app	The Internet Self-Efficacy Scale		Х		
(intervention group only)	User satisfaction	The Cognitive-Affective Model of Perceived User Satisfaction (CAMPUS)		Х		

			Time point of assessment			
Variables	Measure	Instrument	Baseline	Three months	Six months	
	App usage & engagement	The Balanced App database	Cont	tinuous rec	ording	
	App usability	The System Usability Scale		x		
	Utility, advice acceptability & relevance	Semi-structured telephone interviews (Appendix V)		Х		
Sample characteristics	Demographics	Age, gender, height, weight, chronic disease status	Х			
	Socioeconomic factors	Education, income, marital status, occupation, working hours	х			
	Morningness- Eveningness	The Morningness-Eveningness Questionnaire (MEQ)	х			
Moderators/ Mediators	Sleep hygiene behaviours	The Sleep Hygiene index (SHI)	Х	Х	Х	
	Environment	Perceived Neighbourhood Disorder	x	х	х	
	Social cognitive factors	Social cognitive factors relating to physical activity Social cognitive factors relating to sleep hygiene behaviour	x	х	Х	
	Habit	The Automaticity Scale	х	х	х	
	App usage & engagement	The Balanced App database	Cont	tinuous reco	ording	

# Table 5.3

Overview of outcome measures and assessment time points

# **5.4 Primary outcomes**

# 5.4.1 Physical activity

The Active Australia Questionnaire (AAQ) has demonstrated acceptable reliability (rho = 0.64) [48,49], is sensitive to change in interventions [50] and provides a measure of both the frequency and duration of moderate- and vigorous-intensity physical activity

during the last week. This includes the total time spent in recreational walking and transport, moderate-intensity physical activity (e.g., swimming, golfing), aerobic activity (e.g., cycling, jogging) and vigorous gardening or yard work. Total minutes of moderateand vigorous-intensity physical activity will be created by summing minutes of walking, moderate- and vigorous-intensity (weighted by two) physical activity. Although objective assessment methods may be used to measure physical activity, it was not deemed feasible in the current study due to financial and pragmatic issues.

## 5.4.2 Sleep quality

The Pittsburgh Sleep Quality Index (PSQI) consists of 19 items and seven component scores with scores ranging from zero to 21 [51]. Items assess problems with seven different components of sleep health in the last 30 days. Higher scores indicate poorer sleep quality and a score above five is commonly used to indicate poor sleep quality. The current study will use the PSQI as a continuous score. The PSQI is the most frequently used self-report instrument in sleep research [52-54]. The PSQI has demonstrated good reliability ( $\alpha = 0.83$ ), is sensitive to change and has strong psychometric properties [51,55]. The seven PSQI component scores consist of subjective sleep quality, sleep onset latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleep medication and daytime dysfunction, all of which will be reported in addition to the total score. Although objective assessment methods (e.g., polysomnography, accelerometry) are known to provide accurate measures of sleep [56], a global measure of subjective sleep quality will be used in this study to observe the perceived restorative effect of sleep, which is difficult to measure using objective methods [57].

# **5.5 Secondary outcomes**

### 5.5.1 Health-related quality of life

Poor sleep quality and inadequate sleep duration are independently associated with low health-related quality of life [58]. The RAND-12 is a valid and reliable instrument [59] that is widely used to assesses multiple concepts of health such as physical functioning, role limitations due to physical and emotional problems, social functioning, emotional well-being, energy/fatigue, pain and general perceptions of health. In addition to the RAND-12 scale, three additional items that make up the energy/fatigue subscale in the 36-item version of the RAND will be asked (e.g., "How much of the time during the past

four weeks did you feel tired?"), so that this domain can be evaluated separately. This will allow improvements in energy and fatigue during the course of the intervention to be assessed.

#### 5.5.2 Depression, anxiety, and stress

The effect of changes in physical activity and sleep on participants' severity of depression, anxiety and stress symptoms will be assessed using the Depression-Anxiety-Stress Scale (DASS-21). The DASS-21 is reported to have satisfactory levels of internal consistency for its total scale (r = 0.93) as well as for its individual scales for depression (r = 0.88), anxiety (r = 0.82) and stress (r = 0.90) [60]. In addition, DASS-21 scores will be examined as a potential moderator of intervention efficacy.

### 5.5.3 Resistance training

Since the AAQ does not capture resistance training and because the Synergy Study will promote regular resistance training, the number and duration of resistance training sessions per week will be assessed using two items adapted from previous studies that assessed resistance training [61]. One item will ask participants: "In the last week, on how many days have you participated in muscle-strengthening activities (including weight/resistance training)?" and the second item will ask "What do you estimate was the total time (in hours/minutes) that you spent doing muscle strengthening activities (incl. weight/resistance training) in the last week?" The original items were adapted by changing the recall period from the previous month to the last week to align with the recall period used in the AAQ.

### 5.5.4 Sitting time

The Workforce Sitting Questionnaire (WFSQ) will provide a self-report measure of total domain-specific sitting time (over the last week) on workdays and non-workdays [62]. Domains include sitting time accumulated at work, watching TV, using a computer, using transport and doing other leisure activities. The WFSQ captures sitting time across several domains with acceptable validity (r = 0.45) and reliability (ICC = 0.63). Possible reductions in total sitting time may be a result of increased amounts of time allocated to light/incidental or moderate to vigorous physical activity [63].

### 5.5.5 Sleep timing

A modified version of the validated Sleep Timing Questionnaire will be used to assess the variability in bed and wake times on working days as well as non-working days [64]. To minimise participant burden, the instrument will only include items on the stability of *usual* bed and wake times, and the *usual* bed and wake times per se. Response options are categorical and scored on a scale of one to 11 with lower scores indicating less variability in bed or wake times (e.g., 1 = 0-15 min; 2 = 16-30 min; 11 = >4 hours).

### 5.5.6 Insomnia severity

The Insomnia Severity Index (ISI) is a valid and reliable instrument for measuring insomnia severity [65]. It can be used to classify individuals as having no insomnia (0-7), sub-threshold insomnia (8-14), moderate clinical insomnia (15-21) or severe clinical insomnia (22-28). This index will measure the proportion of the sample with potentially severe yet undiagnosed insomnia symptoms. While assessing the severity of sleep problems and the level of dissatisfaction with sleep a person can experience, the ISI also captures the extent to which the consequences of sleep problems manifest themselves in everyday life – for example, "To what extent do you consider your sleep problem to interfere with your daily functioning (e.g. daytime fatigue, mood, ability to function at work/daily chores, concentration, memory, mood, etc.) currently?". Across a total of seven items, responses are scored on a 5-point scale and summed to obtain a total score.

### 5.5.7 Daytime sleepiness

Daytime sleepiness is a further indicator of poor sleep health. It will be measured using the Epworth Sleepiness Scale (ESS), which assesses daytime sleepiness. This scale has demonstrated high internal consistency (Cronbach's *alpha* = 0.88) and good reliability (r = 0.82) [66] and consists of eight items that depict various situations in which a person could experience dozing off (e.g., while sitting and reading or watching TV). Items are summed to calculate a total score from zero to 24, with higher scores indicating higher levels of daytime sleepiness.

# 5.6 Process outcomes<sup>3</sup>

# 5.6.1 Internet self-efficacy

Participants' confidence in using the smartphone app will be assessed using an adaptation of the Internet Self-Efficacy Scale to capture participants' overall understanding of app software, confidence in gathering information using the app and learning to use the app, as well as the ability to troubleshoot and resolve app problems [67]. Participants will rate their agreement using a total of eight statements (e.g., "I feel confident explaining why a task will not run on the smartphone/tablet") on a seven-point scale from *strongly disagree* (1) to *strongly agree* (7).

# 5.6.2 Perceived user satisfaction

The Cognitive-Affective Model of Perceived User Satisfaction (CAMPUS) will be used to ask participants about thoughts and feelings associated with using the mobile app (Balanced). Using a seven-point scale ranging from *strongly disagree* (1) to *strongly agree* (7), a total of 23 items inquire about participants' opinion on the effects and aesthetics as part of the app design (15 items), its effectiveness and efficiency (five items) and the level of satisfaction experienced when using the app (three items) with the following anchors: *frustrated–contented*, *unhappy–gratified* and *sad–joyful*. Items will be adapted to refer specifically to the Balanced app – for example, "I would consider my experience with using the Balanced app as innovative". This instrument has demonstrated adequate levels of reliability and validity [68].

# 5.6.3 App usage

Overall interaction with the app will be measured continuously throughout the study period by the app database, which records the time and date a self-monitoring entry was made and the actual value or response entered into the app. Analysis of usage patterns will include the number of self-monitoring entries made and the duration of self-monitoring throughout the intervention, similar to previous research [69,70]. These data will also be considered as a mediator of behaviour change in the intervention group.

<sup>&</sup>lt;sup>3</sup> See Appendix U.

### 5.6.4 Usability of the App

App usability will be assessed using the 10-item System Usability Scale [71], a valid and reliable tool that assesses participant satisfaction relating to the utility of the websites on a five-point scale (items will be reworded for smartphone app usability). Higher total scores (range 1-100) relate to better usability. Example items include, "I would imagine that most people would learn to use this system very quickly" or "I needed the support of a technical person to be able to use this system".

### 5.6.5 Utility, Advice Acceptability and Relevance of the App

A participant sub-sample (10%) will be determined by random selection for semistructured telephone interviews, which will take place once all participants have completed their six-month assessments. These interviews will contribute valuable information for process evaluation and include general personal feedback, desirable improvements and preferences relating to future use. As part of these interviews, participants will be asked about their perception of the app's usefulness to improve changes in self-efficacy levels (confidence) toward physical activity and sleep health, coping with potential impediments (barriers) to being more active and sleeping better, maintaining new routines/action plans and keeping it a priority to be more active and sleeping better. Finally, advice acceptability and relevance in terms of the content will be examined based on a previously used questionnaire [72].

# 5.7 Mediators and moderators

### **5.7.1 Social Cognitive Factors**

Testing social cognitive factors as potential mediators of intervention efficacy may provide insights into some of the underlying mechanisms of behaviour change, as observed in previous health behaviour interventions [73]. Constructs from Social Cognitive Theory [29] will be assessed using partially modified items from previously developed scales, with distinct items per behaviour relating to the person's projections towards the occurrence of each behaviour *over the next three months*. The constructs of interest include self-efficacy, perceived behavioural capability, outcome expectations and expectancies, goals, action planning and sociostructural factors including social support and the environment. Items are described in more detail below and Table 5.4 summarises the number of items per behaviour per construct and lists response options for each item.

# 5.7.2 Physical Activity Items

For physical activity, a total of 34 items will be used to assess the social cognitive factors and a sum score will be calculated for each construct. Prior to asking these questions, participants will be advised that, in the context of these questions, "regular physical activity is defined as doing at least 150 minutes of moderate intensity physical activity each week. Moderate intensity can be described as any type of aerobic activity performed at a level where a person begins to lightly sweat, but can still carry on a conversation. This may feel different from one person to another."

# Self-efficacy

Self-efficacy levels in the context of barriers will be assessed using a modified version of validated measures [74] consisting of 10 items. Response choices for these items range from not *at all confident* (0) to *extremely confident* (4) and items share the same stem ("I am confident that I can participate in regular physical activity..."), followed by situations or circumstances that may impede regular engagement in physical activity (i.e., "when I am a little tired, I am in a bad mood or feeling depressed, I have to do it by myself, it becomes boring, I can't notice any improvements in my fitness, I have many other demands on my time, I feel a little stiff and sore, the weather is bad, I have to get up early, even on weekends, I am on vacation").

# Behavioural capability

Participants will be asked how confident they are about having the capability to engage in specific amounts and intensities of physical activity, using three statements [75] and response options from *never* (0) to *always* (4). An example statement is "I can run or jog for 10 minutes without stopping".

## **Outcome expectations and expectancies**

Using five items per construct, a total of 10 items will assess participants' expectations and expectancies pertaining to perceived personal gains (outcome expectations) from engaging in regular physical activity, followed by the level of importance associated with these gains (outcome expectancies). On a five-point Likert scale (*strongly disagree* to *strongly agree*), participants will be asked first to indicate their level of agreement with one of five statements (adapted from Dewar et al. [76]) relating to perceived benefits of regular engagement in physical activity (e.g., "Being physically active can reduce my risk for some illnesses and diseases (e.g., heart disease, diabetes, some cancers, etc.).") and then rate the value this would have for themselves (e.g., "How important is [e.g., reducing your risk for illness and disease?]") on a four-point Likert-type scale (*not at all important* to *extremely important*). One sum score will be calculated for outcome expectations and one for outcome expectancies.

### Social support

The role a person's social network plays in influencing physical activity participation will be assessed by asking participants about their level of agreement (on a seven-point scale from *strongly disagree* (0) to *strongly agree* (6) with two items that were previously modified for use in the context of a physical activity intervention [77]: "People in my social network are likely to help me participate in regular physical activity" and "I feel that someone in my social network will provide me with the support I need to get regular physical activity".

### Environment

The impact a person's built and natural environment has on physical activity engagement will be measured using three items from the IPAQ environmental module [78] that are answered on a five-point Likert scale. This scale has shown acceptable levels of reliability, with intra-class correlations ranging from 0.36 to 0.98. The three items are "There are sidewalks on most of the streets in my local area", "There are many interesting things to look at while walking my local area" and "My local area has several free or low-cost recreation facilities, such as parks, walking trails, biking paths, playgrounds, and recreation centres". Higher total scores correspond with an environment that facilitates physical activity, whereas lower scores indicate environmental impediments that may have a negative influence on physical activity levels.

### Goals

To further assess the motivational mechanisms that drive progress towards goal attainment [29], participants will be asked to indicate the extent to which they intend to be active on a regular basis using two adapted items, "Do you intend to do regular physical activity over the next 3 months?" [76] and "How motivated are you to do regular physical activity over the next 3 months?" [79] that are answered using seven-point Likert-type response choices ranging from *no, not really* (0) to *strongly intend* (6) and *not at all motivated* (0) to *extremely motivated* (6) respectively. For both items, higher scores indicate greater strength of goals and the two scores will be summed to obtain a total score for goals.

### Planning

Plans concerning "when", "where", "how" and "what kind" of physical activity participants will engage in will be assessed using a previously modified scale [80] that consists of four respectively worded items, where higher scores are interpreted as more detailed planning (*no plans* (0) to *detailed plans* (6)).

### 5.7.3 Sleep Hygiene Items

To assess the same constructs as above in the context of sleep hygiene practice, a total of 72 items were developed using partially modified scales previously used to assess social cognitive factors in the context of other health behaviours (i.e., physical activity, diet) [74,76]. Each scale will query each of the following nine sleep hygiene practices: (1) avoiding caffeinated beverages (coffee, tea, energy drinks, etc.) in the late afternoon or right before bedtime, (2) avoiding nicotine right before bedtime, (3) avoiding alcohol right before bedtime, (4) exercising regularly, (5) reducing stress levels, (6) reducing the impact of noise and nuisance in the bedroom, (7) keeping sleep and wake times consistent, (8) avoiding daytime naps and (9) avoiding the use of technological devices (e.g., phone, TV, laptop, etc.) right before bedtime or in bed. To avoid overburdening participants, each construct will be assessed using a single item per sleep hygiene behaviour. Thus, each social cognitive construct will have nine items. Each construct will be scored as the sum of the nine sleep hygiene items, with a higher sum score indicating improvement. The environment construct, however, will not be included for sleep hygiene behaviours,

as this is already captured as part of the perceived neighbourhood disorder questionnaire described below.

# Self-efficacy

Items assessing self-efficacy relating to sleep hygiene will be answered on a five-point Likert-type scale (*not at all confident* to *extremely confident*) using the commonly used stem "I can..." [81] in connection with each of the nine sleep hygiene behaviours (e.g., "avoid alcohol right before bedtime", "reduce the impact of noise and nuisance in my bedroom", etc.).

# Behavioural capability

Participants will be asked to rate (*never* (0) to *always* (4)) their perceived behavioural capability to make various choices in favour of keeping good sleep health using "Whenever I have the opportunity to…" as a stem. For example, "Whenever I have the opportunity to use technological devices right before bedtime or in bed, I know how to avoid or remove them". These items were adapted from previously used scales [76] with a focus on situations that challenge the reinforcement of making healthy dietary choices. In the context of avoiding behaviours that do not promote good sleep health, behavioural capability can be thought of as a function of inhibitory control [82].

## **Outcome expectations and expectancies**

Similar to the scales described above for physical activity, those for sleep hygiene will be built on two single stems per sleep hygiene behaviour adapted from previous studies: "For me, [e.g., keeping consistent sleep and wake times] would help me sleep better" [74] and "How important is it to [e.g., keep sleep and wake times consistent] to sleep well?" [76]. The outcome expectations items are answered on a seven-point Likert scale and the outcome expectancies items are answered on a four-point scale ranging from *not at all important* (0) to *extremely important* (3). Sum scores will be reported separately for each of the two constructs.

## Social support

To assess social support as a sociostructural factor that may or may not have a facilitating effect on sleep hygiene practice, the commonly used stem "Most people who are

important to me would encourage me to [e.g., reduce my stress levels]" [79,82] will be used with response choices ranging from *strongly disagree* (0) to *strongly agree* (4)".

## Goals

The extent to which people "intend to…" practice sleep hygiene behaviours will be measured using a seven-point Likert-type scale (from *no, not really* to *strongly intend*), with higher scores indicating stronger goals. This item was used previously in a sleep hygiene context [82].

# Planning

To test participants' plans with regards to practising good sleep hygiene, each of the nine items assessing this construct will ask if a person has planned "where, when and how" to avoid caffeine, avoid nicotine, avoid alcohol, exercise regularly, reduce their stress levels, minimise the impact of noise and nuisance in their bedroom, keep their sleep and wake times consistent, avoid daytime naps and avoid using technological devices right before bedtime or in bed. While previous studies [80] have used four separate items to assess planning to engage in the behaviour ("when", "where", "how" and "what kind" of behaviour), these were collapsed into one item per sleep hygiene behaviour to reduce response burden.

Table 5.4

Construct	Items	Response anchors
Physical Activity		
Self-efficacy	10	<ul><li>(0) not at all confident</li><li>(4) extremely confident</li></ul>
Perceived behavioural capability	3	(0) never (4) always
Outcome expectations	5	<ul><li>(0) strongly disagree</li><li>(6) strongly agree</li></ul>
Outcome expectancies	5	<ul><li>(0) not at all important</li><li>(3) extremely important</li></ul>
Environment	3	<ul><li>(0) strongly disagree</li><li>(4) strongly agree</li></ul>
Social support	2	<ul><li>(0) strongly disagree</li><li>(4) strongly agree</li></ul>
Goals	2	<ul><li>(0) no, not really</li><li>(6) strongly intend; and</li><li>(0) not at all motivated</li><li>(6) extremely motivated</li></ul>
Action planning	4	<ul><li>(0) no detailed plans</li><li>(6) detailed plans</li></ul>
Sleep Hygiene Behaviours		
Self-efficacy	9	<ul><li>(0) not at all confident</li><li>(4) extremely confident</li></ul>
Perceived behavioural capability	9	<ul><li>(0) never</li><li>(4) always</li></ul>
Outcome expectations	9	<ul><li>(0) strongly disagree</li><li>(6) strongly agree</li></ul>
Outcome expectancies	9	<ul><li>(0) not at all important</li><li>(3) extremely important</li></ul>
Environment	9	<ul><li>(0) strongly disagree</li><li>(4) strongly agree</li></ul>
Social support	9	<ul><li>(0) strongly disagree</li><li>(4) strongly agree</li></ul>
Goals	9	<ul><li>(0) no, not really</li><li>(6) strongly intend</li></ul>
Action planning	9	<ul><li>(0) no detailed plans</li><li>(6) detailed plans</li></ul>

Social cognitive factors related to physical activity and sleep hygiene behaviours

Note. Each item per construct will refer to one of nine different sleep hygiene behaviours

### 5.7.4 Automaticity

Habits relating to lifestyle behaviours are non-conscious processes, which can act as determinants of behaviour and may even regulate behaviour independently of changes in conscious processes such as implementation intentions (goals) [83]. The role behavioural automaticity plays in the context of physical activity and sleep behaviours respectively will be taken into account using one item from the Automaticity Index per sleep hygiene behaviour (nine items) [84] and all four items of the index relating to physical activity (13 items in total) – for example, "Reducing the impact of noise in my bedroom is something I do automatically", "Exercise is something I do without thinking".

#### 5.7.5 Sleep hygiene

Sleep hygiene will be assessed to measure changes in in sleep hygiene behaviour using the 13-item Sleep Hygiene Index (SHI) developed by Mastin et al. [85]. Higher global scores indicate poorer sleep hygiene behaviour, but there is no cut-off to label categories of sleep hygiene engagement. This instrument demonstrates acceptable internal consistency ( $\alpha = 0.66$ ) and test-retest reliability (r = 0.71, p < 0.01) [85]. Importantly, the SHI shows positive correlations (r = 0.48) with both the global scores (p < 0.01) and the component scores (p < 0.05 or less) of the Pittsburgh Sleep Quality Index [85]. Items are answered using a five-point Likert scale from *never* (0) to *always* (4).

#### 5.7.6 Environment

Perceptions about the order or disorder within a person's physical and/or social environment (i.e., neighbourhood peacefulness, safety, cleanliness) can have a significant influence on physical activity levels and the quality and duration of sleep [86–88]. A person's neighbourhood environment can also negatively affect mental health and participation in other health behaviours [89]. Based on an existing scale of neighbourhood disorder, which demonstrated good levels of construct validity and internal consistency/reliability [90], four items will assess each of the following characteristics of neighbourhood disorder: *physical disorder* and *physical order*, *social disorder* and *social order*. These are assessed using the following items: (1) "My neighbourhood is noisy", (2) "My neighbourhood is clean", (3) "There is a lot of crime in my neighbourhood" and (4) "My neighbourhood is safe". These items will be answered on a five-point scale from

*strongly disagree* (1) to *strongly agree* (5) and the average responses across the four items will be calculated.

### 5.7.7 Sample characteristics

A range of demographic and socioeconomic factors such as age, gender, height and weight, education, income, marital status, occupation, working hours, etc. will be assessed. Participants will be asked to also indicate (allowing multiple selection) whether they have been told by a doctor that they have any of the following chronic diseases: arthritis, asthma, cancer, cerebrovascular disease (stroke), chronic obstructive pulmonary disease (emphysema), coronary heart disease (heart attack, angina), type-1 diabetes, type-2 diabetes, high blood pressure, kidney disease, mental illness (depression, anxiety, etc.), osteoporosis, irritable bowel syndrome, high cholesterol, or any other disease (to be specified by the participant). In addition, participants will be assessed for *morningness* or *eveningness* type [91] as eveningness types are thought to be more prone to engage in activities that cause social jetlag, due to misalignments between times of sleep and times of social activity [92].

# 5.8 Power and sample size

Meta-analyses of physical activity interventions typically report small to moderate increases in physical activity (Cohen's d = 0.14 - 0.68) [93,94]. Moreover, poor sleep health – specifically, the duration or quality of sleep – has small to moderate magnitude associations with lower physical activity levels [95]. Meta-analyses of nonpharmacological sleep interventions report small to medium effect sizes for changes in sleep quality (Hedge's g = 0.35 and Cohen's d = 0.41) in clinical populations [96,97] and medium to large effect sizes (d = 0.74) in studies using exercise to improve sleep [98]. Therefore, based on these observations and feasibility data from a previous study [38] it was assumed that a three-month combined physical activity and sleep intervention that specifically targets behaviours and leverages the bi-directional relationship between behaviours is likely to produce moderate increases in physical activity (d = 0.45) and moderate to large increases in sleep quality (d = 0.65). Pre-post correlations were based on preliminary data taken from a trial targeting and measuring changes in physical activity and sleep [38], which showed correlations of r = 0.57 and r = 0.60 for physical activity and sleep quality respectively; therefore, a pre-post correlation of 0.60 was assumed in the current study. Assuming an alpha of 0.025 (due to measuring two primary outcomes; MVPA and sleep quality), power of 0.80, a moderate effect size (d = 0.45 for physical activity; d = 0.65 for sleep) and a pre-post correlation of 0.60, a total of 60 participants per group will be required for physical activity and 35 per group for sleep quality, the larger sample of which will be used.

Meta-analyses of physical activity and sleep interventions report average drop-out rates of 20% [94,96]; however, the majority of web-based trials report drop-out rates higher than that [93]. As there is insufficient information available on attrition in m-health interventions, the sample size for this study will be inflated to account for a 25% drop-out. Therefore, the total sample size is 80 participants per group, or 160 in total. A sample of this size will also be adequately powered to detect mediated effect sizes of small ( $\beta = 0.14$ ) magnitude [99]. The participant recruitment phase will conclude once 160 complete baseline responses have been obtained.

# **5.9** Analyses

Analyses will apply the *intention-to-treat* principle. Analysis of primary outcomes will be blinded to group allocation and overseen by an independent statistician. The primary aim of this study will be to examine differences in physical activity and sleep quality between the intervention group and the control group at the three-month primary time point. Between-group differences in physical activity (AAQ minutes) and sleep quality (PSQI) will be estimated using Generalised Linear Mixed Models (GLMM) adjusting for baseline measures of the outcome, including all available data in the analysis. The model will include fixed effects for group, time and their interaction. A random intercept will be used to account for repeated measures on individuals. Separate GLMM will be used to examine changes in physical activity and sleep.

Sensitivity analyses using Pattern Mixture Modelling will be conducted to examine the impact of missing data on outcomes. Where the GLMM assumes data are missing at random, Pattern Mixture Modelling is robust to the assumed pattern of missing data. Group differences in secondary outcome measures will be estimated using the same linear mixed modelling approach, setting an alpha of 0.025 for each outcome. Potential mediators and moderators of intervention efficacy will be examined using established

approaches [100]. Generalised linear mixed models and survival analysis will be used to examine differences in usage patterns.

# 5.10 Ethics and dissemination

Any type of adverse events reported by study participants that occurred in relation to their participation in the study will be recorded and reported to the HREC. This may include events reported by participants, including musculoskeletal injuries associated with the uptake or increase in physical activity or emotional distress due to any survey items of sensitive nature. Great care will be taken to avoid and prevent adverse events and the research team will provide every possible assistance to remediate those events, should they occur. The participant information statement, to which interested individuals will have access to prior to consenting to participate, details any potential risks of discomfort associated with participation in the study and provides contact details and information of national support services (e.g., Black Dog Institute, Lifeline, etc.).

Survey data will be exported directly from Qualtrics as a text file and imported in electronic form for scoring and analysis using statistics software. A detailed database will track participants' progress through the trial, including the scheduling of assessments and reminders to complete assessments. Intervention usage will be monitored throughout the trial by BM and MJD by way of the password-protected app database. Given the purpose of the trial, the data to be collected and the nature of the intervention, no Data Monitoring Committee will be established. Detailed strategies, including email/text message reminders, will be used to remind participants about upcoming assessments. All Newcastle-based members of the research team (BM, MJD, ATR, RCP) and other associated personnel will have access to the information in both identified and reidentifiable forms. Should statistical analysis advice be sought, access to the data will be granted in re-identifiable form using unique numerical identifiers and access approved by the relevant Ethics Committee.

Print data will be stored in locked filing cabinets accessible only to the research team. Electronic data will be stored on password-protected computers or servers accessible only to the research team. Data will be retained for 15 years in accordance with section 3.1.1 of the *Australian Code for the Responsible Conduct of Research* and all (paper and

electronic) records will be disposed of in accordance with the requirements of the *Australian Code for the Responsible Conduct of Research*.

Results from the outcome measures will not be presented in a way that adversely affects the confidentiality of participants. The description of participants will not allow identification of individual participants, and individual results and individual names will not be revealed. Final reports and publications will only consist of aggregated results. At the completion of the study, participants will receive a plain English summary of study results. Scientific reports of the main outcomes, secondary outcomes and process evaluation will be submitted to peer-reviewed journals. Results will also be incorporated into student theses and presented at national and international conferences.

# 5.11 Discussion

It is advised that adults accumulate a weekly minimum of 150 minutes of moderate intensity physical activity, combined with muscle strengthening activities on two days per week [7], and also achieve seven to nine hours of good quality sleep each night [101]. Engaging in the recommended levels of physical activity and maintaining good sleep health contributes to overall health and well-being through risk reductions associated with chronic diseases such as heart disease and type-2 diabetes [3-6]. Engaging in optimal levels of physical activity and sleep health can also positively contribute to long-term weight management, mental health and overall quality of life [102-104]. Notwithstanding this wide spectrum of benefits, a large proportion of the population does not accumulate sufficient physical activity and/or achieve optimal sleep.

Wide-reaching behavioural programmes, such as those offered through m-health interventions, have the potential to elicit the much needed shift of relatively large groups of the population toward levels of physical activity and sleep that meet recommendations [105]. Multiple behaviour interventions are effective at changing health behaviours [19] and, while m-health interventions as such have been shown to effectively improve physical activity and sleep health as individual behaviours [106,107], there is additional evidence from website-based interventions supporting the efficacy of remotely delivered interventions targeting multiple behaviours in combination [108,109]. To yield positive changes in health behaviour, such interventions need to include educational information, incorporate behaviour change techniques and deliver a level of guidance that endorses

the initiation and maintenance of health behaviour change [29,110]. Systematic reviews of the effectiveness of multiple health behaviour interventions suggest that those targeting related behaviours (e.g., diet and physical activity) produced greater behaviour change than those targeting unrelated behaviours (e.g., smoking and physical activity) [111] and that specific intervention techniques are necessary for each behaviour [26]. Physical activity and sleep are suggested to have a bi-directional relationship [16], yet no previous RCT has combined physical activity and sleep in one intervention and, therefore, none has utilised the synergistic relationship between physical activity and sleep. The Synergy Study addresses this by targeting physical activity and sleep simultaneously, using specific intervention techniques to enhance participants' self-regulatory skills in relation to the two health behaviours; it thus leverages the potential for synergistic improvements in both behaviours. An advantage of this study lies in its mode of delivery, which involves mobile technology and therefore blends into day-to-day life. A key intervention strategy is the use of goal-setting and feedback to promote behaviour change. It seeks to achieve this through the promotion of dynamic goals and action plans, while the implementation of a personalised support system further addresses potential barriers (i.e., low levels of self-efficacy) that can increase the gap between participant intentions (goals and plans) and behavioural outcomes [112] and contributes to long-term behaviour maintenance. This includes knowledge of how to set attainable goals and having strategies in place that facilitate the occurrence of healthy behaviours, despite challenging situations or unfavourable environmental factors [29]. The structured promotion of goal-setting strategies, combined with action plans that define in detail how an individual will implement the intended behaviour, is known to be effective in changing health behaviours [110].

Additional strengths of this study include its randomised waitlist controlled study design, which will allow inferences about the causal links between the intervention and changes in behaviour. The use of remote delivery through an m-health format makes it possible to recruit nationwide and has the potential to be scaled up further, including an international version of the programme. Delivering the Synergy Study in multiple countries, however, would require further refinement of the contents and adaptation to cross-cultural factors and geographical differences. While the first aim of this study is to test the intervention's efficacy to produce changes in two co-primary outcomes, the pre-specified secondary outcomes (mental health, quality of life) will give insight into changes in

parameters of health and well-being that may be very meaningful to the participant. And, finally, this study will generate knowledge on social cognitive determinants of behaviour change relating to sleep health and explore how these factors differ between physical activity and sleep. This will enhance the understanding of underlying mechanisms associated with successful behaviour change in both behaviours and also further the application of social cognitive theories in the multi-health behaviour context. The limitations of this study include the study duration, which, although at six months is longer than many studies [93], does not provide insight into longer-term changes and behaviour maintenance; and the lack of a comparator condition receiving only the sleep or the physical activity programme to determine the magnitude each intervention component has on its own. It is beyond the scope of this study to test long-term efficacy exceeding six months, but future trials may be encouraged to do this, provided the Synergy Study proves efficacious in the short term with indications of effect retention at the six-month time point.

# 5.12 Conclusion

This study protocol provides the rationale and methods associated with the implementation and evaluation of the Synergy Study, a theory-based m-health intervention including personalised support, with the aim of improving physical activity and sleep health in Australian adults. To the authors' knowledge, this study will be the first to simultaneously target changes in these two behaviours, using a sophisticated combination of technologies and evidence-based strategies and test the efficacy of this approach in a randomised controlled trial. Findings from this trial will provide valuable knowledge pertaining to the design of m-health interventions that combine behaviours in a format with wide reach.

# **References – Chapter 5**

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# CHAPTER 6. EFFICACY OF AN M-HEALTH PHYSICAL ACTIVITY AND SLEEP HEALTH INTERVENTION FOR ADULTS: A RANDOMISED WAITLIST-CONTROLLED TRIAL

The Synergy Study was conducted to address the Primary Aim of this thesis. Chapter 6 presents the empirical evaluation of the trial, the rationale, development and methods of which were described in Chapter 5. This chapter contains the peer-reviewed manuscript, which was published in the American Journal of Preventive Medicine.

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# 6.1 Abstract

Few studies target physical activity and sleep in combination. The purpose of the Synergy Study is to test the efficacy of an m-health intervention targeting physical activity and sleep quality. This randomised, waitlist-controlled trial was conducted nationwide using an app-based delivery mode and included 160 adults who reported insufficient physical activity and poor sleep quality in an eligibility survey. The intervention was a mobile app providing educational resources, goal-setting, self-monitoring, and feedback strategies. It included 12 weeks of personalised support including weekly reports, tool sheets and prompts. Outcomes were assessed at baseline, three months (primary) and six months (secondary endpoint). Self-reported minutes of moderate- to vigorous-intensity physical activity and sleep quality were co-primary outcomes. Resistance training, sitting time, sleep hygiene, sleep timing variability, insomnia severity, daytime sleepiness, quality of life, and depression, anxiety and stress symptoms were secondary outcomes. Data were collected between June 2017 and February 2018 and analysed in August 2018. At three months, between-group differences in moderate- to vigorous-intensity physical activity were not statistically significant (p = 0.139). Significantly more participants in the intervention group engaged in  $\geq 2$  days/week (p = 0.004) of resistance training. The intervention group reported better overall sleep quality (p = 0.009), subjective sleep quality (p = 0.017), sleep onset latency (p = 0.013), waketime variability (p = 0.018),

sleep hygiene (p = 0.027), insomnia severity (p = 0.002), and lower stress symptoms (p = 0.032) relative to waitlist controls. At six months, group differences were maintained for sleep hygiene (p = 0.048), insomnia severity (p = 0.002), and stress symptoms (p = 0.006). Differences were observed for bedtime variability (p = 0.023), sleepiness (p < 0.001), daytime dysfunction (p = 0.039) and anxiety symptoms (p = 0.003) at six months, but not three months. This remotely delivered intervention did not produce statistically significant between-group differences in minutes of moderate- to vigorous-intensity physical activity. Significant short-term differences in resistance training and short- and medium-term differences in sleep health in favour of the intervention were observed.

# **6.2 Introduction**

A large proportion of the adult population is insufficiently active [1] and also reports poor sleep health [2-5]. Accruing <150 minutes/week of physical activity (PA) is considered insufficient [6], and poor sleep health is characterised by the presence of one or multiple complaints relating to the duration, quality or timing of sleep and daytime functioning [7]. The two behaviours are separately associated with increased risk of chronic disease (e.g., cardiovascular disease, Type-2 diabetes) and considerable economic burden [8–14].

Given the high prevalence and associated burden of insufficient PA and poor sleep health in adults [15], wide-reaching interventions for PA and sleep health are needed. M-health interventions have the capacity to deliver accessible, scalable and cost-effective interventions [16], and are known to improve PA [17], and reduce the severity of clinical sleep complaints [18]. A meta-analysis of sleep interventions administered to adults without clinical sleep complaints reported that interventions were effective (Hedge's g =0.54), yet few were delivered using m-health [19]. Behaviour change interventions, which implement evidence-based strategies that conceptually align with theoretic frameworks, are thought to be more effective than those not informed by theory [20]. This is particularly important when multiple behaviours are combined in one intervention [21]. Further, given that both PA and sleep are influenced by individual and environmental factors, it is useful for interventions to be guided by a theory that acknowledges this relationship. Insufficient PA and poor sleep tend to co-occur [15], and there is evidence that PA and sleep share a bi-directional relationship [22-24]. Consequently, interventions targeting PA and sleep concurrently may yield larger improvements in both behaviours and produce greater health benefits than single-behaviour interventions [25]. However, it appears that no previous m-health studies have addressed PA and sleep health simultaneously [26,27].

This study aimed to test the efficacy of a novel m-health intervention to improve PA and sleep health in a randomised waitlist-controlled trial.

# 6.3 Methods

Prospective registration occurred through the Australian New Zealand Clinical Trials Registry (ACTRN12617000376347 (Appendix P)). The Human Research Ethics Committee, University of Newcastle, Australia (H-2016-0181 (Appendix B)) granted ethical approval. Data were collected between June 2017 and February 2018. Trial design, methods and measures are detailed elsewhere [28].

### **6.3.1 Study population**

In June–August 2017, social media (Facebook) advertisements (Appendix D), lifestyle magazine editorials (Appendix E) and eNewsletters invited interested individuals to take part (a web link directed interested individuals to the information and consent forms for this study; Appendices F and G). Participants were eligible if they were aged 18 to 55 years; lived in Australia; reported being insufficiently physically active (<90 minutes/week); and rated their sleep quality as *fairly bad* or *very bad* during screening. Exclusion criteria were a body mass index (BMI) <18.5 or >35, recent pregnancy or childbirth (<12 months), any contraindications for being more physically active or changing sleep behaviours, diagnosed sleep disorders (chronic insomnia, sleep apnoea), hypnotics use, shift-work, frequent jetlag-inducing travel, current use of an app/tracker to self-monitor PA and/or sleep, and no access to an internet-enabled device (smartphone or tablet). Participants who consented were re-directed to the eligibility screening survey (Appendix Q). Following completion of baseline assessments, participants (N = 160) were randomly allocated to the intervention or a waitlist-control group (1:1 ratio). The concealed allocation sequence (numbered opaque envelopes) was generated according to recommended methods for permuted randomisation using blocks of four and eight [29].

### 6.3.2 Intervention

The intervention group (n = 80) received access to the *Balanced* app [28,30], which provided a platform for personalised goal setting, daily logging with dynamic feedback and comprehensive educational content for PA (i.e., moderate- to vigorous-intensity physical activity, daily steps, resistance training [RT]) and for sleep (i.e., bedtimes/waketimes, sleep quality, sleep hygiene practices). Participants received a series of tool sheets (printed materials via mail, followed up with an electronic copy once/month) that was emailed to participants providing guidance on how to set goals, develop action plans and manage stress (Appendix R). During the three-month intervention period, participants were emailed individualised weekly summary reports based on progress in relation to goals (for both behaviours) (Appendix T), as well as weekly SMS (Appendix U) including educational content and separate SMS prompts to re-engage with self-monitoring, if necessary (i.e., self-monitoring on <4 days in the last seven days). The behaviour change strategies used as per alignment with the theoretical framework (i.e., Social Cognitive Theory) were described in the published study protocol [28] and are summarised in Table 6.S1. Following randomisation, participants were mailed a printed handbook including hardcopies of the tool sheets (Appendices R and S) and guidance specific to the initial stages of app installation, usage and troubleshooting, and a pedometer (Yamax SW200) to monitor steps. Waitlist participants (n = 80) were offered full access to the intervention after the six-month assessment.

### 6.3.3 Measures

Sociodemographic and behavioural variables were assessed at baseline (Appendix H). The primary endpoint occurred at three months and the secondary endpoint at six months. Two co-primary and 21 secondary outcomes were assessed at all three time points (baseline, three months and six months). All data were collected via online survey between June 2017 and February 2018. One of the two co-primary outcome was weekly minutes of moderate-to-vigorous physical activity (MVPA) that was assessed using the Active Australia Questionnaire [31], which is reliable and sensitive to change [32.33]. Sleep quality, which was the other co-primary outcome, was assessed using the Pittsburgh Sleep Quality Index (PSQI), which has also shown good reliability and sensitivity to change in intervention studies [34.35]. Secondary outcomes included the seven PSQI component scores, RT (frequency and duration/week) [36], minutes/day of sitting

(Workforce Sitting Questionnaire) [37], sleep hygiene practices (Sleep Hygiene Index) [38], sleep timing variability (Sleep Timing Questionnaire) [39], insomnia symptom severity (Insomnia Severity Index) [40], daytime sleepiness (Epworth Sleepiness Scale) [41], health-related quality of life (RAND-12) [42], the energy/fatigue subscale of the RAND-36 [43], as well as depression, anxiety and stress symptoms (DASS-21) [44]. To measure engagement, the self-monitoring data participants logged in the Balanced app (defined as logged data on a given day for any of the following: active time, steps, RT, sleep duration, sleep quality, sleep hygiene) were exported to calculate the average number of days for which data were logged and the time to non-usage attrition (defined as  $\geq 14$  consecutive days of non-engagement at any given point within a person's 84-day intervention period), as previously used [45]. Participant satisfaction with the app was assessed using the System Usability Scale (scores ranged from 0 to 100 with higher scores indicating greater satisfaction) at three months only [46]. The outcomes assessed and instruments used in this study are described elsewhere [28]. Process evaluation items (intervention group only) are listed in Appendix W).

#### 6.3.4 Power and sample size

Assuming an  $\alpha$  of 0.025 (adjusting for use of two co-primary outcomes), power of 0.80, moderate effects at the three-months primary endpoint (d = 0.45; mean = 88 minutes; SD 194 minutes for PA; and d = 0.65; mean 1.55; SD 2.41 for sleep quality, where d = Cohen's d [47], M = mean value, and SD = standard deviation of the mean) and a prepost correlation of 0.60 (between baseline and three months), a total of 60 participants per group were required for PA and 35 for sleep quality. Thus, the larger sample was used for this study. To account for dropout, the sample size was inflated by 25 per cent (i.e., (60/[1–0.25]), resulting in 80 participants needed per group [48].

#### 6.3.5 Statistical analysis

Differences in sample characteristics (e.g., age, gender, baseline levels of PA and sleep quality) between completers and non-completers (lost to follow-up) were examined using t-tests (continuous data) and chi-square tests (categorical data).

Between-group differences at three and six months were estimated using generalised linear mixed models (GLMMs), except for PSQI component scores (mixed-effects ordered logistic regression). Owing to positive skewness in the data, both resistance training (RT) outcomes were analysed as dichotomised outcomes (with RT frequency dichotomised as <2 days/week or  $\geq$ 2 days/week, as per guidelines [6]; and RT duration dichotomised as less than 10 minutes/week or  $\geq$ 10 minutes/week). All models included fixed effects for group and time, group x time interaction and the baseline value of the outcome, and a random intercept for individuals. White-Huber standard errors were used if departures of homoscedasticity or normality were observed [49]. Residual diagnostics informed the specification of family and link functions (Tables 3.2, 3.3 and supplementary Tables 3.S2 and 3.S3). Models were interpreted using  $\alpha$  levels of 0.025 for co-primary outcomes and 0.05 for secondary outcomes.

The impact of missing data was assessed using sensitivity analyses. Missing data were imputed using chained equations and predicted mean matching. Twenty datasets were imputed, using baseline values of the outcome, predictors of missingness and any variables that predicted a given outcome. The models specified for complete-case analyses were repeated using pooled estimates derived from imputed datasets and coefficients compared for consistency, with little deviation from complete-case analyses indicating robustness of findings.

Secondary analyses using generalised linear mixed models with a binomial logit link function were conducted to examine the proportion of participants meeting guidelines for PA ( $\geq$ 150 minutes of MVPA combined with RT on  $\geq$ 2 days/week) [6], and reporting good sleep (PSQI total score <5) [34]. Data were analysed in August 2018 using Stata, version 14.2 (StataCorp LLC, College Station, Texas).

# 6.4 Results<sup>4</sup>

The flow of participants throughout the trial is shown in Figure 6.S1. The baseline sample included 128 women and 32 men, most of whom were middle-aged and overweight. The majority were married or in a relationship, highly educated, employed in a professional occupation and reported having one or more chronic conditions. Table 6.S2 provides sociodemographic, health, and behavioural characteristics per group. The distribution of participants across Australia is illustrated in Appendix X.

<sup>&</sup>lt;sup>4</sup> At the end of the study, participants were emailed a plain English summary report (Appendix Y).

Groups did not differ in the proportion of withdrawals (p = 0.181). Participants who were lost to follow-up reported more severe depression symptoms (p = 0.035) and lower mental health (p = 0.012). Complete data (primary outcomes) from 125 participants were available at the three-month primary endpoint, which corresponds to overall retention of 78 per cent. Participant retention at the six-month follow-up was 56 per cent. Dropout rates (defined as formal withdrawal from the trial) were nine per cent in both groups. Reasons for withdrawal are listed in Figure 6.S1.

### 6.4.1 Adherence and participant satisfaction

Throughout the 84-day intervention period, participants (intervention group only) logged data for at least one of the two behaviours on an average of 38.2 (SD = 30.09) days. Ten per cent of participants did not log any data during this period. Non-usage attrition occurred for 89 per cent of participants. The average number of days to non-usage attrition was 32 (SD = 25). The average number of days on which data were logged and the proportion of participants logging no data did not differ between PA (36 days and 12.5 per cent, respectively) and sleep (37 days and 10 per cent, respectively). Intervention group participants (n = 58; assessed at three months) reported good usability and acceptance, consistent with a mean system usability score of 70.8 (SD = 19.71) [46].

#### Table 6.1

Marginalised mean estimates (M (SD)) and results from tests of between-group differences for continuous outcomes using complete cases.

	Three months*				Six months**			
Outcomes	IG	WLG	p d*		IG	WLG	р	<i>d</i> *
Co-primary Outcomes								
MVPA minutes/week <sup>a†</sup>	428.4 (523.41)	319.7 (378.23)	0.139	0.24	405.3 (491.45)	400.2 (497.80)	0.952	0.01
Sleep quality (PSQI) <sup>b</sup>	6.7 (3.04)	8.0 (2.34)	0.009	0.48	6.3 (2.98)	7.5 (2.57)	0.040	0.46
Secondary Outcomes								
Sitting minutes <sup>b</sup>	612.3 (160.91)	653.7 (202.12)	0.205	0.22	579.7 (187.83)	581.7 (197.27)	0.960	0.01
Bedtime variability <sup>a</sup>	3.6 (1.70)	4.1 (2.10)	0.171	0.24	3.4 (1.46)	4.2 (1.92)	0.023	0.47
Waketime variability <sup>a</sup>	2.5 (1.84)	3.0 (1.95)	0.018	0.40	2.6 (1.06)	3.0 (1.92)	0.236	0.22
Sleep hygiene <sup>b</sup>	30.0 (4.27)	31.6 (3.98)	0.027	0.40	30.6 (4.33)	32.8 (6.02)	0.048	0.42
Insomnia severity <sup>b</sup>	9.3 (3.80)	11.3 (3.50)	0.002	0.56	8.5 (4.23)	11.4 (4.11)	0.002	0.69
Daytime sleepiness <sup>c</sup>	7.1 (3.44)	8.0 (3.31)	0.103	0.29	5.7 (2.92)	8.4 (3.98)	<0.001	0.74
Depression symptoms <sup>a†</sup>	10.6 (7.62)	12.6 (7.97)	0.120	0.26	10.9 (8.01)	13.3 (9.49)	0.190	0.27
Anxiety symptoms <sup>c†</sup>	6.4 (3.65)	7.5 (5.04)	0.148	0.25	5.9 (3.54)	8.9 (4.70)	0.003	0.57
Stress symptoms <sup>c†</sup>	13.6 (4.20)	15.4 (4.97)	0.032	0.38	13.0 (5.75)	16.3 (5.24)	0.006	0.62
Mental health <sup>b</sup>	44.4 (6.81)	44.9 (7.12)	0.689	0.07	47.6 (5.53)	45.0 (8.12)	0.071	0.37
Physical health <sup>b</sup>	47.6 (5.21)	46.8 (5.54)	0.400	0.15	46.5 (4.95)	47.3 (5.14)	0.467	0.16
Energy/fatigue <sup>b</sup>	52.4 (8.29)	53.4 (11.08)	0.541	0.11	54.7 (9.90)	51.1 (11.49)	0.118	0.33

*Note.* IG = intervention group; WLG = waitlist-control group; MVPA = moderate- to vigorous-intensity physical activity; PSQI = Pittsburgh Sleep Quality Index; GLMM = generalised linear mixed model; DASS = Depression Anxiety and Stress Scales; d =Cohen's d (the magnitude of effects is interpreted as small (0.2), medium (0.5) or large (0.80); \* at 3 months, 125 observations (n = 59 in IG; n = 66 in WLG) were available for analyses of MVPA, sleep quality, mental health, physical health and energy/fatigue, and 124 observations (n = 59 in IG; n = 65 in WLG) were available for analyses of all other outcomes; \*\* at 6 months, 89 observations (n = 35 in IG; n

= 54 in WLG) were available for analyses of MVPA, sleep quality, mental health, physical health and energy/fatigue, and 88 observations (n = 34 in IG; n = 53 in WLG) were available for analyses of all other outcomes; <sup>a</sup> analyzed using a GLMM with gamma distribution and log link function; <sup>b</sup> analyzed using a GLMM with gaussian distribution and log link function; <sup>c</sup> analyzed using a GLMM with gaussian distribution and log link function; analyzed using the robust variance estimator; <sup>†</sup> a small positive constant (+1) was added to minutes of MVPA and the DASS-21 scores for the purpose of data analysis and these outcomes are reported with this constant included; boldface indicates statistical significance at p<0.025 for co-primary outcomes and p<0.05 for secondary outcomes.

#### Table 6.2

	Three months*				Six months**			
Outcomes	OR	SE	95% CI	р	OR	SE	95% CI	р
Resistance training on two or more days/week <sup>a</sup>	20.56	21.36	2.69 to 157.46	0.004	1.05	1.35	0.08 to 13.13	0.970
Resistance training for $\geq 10$ minutes/week <sup>a</sup>	6.71	5.09	1.52 to 29.65	0.012	1.84	1.72	0.30 to 11.43	0.511
Subjective sleep quality <sup>b†</sup>	0.36	0.15	0.16 to 0.84	0.017	0.89	0.50	0.29 to 2.68	0.832
Sleep onset latency <sup>b†</sup>	0.27	0.14	0.10 to 0.76	0.013	0.48	0.32	0.13 to 1.74	0.263
Sleep duration <sup>b†</sup>	0.49	0.25	0.18 to 1.32	0.158	0.45	0.29	0.13 to 1.56	0.208
Sleep efficiency <sup>b†</sup>	0.52	0.23	0.21 to 1.25	0.107	0.64	0.33	0.23 to 1.77	0.392
Sleep disturbances <sup>b†</sup>	0.34	0.22	0.10 to 1.18	0.089	0.25	0.20	0.05 to 1.22	0.086
Sleep medication use <sup>b†</sup>	0.47	0.42	0.08 to 2.72	0.402	0.07	0.10	0.00 to 1.19	0.066
Daytime dysfunction <sup>b†</sup>	0.80	0.41	0.29 to 2.19	0.665	0.28	0.17	0.08 to 0.94	0.039

Odds ratios, 95% CI and results from tests of between-group differences for categorical outcomes using complete cases.

*Note.* OR = odds ratio; SE = standard error; CI = confidence interval; IG = intervention group; WLG = waitlist-control group; GLMM = generalised linear mixed model; PSQI = Pittsburgh Sleep Quality Index; \* at 3 months, 125 observations (n = 59 in IG; n = 66 in WLG) were available for analyses; \*\* at 6 months, 89 observations (n = 35 in IG; n = 54 in WLG) were available for analyses <sup>a</sup> odds ratios for resistance training frequency and duration were calculated using GLMMs with binomial distribution, logit link function and robust variance estimator; <sup>b</sup> estimates for the seven PSQI composites represent proportional odds ratios, robust standard errors and 95% CI based on mixed effects ordered logistic regression that tested between-group differences in the likelihood of shifting to another level of the variable (lower PSQI composites indicate better sleep quality, thus OR <1 indicates the intervention group was less likely to move up a level or report worse outcomes for the composites); <sup>†</sup> a small positive constant (+1) was added to PSQI component scores for the purpose of data analysis; boldface indicates statistical significance at *p*<0.05.

#### **6.4.2 Intervention efficacy**

#### Between-group differences in physical activity, resistance training, and sitting time

At three months, the estimated between-group difference in MVPA was 109 minutes in favour of the intervention group, which was not statistically significant (Table 6.1), corresponding to a small effect size (p = 0.139, d = 0.24). At 6 months, this difference reduced to five minutes (p = 0.952, d = 0.01).

The groups showed significant differences in the relative odds of engaging in at least two days of RT per week (OR = 20.56, [95% CI] 2.69 to 157.46, p = 0.004) and  $\ge 10$  minutes of RT/week (OR = 6.71, [95% CI] 1.52 to 29.65, p = 0.012), favouring the intervention at three months, but these were not maintained at six months (Table 6.2). Differences in average sitting time were not statistically significant at either time point (Table 6.1).

#### Between-group differences in sleep health and sleep hygiene behaviour

The between-group difference in average sleep quality (PSQI total score) at three months was -1.3 points, with medium-sized effect estimates showing significantly better sleep quality in the intervention group (p = 0.009, d = 0.48). This difference was slightly attenuated at six months and no longer statistically significant (p = 0.040, d = 0.46). The intervention group was more likely to report improved subjective sleep quality (p = 0.017) and sleep onset latency (p = 0.013) (Table 6.1). Small-to-medium effect sizes in favour of the intervention were found at three months for waketime variability (p = 0.018, d = 0.40), sleep hygiene (p = 0.027, d = 0.40), and insomnia severity (p = 0.002, d = 0.56). At six months, significant differences in favour of the intervention group were maintained for sleep hygiene (p = 0.048, d = 0.42) and insomnia severity (p = 0.002, d = 0.69), with an increase in the magnitude of differences for insomnia severity. Additional significant differences at six months, which were not statistically significant at three months, were observed for bedtime variability (p = 0.023, d = 0.47), daytime sleepiness (p < 0.001, d = 0.74), and daytime dysfunction (OR = 0.28, [95% CI] 0.08 to 0.94, p = 0.039) (Tables 6.1 and 6.2).

### Between-group differences in health-related quality of life and mental health

No significant differences were observed for mental or physical health-related quality of life, energy/fatigue levels, or for depression symptoms, at either time point (all p > 0.05).

The intervention group reported significantly lower stress symptom severity relative to waitlist-controls at three months (p = 0.032, d = 0.38) with an additional increase in magnitude at six months (p = 0.006, d = 0.62). Further, differences in anxiety symptoms at six months were statistically significant, in favour of the intervention group (p = 0.003, d = 0.57).

### 6.4.3 Sensitivity analyses

Results from analyses using imputed data are provided as supplements (Table 6.S3 and Table 6.S4), showing robustness of findings at three months for all outcomes, except for stress symptoms, which was no longer statistically significant (p = 0.078). Group differences in the co-primary outcome of sleep quality (PSQI total score) were statistically significant at six months based on imputed data (p = 0.015). Differences in bedtime variability, sleep hygiene and anxiety measured at six months, which were statistically significant based on complete-case analysis, no longer reached statistical significance (all p > 0.05).

### 6.4.4 Secondary analyses

Secondary analyses using complete cases showed that at three months participants in the intervention group were significantly more likely to meet aerobic exercise and RT guidelines [6], relative to participants in the waitlist-control group (OR = 16.32, [95% CI] 2.24 to 119.00, p = 0.004). This difference was not maintained at six months (OR = 1.05, [95% CI] 0.08 to 13.13, p = 0.970) (Figure 6.S2). The proportion of participants reporting good sleep (Figure 6.S3) was significantly higher in the intervention group relative to the control group at three months (OR = 13.13, [95% CI] 2.94 to 58.64, p = 0.001), but not at six months (OR = 4.47, [95% CI] 0.96 to 20.79, p = 0.056). Results from analyses using imputed data were consistent with these results, except that the proportion of participants reporting good sleep quality at six months (OR = 4.05, [95% CI] 1.11 to 14.75, p = 0.034).

# 6.5 Discussion

The Synergy Study was a combined behaviour m-health intervention that improved sleep quality and a range of secondary outcomes, including RT, sleep time variability, sleep hygiene, subjective sleep quality, sleep onset latency, insomnia severity and symptoms of stress and anxiety. Moreover, participants were more likely to meet guidelines for aerobic PA and RT and report good sleep quality after the three-month intervention.

Although group differences in MVPA were not statistically significant at either endpoint, several promising changes were observed. At three months, the intervention group engaged in an additional 109 minutes/week of MVPA, relative to waitlist control, which is encouraging given that even small improvements in MVPA are beneficial for longterm health [50]. The effect size of this non-significant difference (d=0.24) was consistent with previous meta-analyses of m-health PA interventions [48]. The lack of statistically significant between-group differences in MVPA may have been due to the large variation in activity at all time points and the increased activity reported in the control group, which is commonly observed [51]. Secondary analyses showed a significantly greater proportion of intervention group participants (37.3 per cent) met PA guidelines (≥150 minutes of MVPA and RT on  $\geq 2$  days/week). These improvements may be attributable to the detailed strategies provided for both MVPA and RT, and thus supports their use in multi-behaviour interventions. This finding is relevant from a public health perspective, given that the majority of adults do not engage in RT [52], and only approximately 15 per cent meet guidelines for both MVPA and RT, although this would confer significant reductions for morbidity and mortality [53-55]. However, this outcome should be interpreted with caution, as the analyses of meeting PA guidelines were exploratory. Also, although both minutes of MVPA and frequency of RT increased, the higher proportion of participants meeting PA guidelines at three months appeared to be largely driven by an increased frequency of RT.

A unique contribution of this study is that it assessed sleep quality at three and six months, which is longer than the intervention periods and follow-up intervals of many sleep interventions [56]. The magnitude of the between-group difference in favour of the intervention group at three months is consistent with findings from trials in subclinical population groups [19]. Although sleep quality continued to improve at six months, the difference between groups was no longer statistically significant for complete-case analysis, but was for analysis based on multiple imputation (at  $\alpha = 0.025$ ). Given the observed effect sizes at three months (d = 0.48) and six months (d = 0.46) were consistent, this may have been due to improvements in both groups and the lack of power at the six-

month time point. The intervention was designed for a population with poor sleep quality, but without a diagnosed sleep disorder. Baseline values of the PSQI, Insomnia Severity Index and the Epworth Sleepiness Index suggest that the majority of participants did have poor sleep quality but did not have a clinical sleep disorder (e.g., above clinical threshold for insomnia or sleep apnoea). A smaller margin for improvement relative to that typically seen in clinical population groups was a function of studying a subclinical group with lower baseline symptom severity. Accordingly, the shift in scores observed in the Synergy Study was deemed satisfactory, especially given the effect size (d = 0.48)associated with between-group differences in sleep quality was comparable to that reported in a systematic review of internet-delivered cognitive behavioural therapy interventions for insomnia (d = 0.49) [56]. This is important considering the high percentage of the population with poor sleep quality, but without a clinical sleep disorder and with limited access to practitioner-based treatment [57,58]. PSQI scores below five indicate remission of sleep problems [59], and despite the magnitude of improvement observed in the intervention group, average scores remained >5, which is consistent with most studies in sub-clinical populations [19]. However, the intervention group had 32 per cent more participants reporting good sleep quality (PSQI scores <5) (Figure 6.S3), indicating the intervention may have considerable public health utility. The hypothesised synergistic relationship between PA and sleep was not examined in this study. However, changes in MVPA and sleep quality were lower in magnitude than anticipated. It is possible the magnitude of change in PA was not large enough to leverage larger increases in sleep quality and vice versa, or that the study duration was too short to detect this.

The intervention group further exhibited significantly better sleep hygiene practices and improvements in subjective sleep quality and sleep onset latency. More-pronounced improvements in sleep onset latency for the intervention group were likely a result of adherence to and improvements in sleep hygiene practices, which were targeted specifically in the Synergy Study. Moreover, PA is associated with reduced sleep onset latency [60], and the large amount of additional MVPA reported in the intervention group (adjusted group difference 109 minutes, d = 0.24), albeit not statistically significant, combined with the greater increase in RT may have contributed to improvements in sleep health indicators (i.e., sleep onset latency), which is consistent with the literature [61,62]. These improvements, combined with those seen for insomnia severity, which capture

clinically relevant characteristics of poor sleep health, support the overall finding that the intervention was efficacious in improving sleep.

The lack of group differences in health-related quality of life might indicate that changes in these parameters take longer than 3–6 months to manifest and may be of small magnitude in a population with non-acute conditions [63]. Long-term follow-up assessments are therefore warranted. The Synergy Study provided detailed stress management resources (but none specifically for depression or anxiety), which may explain the significantly greater improvements in stress symptoms observed in the intervention group. Given that high stress levels are associated with engagement in unhealthy behaviours and poorer sleep quality [64], facilitating stress management to reduce symptoms is important for multiple behaviour interventions, particularly those targeting sleep.

App usability ratings were fair, time to non-usage attrition was 32 days, and 89 per cent of participants suffered non-usage attrition. Although there are few app usage data available from multiple behaviour interventions, the proportion of participants making at least one entry (90 per cent) is similar to that observed in single behaviour m-health programs [65]. However, there is no evidence that defines the minimum amount of app usage needed for behaviour change to occur and whether continuous usage differs from intermittent usage with regard to the magnitude of behaviour change it confers. Time to non-usage attrition in the current study (32 days) appears to indicate moderate usage in comparison to other studies, for which time to non-usage attrition ranged from 1.5 weeks to 25 weeks [66]. These results suggest targeting two behaviours simultaneously does not adversely impact app usage rates. Despite fair participant ratings for app usability and time to non-usage attrition, almost all participants in the intervention group still suffered non-usage attrition during the intervention period. Several devices exist that allow automated self-monitoring of PA and sleep [67]. However, manual data entry was used for pragmatic reasons (e.g., cost) and this may have contributed to non-usage attrition, although it is unknown which method (manual or automated) is optimal for use in behaviour change interventions. Moreover, it is possible that some participants reached personal goals relating to PA and sleep sooner than others, or lost motivation over time. Furthermore, participants may have engaged in PA and sleep hygiene practice more frequently than indicated by the completed logs, possibly because of not feeling any need

to keep track or lacking time to do so. This is in line with findings from a study indicating that participants only log approximately 60 per cent of their objectively measured daily activity [24].

To the authors' knowledge, this was the first trial of its kind to target physical activity and sleep in combination using an RCT design. Trial strengths included its potential for wide reach, given the remote delivery, which made it accessible for those living outside metropolitan areas, as well as the personalised approach, which reinforced personally meaningful goals.

## 6.5.1 Limitations

Several factors reduced the power to detect significant between-group differences in MVPA. Despite requiring participants report <90 minutes/week to be eligible, 41.25 per cent reported doing >150 minutes at baseline. This may indicate that this single-item measure used has limited usefulness as a screening tool for interventions [68,69]. Discrepancies between the levels of PA participants reported at the eligibility screening and those reported at baseline may have been due to the different methods of assessment used (e.g., eligibility survey: single item versus baseline survey: multiple items). Selfreport measures of PA are subject to recall bias, and there was large variation in minutes of PA at baseline and follow-up in both groups. In addition, the waitlist-control group reported substantial increases in activity, which reduced the difference between groups. Given participants volunteered to take part, this could have been due to high levels of readiness to make changes to PA and sleep behaviours upon enrolment in the study, as seen in previous trials [51,70]. However, participants' readiness to change behaviour was not assessed in this study. Moreover, the study was powered based on effect sizes that assumed a synergistic effect between PA and sleep, and this may have been overestimated. The use of objective measures (e.g., accelerometry, polysomnography), however, was not feasible in this trial. Moreover, the self-report sleep measure (PSQI) was likely able to better capture the restorative effects of improved sleep, which is not possible using objective measures [71]. A number of secondary outcomes were examined, and this may have increased the risk of Type-1 errors. The classification of RT duration may have been somewhat arbitrary, and it is unknown if a minimum duration of 10 minutes confers a health benefit. Finally, it is possible that access to an internet-enabled device as an eligibility criterion reduced the representativeness of the sample. However,

the associated risk of bias may be minimal, given the widespread ownership of smartphones in Australia [72].

# 6.6 Conclusion

This remotely delivered intervention produced short-term improvements in RT and shortand medium-term improvements in sleep health. Some of the group differences seen at three months were not sustained at the six-month follow-up. The capacity of m-health interventions to foster long-term engagement and maintain changes in multiple behaviours remains to be determined, but practitioners are encouraged to promote PA and sleep health in combination.

# **References – Chapter 6**

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# **Supplementary Material – Chapter 6**

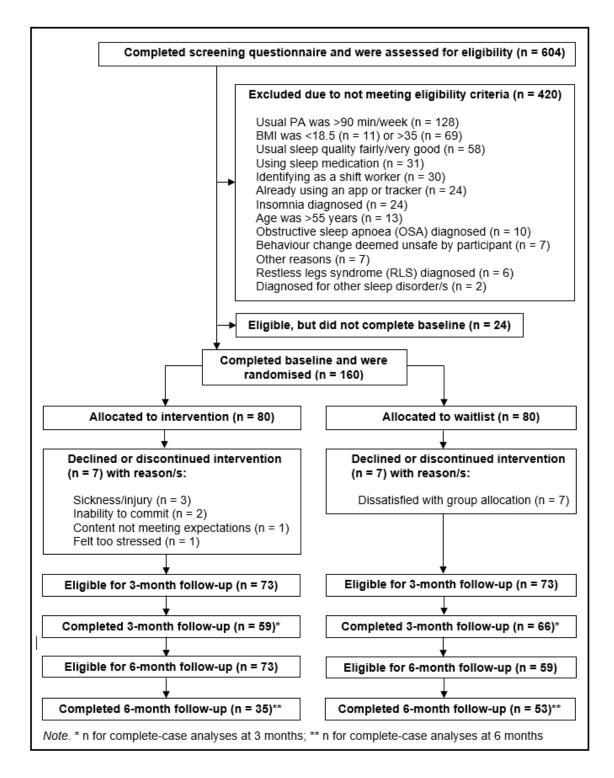
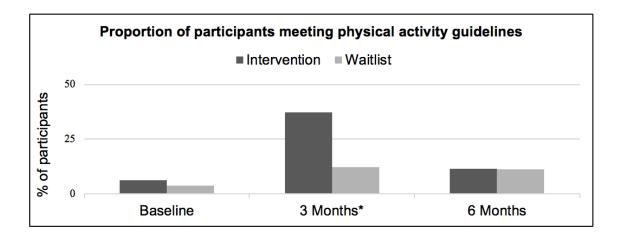
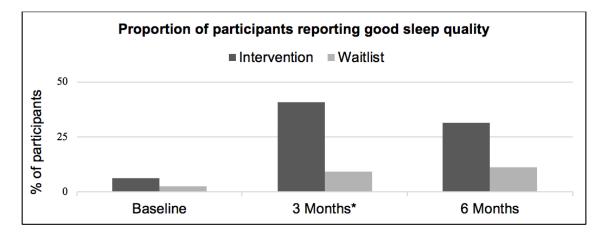


Figure 6.S1. Participant flow chart



*Figure 6.S2.* Bar charts illustrate the percentage of participants (out of 125 and 89 available observations at three and six months, respectively) by group and time point who met guidelines for aerobic exercise and resistance training. In the intervention group, the proportion of participants meeting guidelines at baseline, three and six months was 6.3%, 37.3%, and 11.4%, respectively. In the waitlist-control group, the proportions were 3.8%, 12.1%, and 11.1%, respectively. \* indicates a significant between-group difference in the relative odds of meeting guidelines (p < 0.05).



*Figure 6.S3.* Bar charts illustrate the percentage of participants (out of 125 and 89 available observations at three and six months, respectively) by group and time point who reported good quality sleep. In the intervention group, the proportion of participants reporting good sleep quality at baseline, three and six months was 6.3%, 40.7%, and 31.4%, respectively. In the waitlist-control group, the proportions were 2.5%, 9.1%, and 11.1%, respectively. \* indicates a significant between-group difference in the relative odds of reporting good sleep (p < 0.05).

Table 6.S1

*Operationalisation of psychosocial constructs and behaviour change techniques in the Synergy Study* 

## SELF-EFFICACY

Behaviour Change Techniques	Intervention components
<ul><li>Graded tasks</li><li>Self-monitoring</li><li>Goal review</li></ul>	App-based log: Participants were asked to recall and enter their activity and sleep behaviours. This allowed entries for active minutes, daily steps, resistance training sessions, sleep and wake times, a sleep quality rating, and 10 sleep hygiene practices.
Feedback on	App-based progress charts: Bar charts for daily, weekly and three-month progress (logged data) in relation to goals per behaviour.
<ul> <li>performance</li> <li>Praise/rewards</li> <li>Relapse prevention/coping</li> </ul>	App-based dashboard traffic light: For physical activity, the dashboard produced a traffic light color relating to total active minutes, while the color of the sleep dashboard related to total sleep duration. Data could be logged and goals adjusted at any time, which determined the colors of the traffic
<ul> <li>Barrier identification/problem solving</li> </ul>	light (a green light indicated a participant met, exceeded or was close to their goal; an orange light indicated progress toward the goal, although not close; and a red light indicated being markedly below the goal).
<ul> <li>Stress management</li> </ul>	Tool sheets: A series of tool sheets delivered at weeks three, six, and nine promoted goal-setting, action planning and stress management.
	Weekly summary report (email): An overview of weekly totals and averages per behaviour (if sufficient data were available) and prompted participants to review goals, if needed.
	Prompts (Reminder SMS): If participants failed to log any data on more than four days per week, they received a message prompting them to resume logging.

### PERCEIVED BEHAVIOURAL CAPABILITY

Behaviour Change Techniques		Intervention components			
•	Information on where and when to be active/engage in in sleep promoting behaviours	App-based resources (educational materials): The resources section included the current national guidelines (i.e., how much physical activity/week and how many hours of sleep/night adults need, and brief content on the when, where, who with and how of being active and sleeping well.			
•	Instructions on how to be active and engage in sleep promoting behaviours	Weekly facts (SMS): Participants received a short text message each week with educational content on activity and/or sleep and health to reinforce the importance of both behaviours.			
		Tool sheets: Tool sheets provided detailed information on goal-setting for physical activity and sleep health, action plan templates including examples of exercises and stress management techniques, such as progressive muscle relaxation or controlled breathing.			

### OUTCOME EXPECTATIONS AND EXPECTANCIES

Table 6.S1

Operationalisation of	psychosocial	constructs (	and behaviour	change techniques	in the Synergy
Study					

Behaviour Change Techniques	Intervention components				
• Information about the behaviour in relation to health	Tool sheets: As part of the goal-setting tool sheet, participants were asked to think about reasons to improve their health behaviours and what they anticipate as personal benefits of improved physical activity and sleep (examples were provided).				
	App-based resources: Information on why activity and sleep are important for health and wellbeing.				
	App-based goal-setting: Participants were asked to personalise their goals, but work towards guideline- recommended minima for physical activity (150 min of moderate-intensity or 75 min of vigorous-intensity physical activity and resistance training on two days/week) and sleep duration (7–9h sleep/night).				
GOALS					
Behaviour Change Techniques	Intervention components				
<ul><li>Goal-setting</li><li>Action Planning</li></ul>	App-based dashboard traffic light: Participants were encouraged to put equal effort into improving both physical activity and sleep.				
	Tool sheets. Participants receive goal-setting strategies and example action				

- Self-monitoring
  Prompt practice
  Time Management
  Tool sheets: Participants receive goal-setting strategies and example action plans for guidance. One of 3 tools was promoted via email at week three, six and nine, respectively.
  Reminders: Participants were advised to set a daily bedtime reminder
- Teach use of prompts
  Time management
  Time management
  (optional) on their phone, which was intended to prompt a person's bedtime routine to improve the consistency of regular bed times.
  App-based resources: Environmental restructuring as part of good sleep hygiene was described in the resource section and included details on *how*

#### SOCIOSTRUCTURAL FACTORS (SOCIAL & PHYSICAL ENVIRONMENT)

to manage the bedroom environment.

Behaviour Change Techniques	Intervention components
<ul><li>Use of prompts</li><li>Environmental</li></ul>	App-based resources: Information on physical activity and sleep in a social context and how to seek support from people in the same household (housemates, partner, and family members).
<ul><li>restructuring</li><li>Barrier identification</li><li>Plan social support</li></ul>	Tool sheets: Short examples on how to identify and manage barriers around being active and getting good sleep and how to utilise one's social support and environment in favour of personal goals.

*Note.* <sup>1</sup>Behaviour changes techniques were specified in accordance with the 40-item taxonomy of behaviour change techniques by Michie et al. [73].

Table 6.S2

Characteristics	IG (n = 80)	WLG (n = 80)
Age in years, M (SD)	41.1 (9.84)	41.9 (10.07)
Gender n (%)		
Male	14 (17.50)	18 (22.50)
Female	66 (82.50)	62 (77.50)
Body Mass Index M (SD)	28.7 (4.64)	27.2 (4.01)
Weight status		
Normal weight ( $\leq 25.0$ )	23 (28.75)	28 (35.00)
Overweight (25.1-30)	23 (28.75)	33 (41.25)
Obese (>30.0)	34 (42.50)	19 (23.75)
Marital status n (%)		
Single	22 (27.50)	20 (25.00)
Married/De Facto	48 (60.00)	45 (56.25)
Divorced/separated	10 (12.50)	12 (15.00)
Widowed/not stated	2 (2.50)	1 (1.25)
Ethnicity n (%)		
Caucasian	75 (93.75)	71 (88.75)
Asian	3 (3.75)	7 (8.75)
Not stated	2 (2.50)	2 (2.50)
Area of residence <sup>a</sup>		
Major city	56 (70.00)	52 (65.00)
Regional or remote	24 (30.00)	28 (35.00)
Education in years M (SD)	16.3 (2.71)	15.8 (2.87)
Occupation n (%)		
Professional	51 (63.75)	49 (61.25)
White-collar	16 (20.00)	9 (11.25)
Blue-collar	0 (0.00)	4 (5.00)
Not working <sup>b</sup>	13 (16.25)	17 (21.25)
Hours of work n (%)		
Daytime only	67 (83.75)	62 (77.50)
Other (including not working)	13 (16.25)	18 (22.50)

Baseline sociodemographic, health and behavioural characteristics of study participants

Table 6.S2

Characteristics	IG (n = 80)	WLG (n = 80)
Annual income n (%)		
<\$30,000	13 (16.25)	20 (25.00)
\$30,001-\$50,000	13 (16.25)	9 (11.25)
\$50,001-\$70,000	24 (30.00)	17 (21.25)
\$70,001-\$100,000	14 (17.50)	16 (20.00)
≥\$100,001	9 (11.25)	13 (16.25)
Not stated	7 (8.75)	5 (6.25)
Chronic disease status n (%)		
None	26 (32.50)	28 (35.00)
One	22 (27.50)	19 (23.75)
≥Two	32 (40.00)	33 (41.25)
Alcohol consumption n (%) <sup>c</sup>		
Never	9 (12.00)	16 (21.62)
Monthly or less	23 (30.67)	13 (17.57)
2–4 times/month	18 (24.00)	19 (25.68)
$\geq 2$ times/week	25 (33.34)	26 (35.13)
Caffeine consumption n (%) <sup>c</sup>		
2–4 times/month or less	20 (26.66)	13 (17.58)
≥2 times/week	55 (73.34)	61 (82.42)
Smoking n (%) <sup>c</sup>		
Yes	6 (8.00)	5 (6.76)
No	69 (92.00)	69 (93.24)
Physical activity M (SD)		
MVPA minutes/week	164.0 (165.45)	191.3 (244.12)
Resistance training frequency n (%)		
<2 days/week	72 (90.00)	76 (95.00)
$\geq 2$ days/week	8 (10.00)	4 (5.00)
Resistance training duration n (%)		
<10 minutes/week	65 (81.25)	73 (91.25)
≥10 minutes/week	15 (18.75)	7 (8.75)
Sitting minutes M (SD)	661.4 (197.71)	671.9 (180.43)

Baseline sociodemographic, health and behavioural characteristics of study participants

Table 6.S2

Characteristics	IG (n = 80)	WLG $(n = 80)$
Sleep quality M (SD)		
PSQI total score <sup>d</sup>	9.2 (3.07)	9.2 (2.86)
Subjective quality	2.0 (0.56)	1.9 (0.56)
Sleep onset latency	1.8 (1.01)	1.7 (1.06)
Sleep duration	1.0 (0.91)	1.2 (0.96)
Sleep efficiency	1.1 (1.03)	1.1 (1.03)
Sleep disturbances	1.6 (0.51)	1.5 (0.55)
Sleep medication	0.2 (0.53)	0.3 (0.66)
Daytime dysfunction	1.6 (0.67)	1.7 (0.73)
iming variability <sup>e</sup>		
Bedtime	3.9 (1.96)	3.5 (1.85)
Waketime	2.7 (1.51)	2.4 (1.25)
eep hygiene <sup>f</sup>	32.3 (6.72)	32.4 (6.63)
somnia severity <sup>g</sup>	12.4 (4.23)	12.7 (3.82)
aytime sleepiness <sup>h</sup>	8.9 (4.68)	7.9 (4.42)
ymptom severity		
Depression <sup>i</sup>	11.3 (7.87)	12.6 (8.84)
Anxiety <sup>j</sup>	6.9 (5.94)	7.1 (6.83)
Stress <sup>k</sup>	15.3 (6.02)	15.4 (7.46)
uality of life <sup>1</sup>		
Mental health	47.5 (4.96)	47.44 (5.13)
Physical health	44.6 (7.74)	44.19 (8.00)
Energy/fatigue	54.0 (10.74)	55.19 (9.63)

Baseline sociodemographic, health and behavioural characteristics of study participants

*Note.* IG = intervention group; WLG = waitlist-control group; MVPA = moderate- to vigorous-intensity physical activity; PSQI = Pittsburgh Sleep Quality Index; <sup>a</sup> area of remoteness was determined via residential postcode using *the Accessibility and Remoteness Index of Australia (ARIA);* <sup>b</sup> 'not working' included participants who were on home duties, retired, or a student; <sup>c</sup> for the lifestyle items, only 149/160 participants provided valid data; <sup>d</sup> scores range from 0–21 with scores >5 indicating poor quality sleep; <sup>c</sup> scores range from 1–11 where lower scores indicate less variability in bed- or waketimes; <sup>f</sup> scores range from 13–65 (lower scores indicate better sleep hygiene); <sup>g</sup> scores range from 0–7 (no clinically significant insomnia), 8–14 (subthreshold insomnia), 15–21 (moderate clinical insomnia), 22–28 (severe clinical insomnia); <sup>h</sup> scores range from 0–24 where higher scores indicate higher levels of daytime sleepiness; <sup>i</sup> scores for depression symptoms range from 0–9 (normal), 10–13 (mild), 14–20 (moderate), 21–27 (severe), 29+ (extremely severe); <sup>j</sup> scores for anxiety symptoms range from 0-7 (normal), 8-9 (mild), 10-14 (moderate), 15–19 (severe), 20+ (extremely severe); <sup>k</sup> scores stress symptoms range from 0–14 (normal), 15–18 (mild), 19–25 (moderate), 26–33 (severe), 34+ (extremely severe); <sup>1</sup> higher scores for mental and physical health and the energy/fatigue subscale indicate better quality of life.

# Table 6.S3

Marginalised mean estimates (M (SE)) and results from tests of between-group differences for continuous outcomes using imputed data

	Tł	ree months			Six months	
Outcomes	IG (n = 80)	WLG (n = 80)		IG (n = 80)	WLG (n = 80)	
	IG (II – 80)	WLG (II – 80)	<i>p</i>	IG (II – 80)	WLG (II – 80)	р
Co-primary Outcomes						
MVPA minutes/week <sup>a†</sup>	342.8 (1.16)	275.6 (1.16)	0.281	386.5 (1.19)	317.74 (1.16)	0.413
Sleep quality (PSQI) <sup>b</sup>	7.1 (0.40)	8.3 (0.34)	0.023	6.5 (0.54)	7.9 (0.38)	0.015
Secondary Outcomes						
Sitting minutes <sup>b</sup>	628.5 (22.82)	646.5 (23.65)	0.601	610.3 (34.22)	604.2 (27.78)	0.889
Bedtime variability <sup>a</sup>	3.5 (1.07)	4.0 (1.07)	0.123	3.3 (1.08)	4.0 (1.07)	0.064
Waketime variability <sup>a</sup>	2.4 (1.07)	3.0 (1.07)	0.017	2.6 (1.09)	2.9 (1.09)	0.264
Sleep hygiene <sup>b</sup>	30.1 (0.64)	31.8 (0.50)	0.025	31.6 (1.29)	34.1 (0.95)	0.124
Insomnia severity <sup>b</sup>	9.7 (0.53)	11.4 (0.47)	0.014	8.1 (0.69)	11.5 (0.61)	<0.001
Daytime sleepiness <sup>c</sup>	6.6 (1.07)	7.4 (1.06)	0.184	5.9 (1.11)	8.9 (1.08)	0.001
Depression symptoms <sup>a†</sup>	10.0 (1.08)	11.2 (1.07)	0.307	11.2 (1.14)	11.8 (1.10)	0.743
Anxiety symptoms <sup>c†</sup>	6.3 (1.12)	7.0 (1.09)	0.353	7.6 (1.14)	9.3 (1.09)	0.180
Stress symptoms <sup>c†</sup>	14.2 (1.05)	15.8 (1.04)	0.078	13.7 (1.08)	17.2 (1.05)	0.011
Mental health <sup>b</sup>	43.9 (0.90)	44.5 (0.88)	0.612	45.8 (1.53)	44.3 (1.14)	0.438
Physical health <sup>b</sup>	47.4 (0.74)	46.9 (0.67)	0.600	46.4 (0.90)	46.7 (0.80)	0.778
Energy/fatigue <sup>b</sup>	51.7 (1.15)	52.9 (1.29)	0.443	54.5 (1.72)	50.9 (1.57)	0.119

*Note.* IG = intervention group; WLG = waitlist-control group; MVPA = moderate- to vigorous-intensity physical activity; PSQI = Pittsburgh Sleep Quality Index; GLMM = generalised linear mixed model; DASS = Depression Anxiety and Stress Scales; \* at 3 months, 35 cases (22%) were imputed for analyses of MVPA, sleep quality, mental health, physical health and energy/fatigue, and 36 cases (23%) were imputed for analyses of all other outcomes; \*\* at 6 months, 71 cases (44%) were imputed for analyses of MVPA, sleep quality, mental and physical health and energy/fatigue, and 72 cases (45%) were imputed for analyses of all other outcomes; a analysed using a GLMM with gamma distribution and log link function; b analysed using a GLMM with gaussian distribution and log link function; all GLMM were fitted using an unstructured covariance matrix and the robust variance estimator; a small positive constant (+1) was added to minutes of MVPA and the DASS-21 scores for the purpose of data analysis and these outcomes are reported with this constant included; boldface indicates statistical significance at *p*<0.025 for co-primary outcomes and *p*<0.05 for secondary outcomes.

#### Table 6.S4

	Three months				Six months			
Outcome	OR	SE	95% CI	р	OR	SE	95% CI	р
Resistance training on $\geq 2$ days/week <sup>a</sup>	6.47	4.41	1.70 to 24.60	0.006	1.53	1.10	0.37 to 6.29	0.553
Resistance training for $\geq 10$ minutes/week <sup>a</sup>	4.02	2.37	1.27 to 12.76	0.018	1.78	1.12	0.51 to 6.14	0.364
Subjective sleep quality <sup>b†</sup>	0.47	0.17	0.22 to 0.97	0.041	0.79	0.35	0.33 to 1.89	0.600
Sleep onset latency <sup>b†</sup>	0.41	0.17	0.18 to 0.93	0.032	0.65	0.34	0.23 to 1.80	0.403
Sleep duration <sup>b†</sup>	0.70	0.28	0.33 to 1.52	0.373	0.48	0.26	0.16 to 1.41	0.180
Sleep efficiency <sup>b†</sup>	0.62	0.27	0.26 to 1.45	0.272	0.60	0.23	0.28 to 1.25	0.173
Sleep disturbances <sup>b†</sup>	0.50	0.23	0.20 to 1.21	0.123	0.41	0.24	0.14 to 1.27	0.124
Sleep medication use <sup>b†</sup>	0.62	0.37	0.19 to 2.01	0.423	0.36	0.33	0.06 to 2.17	0.265
Daytime dysfunction <sup>b†</sup>	0.83	0.33	0.38 to 1.79	0.630	0.37	0.18	0.14 to 0.98	0.046

*Note.* OR = odds ratio; SE = standard error; CI = confidence interval; IG = intervention group; WLG = waitlist-control group; GLMM = generalised linear mixed model; PSQI = Pittsburgh Sleep Quality Index \* at 3 months, 35 cases (22%) were imputed for analyses; \*\* at 6 months, 71 cases (44%) were imputed for analyses; a odds ratios were calculated using GLMMs with a binomial distribution, logit link function, unstructured covariance matrix and the robust variance estimator; <sup>b</sup> estimates for the seven PSQI composites represent proportional odds ratios, robust standard errors and 95% CI based on mixed effects ordered logistic regression that tested betweengroup differences in the likelihood of shifting to another level of the variable (i.e., lower PSQI composites indicate better sleep quality, thus OR <1 indicates the intervention group was less likely to move up a level or report worse outcomes for the composites); <sup>†</sup> a small positive constant (+1) was added to PSQI component scores for the purpose of analysis; boldface indicates statistical significance at p < 0.05.

#### CHAPTER 7. EXAMINING **MEDIATORS** OF INTERVENTION EFFICACY IN A RANDOMISED CONTROLLED M-HEALTH TRIAL TO **IMPROVE** PHYSICAL ACTIVITY AND SLEEP HEALTH IN ADULTS

The study presented in this chapter addressed Secondary Aim 3 of the thesis, which was dedicated to examining the potential mechanisms of intervention efficacy in the Synergy Study. Chapter 7 presents the version of the paper that is currently under review at a peer-reviewed journal.

## 7.1 Abstract

There has been little explanatory evaluation of the mechanisms causing change in multibehaviour interventions. Physical inactivity and poor sleep health both contribute to morbidity risk and cause immense economic burdens and should be targeted in combination for better health outcomes. To examine mediators of intervention efficacy in the Synergy Study, an m-health intervention designed to improve physical activity and sleep in Australian adults (n = 160). A nationwide randomised controlled trial was conducted to determine intervention efficacy at three (primary endpoint) and six months (follow-up). Co-primary outcomes were weekly minutes of moderate-to-vigorous intensity physical activity (MVPA) and sleep quality. Sleep hygiene practices were a secondary outcome. Hypothesised psychosocial and behavioural mediators of intervention efficacy were tested on primary endpoint data using bias-corrected bootstrapping (PROCESS 2 for SPSS). At three months, the intervention had significantly improved sleep quality and sleep hygiene. For MVPA, groups differed by 109 minutes/week, but this was not statistically significant. Changes in MVPA were mediated by self-efficacy, perceived capability, environment, social support, intention and planning. There was no evidence of the hypothesised psychosocial mediators having an effect on the two sleep outcomes, but changes in sleep hygiene mediated changes in sleep quality. Improvements in physical activity were mediated by several psychosocial factors, some of which showed inconsistent mediation (suppression). Mediation effects of sleep hygiene on sleep quality highlight the importance of providing evidence-based strategies to change these practices to improve sleep quality.

### 7.2 Background

Reductions in the global incidence of non-communicable diseases (e.g., heart disease, type-2 diabetes, obesity) will rely on substantial improvements in multiple health behaviours [1], including physical activity and sleep. However, relative to single-behaviour approaches, fewer interventions have targeted multiple behaviours [2]. The evidence shows there is potential for greater health improvements if multiple behaviours are targeted together [3], and there are studies suggesting results may be more favourable if behaviours that share a synergistic relationship are combined in a single intervention [4,5].

Insufficient physical activity and poor sleep health are both highly prevalent in the adult population [6]. They also are thought to share a reciprocal relationship [7], whereby changes in one behaviour produce changes in the other and vice versa. Many interventions seek to foster behaviour change by enhancing processes of self-regulation. Both physical inactivity and poor sleep health can be improved, if evidence-based behaviour change techniques (BCTs) are implemented to initiate or modify self-regulatory processes [8–10]. Yet no previous studies have targeted physical inactivity and poor sleep health in combination using a delivery format with potential for wide reach [6]. Consequently, there is relatively little knowledge of the factors that operate in an intervention combining these two behaviours. Testing mediators of intervention efficacy contributes essential knowledge on mechanisms of behaviour change and may help increase the effectiveness of behavioural interventions. This knowledge is important, even in the absence of a statistically significant intervention effect [11].

The evidence indicates that improvements in mediators specific to self-regulation (e.g., planning) are associated with larger increases in physical activity; however, the evidence for other psychosocial mediators of physical activity (e.g., self-efficacy, outcome expectations) is mixed [12]. In the context of sleep health, studies that have examined psychosocial mediators of behaviour change are scarce, but the evidence shows that improved sleep hygiene practices are linked to improved sleep quality [13].

The Synergy Study employed a randomised waitlist-controlled design and targeted physical activity and sleep quality as co-primary outcomes in a three-month intervention using an m-health approach [6]. The primary endpoint of the intervention was three months and the intervention consisted of a mobile app (Balanced) that promoted goal-setting, self-monitoring and utilisation of feedback combined with educational resources,

weekly summary reports and engagement prompts. Variables that are thought to change as a result of modified self-regulation were selected for examination in the current study, as the Synergy Study purposefully operationalised key constructs of the psychosocial theories (i.e., Social Cognitive Theory [14]) that guided the development of the intervention [6].

The intervention significantly improved sleep quality and resulted in a higher proportion of participants reporting good quality sleep at three months. Significant short-term improvements were also observed in resistance training frequency and duration, subjective sleep quality, sleep onset latency, wake time variability, sleep hygiene practice, insomnia severity, daytime sleepiness, and symptom severity for stress in the intervention group. There was no significant between-group difference for minutes of MVPA; however, participants in the intervention group were significantly more likely to meet guidelines for MVPA and resistance training. The primary aim of the current study was to examine potential mediators of intervention effects in the Synergy Study on the outcomes of MVPA, sleep quality and sleep hygiene.

## 7.3 Methods

#### 7.3.1 Trial Registration, Ethics and Study Protocol

The trial was prospectively registered with the Australia New Zealand Clinical Trials Registry (ACTRN12617000376347 (Appendix P)) and the Human Research Ethics Committee of the University of Newcastle, NSW, Australia (H-2016-0181 (Appendix B)) granted full ethical approval. The methods, measures and operationalisation of intervention components are described in greater detail in a protocol paper [6].

### 7.3.2 Study Design

The Synergy Study was a randomised waitlist-controlled trial with online assessments at baseline, three months and six months. Participants were recruited nationwide through social media (Facebook). Participant consent, eligibility screening, enrolment and baseline assessments were completed between June and August 2017 via the online platform Qualtrics (Provo, Utah). After completing baseline, participants were randomly allocated to either the intervention group or the waitlist group (n = 80 per group). Allowing for attrition of 25 per cent, a sample size of 160 was required to detect a

statistically group difference in the co-primary outcomes of minutes of MVPA and sleep quality at the primary endpoint (three months). This sample size also provided adequate power to detect mediation effects at the primary endpoint (three months), based on using bias-corrected bootstrapping of confidence intervals [15].

## 7.3.3 Participants

To take part in the study, participants had to live in Australia, be 18 to 55 years of age, and self-report being insufficiently physically active and sleeping poorly. The flow of participants is illustrated in Figure 7.1 and lists all reasons for exclusion. Additional details can also be found in the study protocol [6].

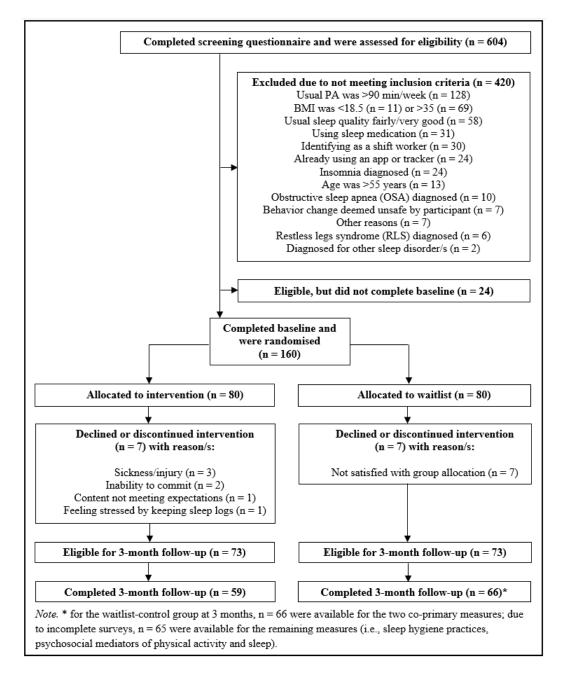


Figure 7.1. Participant flow diagram

## 7.3.4 Intervention

The Synergy Study purposely targeted a range of psychosocial factors (e.g., self-efficacy, outcome expectations) that are known to explain behaviour [16] and operationalised those using evidence-based strategies, such as self-monitoring and action planning (see Table 7.1 for a detailed overview) [17,18]. The intervention was delivered through a mobile app (Balanced) featuring educational resources, personal goals, self-monitoring logs (manual data entry by the user) and feedback in relation to personal goals, all in relation to a range

of physical activity and sleep health components (i.e., active minutes, step count, resistance training, sleep duration, sleep/wake timing, sleep quality, sleep hygiene); the app was complemented by a 12-week support package including personalised weekly summary reports, tool sheets with useful instructions and prompts upon disengagement. All aspects of the intervention were delivered using the app, or via email and text messages. Although the intervention highlighted the importance of personally meaningful and achievable goals, participants were encouraged to gradually work towards the amount of weekly physical activity recommended for adults (at least 150 minutes of moderate or 75 minutes of vigorous intensity physical activity, or an equivalent combination, and resistance training on two days/week) and seven to nine hours of sleep [19,20]. A comprehensive handbook with guidance on getting started and a pedometer were sent to participants in the mail. All assessments were hosted via online survey on the Qualtrics platform (Provo, Utah).

#### 7.3.5 Measures

Sociodemographic variables (e.g., age, gender, education, chronic disease status, etc.) were assessed at baseline (see published protocol [6]). Behavioural outcomes and hypothesised mediators were assessed at baseline, three and six months.

Although the active part of the intervention (i.e., personalised support) ceased at three months, participants were able to continue to use the app beyond the three-month time point to set or review goals, log data, and view progress over time. However, the current paper only examines the mediation effects that occurred between baseline and the primary endpoint (three months).

Intervention strategies (BCTs), intervention components, and scale characteristics

SELF-EFFICACY	
ВСТ	Graded tasks, self-monitoring, goal review, feedback on performance, praise/rewards, relapse prevention/coping, barrier identification/ problem-solving stress management.
Intervention components	<ul> <li><i>In-app logs:</i> Allowed entries for active minutes, daily steps, resistance training sessions, sleep and wake times, a sleep quality rating, as well as a checklist of 10 sleep hygiene goals.</li> <li><i>In-app progress charts:</i> Provided a history with daily, weekly, and 3-month progress in relation to goals per behaviour.</li> <li><i>In-app dashboard traffic light:</i> Produced feedback relating to goals based on total active minutes and total sleep duration.</li> <li><i>Weekly summary reports (email):</i> Provided weekly totals and averages by behaviour and prompted goal review, if needed.</li> <li><i>SMS Prompts:</i> Encouraged participants to resume logging (if no data were logged on &gt;4 days/week).</li> </ul>
PA scales to assess so	elf-efficacy
Item total (source)	10 items (Plotnikoff et al., 2008) [21]
Example item	'I am confident that I can participate in regular physical activity when I am a little tired.'
Response options	Not at all confident (0) to extremely confident (4)
Total score range	0-40
Scale reliability	0.90
Sleep scales to assess	s self-efficacy
Item total (source)	9 items (Schwarzer & Luszczynska, 2015) [22]
Example item	'I am confident that I can avoid alcohol right before bedtime.'
Responses	Not at all confident (0) to extremely confident (4)
Total score range	040
Scale reliability	0.76
BEHAVIOURAL CA	APABILITY
ВСТ	Information on where and when to be active/engage in sleep promoting behaviours instructions on how to be active and engage in sleep promoting behaviours.

Intervention strategies (BCTs), intervention components, and scale characteristics

Intervention components	<ul> <li><i>In-app resources:</i> Included current national guidelines on how much physical activity/week and how much sleep/night adults need as well as brief content on the when, the where, who with, and how of being active and sleeping well (e.g., sleep hygiene practices).</li> <li><i>Weekly fact SMS:</i> Short weekly text messages with educational content related to activity and/or sleep, and health to reinforce the importance of both behaviours.</li> <li><i>Tool sheets (Email):</i> Promoted goal-setting, action planning, and stress management strategies (delivered in weeks 3, 6, 9).</li> </ul>
PA scales to assess l	oehavioural capability
Item total (source)	3 items (Rogers et al., 1998) [23]
Example item	'I can run or jog for 10 minutes without stopping.'
Response options	Never (0) to always (4)
Total score range	0–40
Scale reliability	0.70
Sleep scales to asses	s behavioural capability
Item total (source)	9 items (Dewar et al., 2012 & 2013) [24,25]
Example item	'Whenever I have the opportunity to use technological devices right before bedtime or in bed, I know how to avoid or remove them.'
Responses	Never (0) to always (4)
Total score range	0–40
Scale reliability	0.77
OUTCOME EXPE	CTATIONS
ВСТ	Information about the behaviour in relation to health.
Intervention components	<ul> <li><i>Tool sheets (email):</i> On the goal-setting tool sheet, participants were asked to think about the reasons for wishing to improve their health behaviours and what they anticipate as personal benefits from improved levels of activity and sleep (examples were provided).</li> <li><i>In-app resources:</i> This section included information on how physical activity and sleep contribute to health and well-being.</li> </ul>
PA scales to assess	outcome expectations
Item total (source)	5 items (Dewar et al., 2012 & 2013) [24,25]
Example item	'Being physically active can reduce my risk for some illnesses and diseases (e.g., heart disease, diabetes, some cancers, etc.)'
Response options	Strongly disagree (0) to strongly agree (6)
Total score range	0–30

Intervention strategies (BCTs), intervention components, and scale characteristic.	Intervention strategies	(BCTs), interventic	n components, and	l scale characteristics
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Sleep scales to assess	outcome expectations
Item total (source)	9 items (Plotnikoff et al., 2008) [21]
Example item	'For me, keeping consistent sleep and wake times would help me sleep better.'
Responses	Strongly disagree (0) to strongly agree (6)
Total score range	0–54
Scale reliability	0.84
OUTCOME EXPEC	TANCIES
ВСТ	Information about the behaviour in relation to health.
Intervention components	<ul> <li><i>Tool sheets (email):</i> On the goal-setting tool sheet, participants were asked to think about the reasons for wishing to improve their health behaviours and why this is important.</li> <li><i>In-app resources:</i> This section included information on why physical activity and sleep are important.</li> </ul>
PA scales to assess or	
Item total (source)	5 items (Dewar et al., 2012 & 2013) [24,25]
Example item	'To you, how important is reducing your risk for illness and disease?'
Response options	<i>Not at all important</i> (0) to <i>extremely important</i> (3)
Total score range	0–15
-	
Scale reliability	0.79
-	outcome expectancies
Item total (source)	9 items (Dewar et al., 2012 & 2013) [24,25]
Example item	'To you, how important is keeping sleep and wake times consistent to sleep well?'
Responses	Not at all important (0) to extremely important (3)
Total score range	0–27
Scale reliability	0.82
SOCIAL SUPPORT	
BCT	Plan social support, barrier identification.
Intervention components	<ul> <li><i>Tool sheets (email):</i> Included short examples on how to identify and manage barriers to being active and getting good sleep and how to use one's social support in favour of activity and sleep.</li> <li><i>In-app resources:</i> Encouraged participants to utilise their social support to be physically active (e.g., finding an exercise buddy).</li> </ul>
PA scales to assess so	ocial support
Item total (source)	2 items (Liebreich et al., 2009) [26]
Example item	'People in my social network are likely to help me participate in regular physical activity.'

Intervention strategies (BCTs), intervention components, and scale characteristics

Response options	Strongly disagree (0) to strongly agree (4)
Total score range	0-8
Scale reliability	0.89
Sleep scales to asses	s social support
Item total (source)	9 items (Kor & Mullan, 2011; Rhodes et al., 2010) [27,28]
Example item	'Most people who are important to me would encourage me to (e.g., reduce my stress levels).'
Responses	Strongly disagree (0) to strongly agree (4)
Total score range	0–36
Scale reliability	0.86
ENVIRONMENT	
ВСТ	Use of prompts, environmental restructuring, barrier identification.
Intervention components	<ul> <li><i>Tool sheets (email):</i> Included short examples on how to identify and manage barriers to being active and getting good sleep, and how to use one's environment in favour of activity and sleep.</li> <li><i>In-app resources:</i> Encouraged participants to modify their environment to promote good sleep (e.g., bedroom temperature).</li> </ul>
PA scales to assess	environment
Item total (source)	3 items (Alexander et al., 2006) [29]
Example item	There are sidewalks on most of the streets in my local area.'
Response options	Strongly disagree (0) to strongly agree (4)
Total score range	0–12
Scale reliability	0.56
Sleep scales to asses	s environment
Item total (source)	4 items (Hale et al., 2010) [30]
Example item	'My neighbourhood is noisy'
Responses	Strongly disagree (0) to strongly agree (4)
Total score range	0–4
Scale reliability	0.82
INTENTION	
ВСТ	Goal-setting, self-monitoring, prompt practice, teach use of prompts.

Intervention strategies (BCTs), intervention components, and scale characteristics

Intervention components	<ul> <li><i>In-app personal goal-setting:</i> Participants were asked to personalise their goals but work towards recommended minima of physical activity and sleep duration (150 MVPA/week; 7–9h sleep/night); goals were carried forward from previous days, unless adjusted.</li> <li><i>In-app dashboard traffic light:</i> Participants were encouraged to put equal effort into improving both PA and sleep (i.e., two amber lights were better than one green and one red light).</li> <li><i>Tool sheets (email):</i> Participants received goal-setting strategies for guidance (per behaviour). Examples were provided.</li> </ul>
PA scales to assess i	ntention
Item total (source)	1 item (Dewar et al., 2012 & 2013) [24,25]
Example item	'Do you intend to do regular physical activity over the next three months?'
Response options	No, not really (0) to strongly intend (6)
Total score range	0–6
Scale reliability	N/A
Sleep scales to asses	s intention
Item total (source)	9 items (Dewar et al., 2012 & 2013; Kor & Mullan, 2011) [24,25,28]
Example item	'I intend to avoid using technological devices, especially right before bedtime or in bed.'
Responses	No, not really (0) to strongly intend (6)
Total score range	0–59
Scale reliability	0.85
PLANNING	
ВСТ	Action planning, time management, barrier identification.
Intervention components	<ul> <li>Tool sheets (email): Participants received action planning strategies for guidance (per behaviour). Examples were provided.</li> </ul>
PA scales to assess	olanning
Item total (source)	4 items (Trinh et al., 2012) [31]
Example item	'I have made plans concerning how I am going to get to a place to engage in regular physical activity.'
Response options	No detailed plans (0) to detailed plans (6)
Total score range	0–24
Scale reliability	0.96
Sleep scales to asses	s planning
Item total (source)	9 items (Trinh et al., 2012) [31]
Example item	'I have planned where, when and how to avoid caffeine.'

Table 7.1

Intervention strategies (BCTs), intervention components, and scale characteristics

Responses	No detailed plans (0) to detailed plans (6)
Total score range	0–54
Scale reliability	0.92

*Note.* The scales' internal consistency was assessed using Cronbach's alphas [32]. Values of 0.8 to 0.9 indicate good internal consistency and values greater than 0.9 are considered excellent [33]; The reliability coefficients (Cronbach's alphas) for the sleep hygiene items reported in this table are the same as those reported in Chapter 4. The reported scale reliability coefficients for the physical activity items were assessed using the same methods that were described in Chapter 4 for the sleep hygiene items

**Behavioural outcomes.** The Active Australia questionnaire (AAQ) was used to assess minutes of moderate-to-vigorous physical activity (MVPA) [34]. This instrument measures the duration and frequency of walking, moderate and vigorous intensity physical activity. Weekly totals for minutes of MVPA were calculated according to standard scoring criteria (the sum of minutes of walking, moderate-and vigorous-intensity (weighted by two) physical activity) and was one of two co-primary outcomes in the Synergy Study. The AAQ has acceptable psychometric properties and can be used to assess behaviour change in interventions [35,36].

Sleep quality was specified as the second co-primary outcome to examine intervention efficacy. Sleep quality was assessed using the Pittsburgh Sleep Quality Index (PSQI). The PSQI is a valid, reliable and commonly used self-report measure [37]. It encompasses several indicators of sleep health (i.e., subjective sleep quality, sleep onset latency, sleep duration, sleep efficiency, sleep disturbances, sleep medication use and daytime dysfunction) and also captures participants' perceptions of the restorative effects of sleep [38,39]. The seven component scores are summed to create a total score ranging from 0 to 21, with lower scores indicating better sleep quality.

Sleep quality is a multi-component concept [13], inclusive of aspects that fluctuate daily and may not be under the direct control of the individual. However, a range of daytime (and bedtime) behaviours can be modified to promote good overall sleep quality. These behaviours are commonly referred to as sleep hygiene practices and encompass selfregulatory processes that can be consciously controlled by the individual [40]. Thirteen different practices that are thought to influence sleep quality (e.g., different bed- and wake-times, sleeping in an uncomfortable environment, consuming stimulating beverages close to bedtime) were assessed using the Sleep Hygiene Index, which is a valid and reliable measure that also positively correlates with the PSQI [41]. Higher total scores correspond to sleep hygiene practices that are less favourable for good sleep quality. Additionally, in line with the wording of items used to assess the psychosocial mediators of sleep (see Table 7.1), sleep hygiene was assessed as an additional behavioural variable in this study. It was treated as a secondary outcome variable for the testing of sleep-specific psychosocial factors and as a mediator variable in a model where sleep quality was the outcome.

**Hypothesised mediators.** Changes in psychosocial and behavioural factors were specified as potential mechanisms driving changes in the co-primary outcomes during the intervention. The psychosocial mediators assessed in the Synergy Study included self-efficacy, perceived behavioural capability, environment, social support, outcome expectations, outcome expectancies, intention and planning. Items to assess these constructs were based on previously used items for physical activity and adapted for sleep as described in the study protocol [6]. Separate sum scores were calculated for each construct with higher scores, indicating stronger dispositions toward the behaviour (e.g., stronger intentions). MVPA was a hypothesised mediator of change in sleep quality and vice versa to evaluate the bi-directionality of the relationship between these two behaviours [7]; and sleep hygiene was a hypothesised mediator of sleep quality, because the evidence shows that sleep hygiene interventions effectively improves sleep health [40].

#### 7.3.6 Analyses

Analyses were conducted in SPSS 25 using PROCESS v2.16.3 following Preacher and Hayes' procedures for simple mediation, and all analyses used single mediator models [42]. The paths of mediation examined in this study are illustrated in Figure 7.2. Differences in sample characteristics (e.g., age, gender) and differences in baseline values of the outcomes (e.g., physical activity, sleep quality) between completers and non-completers (lost to follow-up) were examined using t-tests for continuous data and chi-squared tests for categorical data.

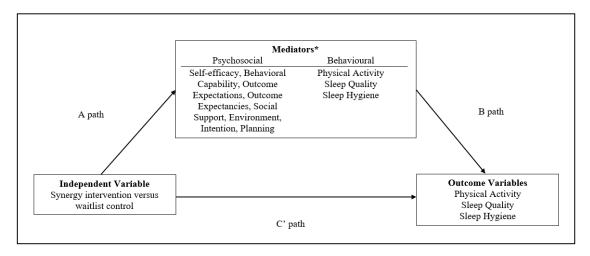


Figure 7.2. Overview of variables tested in simple mediation models using single mediators.\* All mediators were examined as single mediators.

Prior to testing for mediation, ANCOVAs were fitted to complete case data, with fixed effects for baseline-values of the outcome and for group (intervention versus control), to test the difference between groups (intervention effect) for physical activity and sleep quality. Alpha levels of 0.025 were set to test the intervention effect on the two co-primary outcomes (physical activity and sleep quality). A similar ANCOVA approach (e.g., adjusted for baseline values of the outcome) was used to assess changes in the secondary outcome of sleep hygiene using an alpha of 0.05.

The conceptual model to examine mediation is shown in Figure 2, corresponding to the PROCESS macro Model Four. [43]. In each of the models, Path A coefficients (denoted by lower case letter a) give a measure of the effect of the intervention on the hypothesised mediator variable, Path B coefficients (denoted by letter b) represent the association between the mediator and outcome variables and Path C' coefficients (denoted by c') are estimates of the direct effect of the intervention on the outcome variable, conditional on holding the mediator variable constant. Coefficients for the A\*B path (denoted by a\*b) represent the indirect or mediated effect. Alpha levels were set to 0.05 for all tests of mediation.

Estimates were calculated using bias-corrected bootstrapping on 5000 samples (95% CI), adjusted for baseline values of the outcome and mediator variables. Results are expressed as unstandardised, baseline-adjusted coefficients, and confidence intervals that do not include zero indicate statistically significant mediation [42]. Missing values were imputed using expectation maximisation (EM) [44]. Little's test was used to confirm if the data

were missing completely at random (MCAR) [45]. Consistent with intention-to-treat, and to maximise power, EM was favoured over using complete cases or baseline carried forward (results based on the latter datasets are supplied as supplementary material; Table 7.S1).

## 7.4 Results

Participants (n = 160) were middle-aged (M 41.5, SD 9.93), predominantly female (80%), overweight or obese (68%), of Caucasian descent (91.3%) and married or in a relationship (58.1%). Large proportions of participants reported living in an urban area (70.0%) and working primarily during daytime (83.1%). Two-thirds (66.3%) had one or more diagnosed chronic diseases and the sample had average symptom severity scores, consistent with mild depression (M 11.9, SD 8.37), normal to mild anxiety (M 7.0, SD 6.38) and mild stress levels (M 15.3, SD 6.9). At baseline, 58.8 per cent of participants were insufficiently physically active (<150 minutes MVPA/week) and 95.6 per cent reported poor quality sleep (PSQI total score >5). Sample characteristics including baseline values of proposed mediators are presented in Table 7.2.

Data from 125 participants were available from online surveys at the three-month endpoint (Figure 1), with 22 per cent of missing data requiring imputation for intention-to-treat analyses. Data were missing completely at random ( $\chi 2 = 53.27$ , DF = 43, p = 0.136). The difference in number of withdrawals per group was not statistically significant (p = 0.181), however those who did not provide follow-up data tended to be more severely depressed (p = 0.035) and reported lower mental health-related quality of life (p = 0.012). Mean values for mediators and outcomes, based on complete case data, baseline carried forward and expectation maximisation (intention-to-treat) are presented as supplementary material (Table 7.S2).

#### 7.4.1 Mediators of Physical Activity

Effect of the intervention on physical activity (C' path). An adjusted between-group difference of 109 minutes was found, but this difference was not statistically significant (p = 0.139). Analyses of the direct effect of the intervention on the outcome adjusted for the mediator (C' path) were consistent with this finding, except for the model examining the mediator of self-efficacy (Table 7.3), where, conditional on holding self-efficacy constant, the C' path coefficient showed a statistically significant effect (p = 0.019).

Effect of the intervention on hypothesised mediators of physical activity (A path). Coefficients for direct baseline-adjusted effects of the intervention on hypothesised mediators (A path) are reported in Table 7.3. Statistically significant inverse effects were observed for self-efficacy (a = -3.04, p = 0.010), outcome expectancies (a = -0.60, p = 0.034), environment (a = -1.25, p < 0.001) and social support (a = -1.04, p = 0.033), all of which showed weakening psychosocial dispositions toward physical activity.

Baseline sociodemographic, health, behavioural and psychosocial character	ristics	3
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	Intervention (n = 80)	Waitlist (n = 80)
Age M (SD)	41.1 (9.84)	41.9 (10.07)
Gender n (%)		
Male	14 (17.50)	18 (22.50)
Female	66 (82.50)	62 (77.50)
Body Mass Index (kg/m <sup>2</sup> ) M (SD)	28.7 (4.64)	27.2 (4.01)
Chronic disease status n (%)		
None	26 (32.50)	28 (35.00)
One or more	54 (67.50)	52 (65.00)
Symptom severity		
Depression <sup>a</sup>	11.3 (7.87)	12.6 (8.84)
Anxiety <sup>b</sup>	6.9 (5.94)	7.1 (6.83)
Stress <sup>c</sup>	15.3 (6.02)	15.4 (7.46)
Physical activity M (SD)		
MVPA minutes/week	164.0 (165.45)	191.3 (244.12)
RT days/week	0.4 (0.92)	0.1 (0.52)
RT minutes/week	8.3 (23.64)	1.9 (7.81)
Sleep quality M (SD) <sup>d</sup>	9.2 (3.07)	9.2 (2.86)
Sleep hygiene <sup>e</sup> M (SD)	32.3 (6.72)	32.4 (6.63)
Psychosocial mediators PA M (SD) <sup>f</sup>		
Barrier self-efficacy	18.5 (7.42)	17.9 (7.36)
Behavioural capability	7.1 (2.66)	6.4 (2.78)
Outcome expectations	18.1 (3.67)	17.5 (4.74)
Outcome expectancies	13.0 (2.27)	13.2 (2.18)
Environment <sup>g</sup>	9.0 (2.58)	8.4 (2.49)
Social support	7.2 (4.03)	6.7 (3.50)
Intention	4.4 (1.60)	4.3 (1.36)
Planning	10.0 (7.79)	9.9 (7.42)

Table 7.2

	Intervention (n = 80)	Waitlist $(n = 80)$
sychosocial mediators Sleep M (SD) <sup>f</sup>		
Self-efficacy	25.0 (5.75)	23.8 (5.17)
Behavioural capability	26.4 (5.20)	24.9 (5.52)
Outcome expectations	39.9 (10.67)	42.1 (9.02)
Outcome expectancies	20.3 (5.08)	20.6 (4.89)
Environment	3.0 (0.73)	2.9 (0.72)
Social support	27.1 (5.78)	26.7 (6.67)
Intention	45.2 (8.34)	44.4 (7.65)
Planning	27.0 (16.07)	27.4 (16.06)

Baseline sociodemographic, health, behavioural and psychosocial characteristics

*Note.* <sup>a</sup> depression scores range from 0–9 (normal), 10–13 (mild), 14–20 (moderate), 21–27 (severe), 29+ (extremely severe); <sup>b</sup> anxiety scores range from 0–7 (normal), 8–9 (mild), 10–14 (moderate), 15–19 (severe), 20+ (extremely severe); <sup>c</sup> stress scores range from 0–14 (normal), 15–18 (mild), 19–25 (moderate), 26–33 (severe), 34+ (extremely severe); <sup>d</sup> scores range from 0–21 (scores >5 indicate poor quality sleep); <sup>e</sup> scores range from 13–65 (lower scores indicate better sleep hygiene); <sup>f</sup> higher scores indicate stronger psychosocial dispositions towards behaviour.

Effect of the hypothesised mediators on physical activity (B path). B path coefficients represent associations between changes in mediators and changes in the behavioural outcome (i.e., MVPA). The mediators for which there were statistically significant positive associations with physical activity included self-efficacy (b = 14.55; p < 0.001), perceived capability to be physically active (b = 39.57, p < 0.001), environment (b = 22.91, p = 0.049) and social support (b = 23.75, p = 0.002). A one-unit increase in intention was associated with an additional 64.67 minutes of MVPA per week (p < 0.001), and a one-unit increase in scores for plans to be physically active was associated with an additional 9.44 minutes per week (p = 0.008).

Significance of the mediated effect on physical activity (A\*B path). The mediated effect is the product of coefficients from the A and B paths. Coefficients are shown in Table 7.3. Statistically significant effects were observed for self-efficacy, which accounted for 22 per cent of the effect of the intervention on changes in weekly minutes of MVPA (a\*b [95% CI] –44.23 [–94.21 to –13.37]) and for perceived capability (a\*b [95% CI] –27.47 [–73.88 to –2.43]), environment (a\*b [95% CI] –28.57 [-69.42 to – 5.84]), social support (a\*b [95% CI] –24.66 [–71.98 to –2.51]), intention (a\*b [95% CI] 25.38 [1.83 to 63.92]) and planning (a\*b [95% CI] 18.80 [2.14 to 54.07]), which explained between 11 and 19 per cent of the variance explained by the mediators.

Opposite signs for C' and A\*B path coefficients indicate inconsistent mediation [46], which occurred for all MVPA-specific psychosocial factors except for intention and planning, where greater intention and planning related to physical activity also resulted in more physical activity.

	A path (X on M)		B path (M on Y)		C' path (X on Y <sup>a</sup> )		A*B (Mediated effect)		
	a (SE)	р	b (SE)	р	c' (SE)	р	ab (SE)	95% CI	R <sup>2</sup>
DV = Physical activity									
Self-efficacy	-3.04 (1.16)	0.010	14.55 (2.95)	<0.001	103.24 (43.66)	0.019	-44.23 (20.28)	-94.21 to -13.37	0.22
Behavioural capability	-0.69 (0.36)	0.056	39.57 (9.81)	<0.001	77.77 (44.72)	0.084	-27.47 (17.24)	-73.88 to -2.43	0.19
Outcome expectations	-1.00 (0.58)	0.083	12.12 (6.39)	0.060	72.91 (46.39)	0.118	-12.17 (9.04)	-35.82 to 0.55	0.11
Outcome expectancies	-0.60 (0.28)	0.034	21.39 (13.06)	0.104	77.89 (46.57)	0.097	-12.87 (12.64)	-50.70 to 1.74	0.11
Environment	-1.25 (.32)	<0.001	22.91 (11.53)	0.049	92.22 (48.28)	0.058	-28.57 (15.46)	-69.42 to -5.84	0.11
Social support	-1.04 (0.48)	0.033	23.75 (7.46)	0.002	87.85 (45.71)	0.057	-24.66 (16.51)	-71.98 to -2.51	0.14
Intention	0.39 (0.20)	0.052	64.67 (17.70)	<0.001	34.40 (44.82)	0.444	25.38 (15.81)	1.83 to 63.92	0.17
Planning	1.99 (1.04)	0.056	9.44 (3.51)	0.008	43.70 (45.88)	0.342	18.80 (12.29)	2.14 to 54.07	0.13
Sleep quality	-1.35 (0.40)	0.001	-7.61 (9.17)	0.408	52.19 (47.91)	0.278	10.25 (13.26)	-12.89 to 40.83	0.09
DV = Sleep quality									
Self-efficacy	-0.48 (0.66)	0.472	-0.04 (0.05)	0.396	-1.25 (0.40)	0.002	0.02 (0.06)	-0.04 to 0.22	0.36
Behavioural capability	-0.71 (0.71)	0.322	-0.10 (0.04)	0.030	-1.26 (0.40)	0.002	0.07 (0.10)	-0.04 to 0.36	0.38
Outcome expectations	-1.24 (1.22)	0.313	0.06 (0.03)	0.029	-1.22 (0.40)	0.003	-0.07 (0.09)	-0.34 to 0.04	0.36
Outcome expectancies	-0.03 (0.61)	0.959	0.05 (0.05)	0.329	-1.30 (0.40)	0.002	0.00 (0.05)	-0.12 to 0.08	0.36

Results from simple mediation testing psychosocial and behavioural mediators of changes in physical activity, sleep quality and sleep hygiene

Tab	le	7	.3

	<i>y</i> 1	01 5			5	0 1 2			1 20	
	Environment	0.02 (0.07)	0.758	-0.23 (0.44)	0.607	-1.31 (0.41)	0.002	-0.01 (0.04)	-0.13 to 0.05	0.34
	Social support	-0.79 (0.91)	0.386	0.05 (0.04)	0.138	-1.31 (0.40)	0.001	-0.04 (0.07)	-0.27 to 0.04	0.37
	Intention	0.58 (1.27)	0.650	0.02 (0.03)	0.515	-1.32 (0.41)	0.001	0.01 (0.05)	-0.04 to 0.17	0.34
	Planning	0.21 (1.97)	0.916	-0.01 (0.02)	0.524	-1.31 (0.40)	0.001	0.00 (0.05)	-0.14 to 0.07	0.35
	Physical activity	62.44 (46.24)	0.179	-0.001 (0.001)	0.408	-1.31 (0.41)	0.002	-0.04 (0.06)	-0.23 to 0.04	0.35
	Sleep hygiene	-2.26 (0.71)	0.002	0.11 (0.04)	0.020	-1.08 (0.41)	0.009	-0.24 (0.13)	-0.58 to -0.05	0.37
D	V = Sleep hygiene									
	Self-efficacy	-0.47 (0.66)	0.477	-0.14 (0.09)	0.104	-2.25 (0.71)	0.002	0.07 (0.14)	-0.10 to 0.55	0.42
	Behavioural capability	-0.68 (0.71)	0.341	-0.24 (0.08)	0.003	-2.37 (0.70)	0.001	0.16 (0.19)	-0.13 to 0.66	0.44
	Outcome expectations	-1.24 (1.23)	0.314	-0.03 (0.05)	0.517	-2.32 (0.72)	0.002	0.04 (0.10)	-0.06 to 0.39	0.41
	Outcome expectancies	-0.04 (0.61)	0.951	-0.04 (0.09)	0.640	-2.30 (0.71)	0.001	0.00 (0.07)	-0.12 to 0.18	0.42
	Environment	0.02 (0.07)	0.754	-0.85 (0.78)	0.276	-2.19 (0.71)	0.003	-0.02 (0.09)	-0.35 to 0.08	0.41
	Social support	-0.79 (0.90)	0.385	-0.06 (0.06)	0.304	-2.27 (0.70)	0.002	0.05 (0.10)	-0.06 to 0.41	0.42
	Intention	0.57 (1.27)	0.652	-0.02 (0.04)	0.651	-2.21 (0.71)	0.002	-0.01 (0.07)	-0.21 to 0.08	0.41
	Planning	0.21 (1.97)	0.913	-0.02 (0.03)	0.471	-2.25 (0.71)	0.002	0.00 (0.08)	-0.21 to 0.13	0.41

Results from simple mediation testing psychosocial and behavioural mediators of changes in physical activity, sleep quality and sleep hygiene

*Note.* <sup>a</sup> the effect of the intervention on given outcome holding the mediator variable constant; X = Independent variable (Intervention); M = Mediator variable; Y = Dependent variable (Outcome); SE = Standard error; CI = Confidence interval; (100\*R<sup>2</sup>) = percent variance explained; numbers in bold font indicate a statistically significant effect.

#### 7.4.2 Mediators of Sleep Quality

Effect of the intervention on sleep quality (C' path). The intervention had a statistically significant effect on sleep quality, with the intervention group reporting greater improvements in sleep quality, relative to waitlist-controls (p = 0.009)

Effect of the intervention on hypothesised mediators of sleep quality (A path). None of the hypothesised psychosocial mediators changed significantly as a result of the intervention (all p > 0.05). Statistically significant effects were observed for sleep hygiene practices (a = -2.26, p = 0.002), indicating that the intervention improved sleep hygiene scores (with a possible range of 15–65, where higher scores indicate poorer sleep hygiene practices).

Effect of the hypothesised mediators on sleep quality (B path). Changes in perceived capability were negatively associated with changes in PSQI scores, showing that for each one-unit increase in perceived capability levels there was a 0.10-point decrement in PSQI scores (p = 0.030), which indicates improved sleep quality. An increase in outcome expectations, however, was significantly associated with higher PSQI scores and thus a reduction in sleep quality of 0.06 points (p = 0.029). Further, there was a statistically significant positive relationship between sleep hygiene and sleep quality (b = 0.11, p = 0.020).

Significance of the mediated effect on sleep quality (A\*B path). All the boot-strapped confidence intervals for tests of the mediated effect (A\*B paths) included zero, indicating none of the psychosocial mediators had a statistically significant effect. However, sleep hygiene mediated the effect of the intervention on sleep quality (a\*b [95% CI] –0.24 [–0.58 to –0.05]), with 37 per cent of the changes in sleep quality explained by changes in sleep hygiene.

#### 7.4.3 Mediators of Sleep Hygiene

Effect of the intervention on sleep hygiene (C' path). The intervention had a statistically significant effect on sleep hygiene in favour of the intervention group (p = 0.027).

Effect of the intervention on hypothesised mediators of sleep hygiene (A path). There was no significant relationship between the intervention and any of the sleep-specific psychosocial mediators. However, changes in sleep quality mediated changes in sleep hygiene, which was shown by the statistically significant improvements in sleep quality associated with the intervention (a = -1.32, p = 0.001).

Effect of the hypothesised mediators on sleep hygiene (B path). There was a statistically significant inverse relationship between changes in participants' perceived capability to keep good sleep hygiene and changes in actual sleep hygiene practices, with stronger perceptions being associated with better sleep hygiene practices (b = -0.24, p = 0.003).

Significance of the mediated effect on sleep hygiene (A\*B path). None of the intervention effects on sleep hygiene were mediated by any of the hypothesised psychosocial factors.

## 7.5 Discussion

The Synergy Study aimed to simultaneously improve physical activity and sleep quality in a sample of Australian adults. The study demonstrated significant group differences for sleep quality and sleep hygiene practices after three months in favour of the intervention. There was a statistically non-significant yet meaningful between-group difference in physical activity at the primary endpoint, as both groups had almost doubled their weekly total of minutes of moderate-to-vigorous physical activity (MVPA).

Despite the absence of significant between-group differences in MVPA at three months, significant mediation effects were observed for six of the nine hypothesised psychosocial mediators (i.e., self-efficacy, perceived capability, environment, social support, intention and planning). However, inconsistent mediation effects were observed for self-efficacy, perceived capability, environment and social support. This is substantiated by the direct effect (c') and the mediated effect (a\*b) having significant associations, but in opposite directions [47]. An inconsistent mediation effect, which is also referred to as a *suppression* effect, occurs if a counter-intuitive change is observed for a given mediator variable (e.g., self-efficacy), where the initial study aim was to strengthen such factors through the strategies provided. Existing evidence shows that stronger dispositions (e.g., higher levels of

self-efficacy) lead to better intervention outcomes (e.g., more physical activity) [48]. Contrary to this, in the current study there was improvement in actual behaviour (i.e., physical activity) albeit a reduction or weakening in some of the psychosocial dispositions toward physical activity. This has been previously observed for the proposed mediators (e.g., self-efficacy, outcome expectations) [49-51]. To some extent, the observed suppression effects could have been due to different mechanisms operating together in a complex pattern, or other unmeasured factors having had a stronger impact on actual behaviour. A systematic review of behaviour change interventions that targeted self-efficacy showed that an increase in physical activity despite reductions in self-efficacy is not uncommon [52]. This can be explained by changes in the way participants self-evaluate throughout the process of receiving an intervention, which is consistent with Response Shift Theory [53]. For example, it is possible that participants felt highly confident about imminent behavioural changes at the study outset and had high expectations of the support offered. Following three months of continuous goal-setting, self-monitoring and goal review based on feedback, participants may have developed more realistic expectations and views of personal barriers to behaviour change (i.e., being sufficiently physically active on a regular basis) [54,55].

Mediation effects without suppression were found for participants' intentions and plans to be physically active, both of which were improved by the intervention and also explained a proportion of the effect the intervention had on changes in physical activity. This may indicate that that the intention–behaviour gap, which is commonly reported in the behaviour change literature, may have been minimised by the use of planning strategies [56,57]. Moreover, it is possible that participants felt an increased sense of being held accountable for progress toward goals (in part through targeted strategies such as use of prompts), which may have encouraged them to develop and adhere to action-oriented plans that favour physical activity. These plans may have helped participants overcome setbacks and impediments to achieve behavioural goals [57,58]. This finding suggests that while it is important to offer participants strategies to enhance their personal capacities to be physically active, it is also important to target intentions and action planning strategies, as these have been associated with significant behaviour change [57,59].

The findings from this study showed significant improvements in sleep quality and sleep hygiene practices in favour of the intervention, indicated by significant group-differences at three months. Separate mediation tests to examine behavioural outcomes, however, revealed sleep hygiene mediated changes in sleep quality. This is consistent with the evidence, as sleep hygiene interventions are known to improve sleep health [40]. However, there was no support for the hypothesis that psychosocial factors specific to sleep act as mechanisms (mediators) of behaviour change, either for an outcome that is somewhat distal (sleep quality) or one that is more proximal (sleep hygiene) to behavioural self-regulation [40]. It is possible that although the intervention significantly improved sleep hygiene practices by providing clear examples of how to implement changes, the psychosocial scales did not capture changes in underlying factors that are thought to be related to changes in these practices, such as a person's self-efficacy in keeping bed- and wake-times consistent. While the measures may need to be refined to better capture underlying constructs, several scales (e.g., social support, outcome expectations) had ceiling effects, limiting the ability to assess mediation.

Based on the behavioural mediation paths examined in this study, there was no evidence of a bi-directional relationship between MVPA and sleep quality. A plausible reason for this could be the composite nature of the PSQI score, which was used to assess changes in sleep quality and is made up of multiple indicators of sleep health [37]. A study that investigated the bi-directional associations between physical activity and different indicators of sleep health found that the quality of sleep (but not the duration) had a bi-directional relationship with physical activity [60]. There is additional evidence from a meta-analysis that found that the effects of physical activity on different indicators of sleep health vary depending on the component of sleep that is assessed, with only small effects shown for sleep duration and larger effects for sleep quality [61]. Thus, the testing of physical activity as a mediator in the context of individual PSQI composites may have resulted in different findings; however, a full evaluation of bi-directionality between the two study outcomes was outside the scope of the current paper.

This study also sought to shed light on whether the ways in which the hypothesised mechanisms of behaviour change operate are behaviour-specific. There was no evidence that the same mechanisms have significant mediation effects across different behavioural (PA,

sleep) outcomes. The absence of mediation effects at the psychosocial level, however, was consistent for both sleep outcomes. Nonetheless, the findings from this study underpin the important role of intentions and action planning in behaviour change. The direction of effects for these constructs was consistent across all three behavioural outcomes and conceptually aligns with psychosocial determinant theories [62], which place intentions and plans in closer proximity to behaviour (outcome) relative to factors such as self-efficacy.

#### 7.5.1 Strengths and Limitations

To the authors' knowledge, this was the first study to examine a comprehensive set of psychosocial and behavioural mediators in an intervention that targeted physical activity and sleep simultaneously. Furthermore, it appears no previous studies have aimed to evaluate intervention efficacy in a sleep intervention conducted in a population group without diagnosed sleep conditions. This is important given the high prevalence of subclinical sleep problems in the general adult population. Few studies have examined psychosocial mediators of behaviour change in multi-behaviour interventions and the results of this study provide initial evidence for mediators of behaviour change in m-health interventions. Future studies with larger sample sizes are needed to examine multiple mediators to account for the complexity and interactive nature of behaviour change mechanisms. There also were some limitations to the current study. The sample size (n = 160) may have limited the power to detect mediators of sleep hygiene (A path) may indicate these measures were insufficiently sensitive to change (see Table 7.3). Although the scales used in this study show acceptable psychometric qualities, they have never before been used in an intervention context.

#### 7.6 Conclusions

Several psychosocial mediators were identified for the outcome of MVPA, but none for sleep quality or sleep hygiene. Changes in sleep hygiene, however, mediated changes in sleep quality, which supports the need for concise instructions and guidance for participants to be able to implement recommended practices. Additional studies are needed to further develop the evidence base for mechanisms of behaviour change in multi-behaviour interventions using an m-health approach.

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# Supplementary Material – Chapter 7

Table 7.S1

Results from mediation analyses based on complete cases (CC), baseline carried forward (BCF) and expectation maximisation (EM)

DV = MVPA		A path (IV	on MV)	B path (MV	on DV)	C' path (IV o	n DV)	A*B (I	Mediated effect)	
Mediators		a (SE)	р	b (SE)	р	c' (SE)	р	ab (SE)	95% CI	R <sup>2</sup>
Barrier self-efficacy	CC	-2.92 (1.46)	0.048	14.20 (3.45)	<0.001	108.14 (56.04)	0.056	-41.39 (23.72)	-98.36 to -3.04	0.23
	BCF	-2.04 (1.17)	0.084	10.67 (3.12)	<0.001	58.58 (46.11)	0.206	-21.71 (13.84)	-57.16 to -0.21	0.21
	EM	-3.04 (1.16)	0.010	14.55 (2.95)	<0.001	103.24 (43.66)	0.019	-44.23 (20.28)	-94.21 to -13.37	0.22
Perceived capability	CC	-0.67 (0.45)	0.139	38.86 (11.62)	0.001	84.09 (57.52)	0.146	-25.88 (20.76)	-82.05 to 3.30	0.19
	BCF	-0.45 (0.36)	0.221	28.84 (10.32)	0.006	41.77 (46.98)	0.375	-12.86 (12.37)	-46.14 to 4.17	0.18
	EM	-0.69 (0.36)	0.056	39.57 (9.81)	<0.001	77.77 (44.72)	0.084	-27.47 (17.24)	-73.88 to -2.43	0.19
Outcome expectations	CC	-1.08 (0.73)	0.146	11.79 (7.36)	0.112	79.97 (59.77)	0.183	-12.69 (10.97)	-42.84 to 2.79	0.12
	BCF	-0.90 (0.61)	0.140	9.39 (6.27)	0.136	45.64 (47.75)	0.341	-8.43 (6.96)	-29.30 to 0.79	0.15
	EM	-1.00 (0.58)	0.083	12.12 (6.39)	0.060	72.91 (46.39)	0.118	-12.17 (9.04)	-35.82 to 0.55	0.11
Outcome expectancies	CC	-0.37 (0.35)	0.286	22.29 (15.72)	0.159	85.76 (59.77)	0.154	-8.25 (12.87)	-51.63 to 3.83	0.12
	BCF	-0.15 (0.27)	0.588	14.68 (13.94)	0.294	44.44 (47.62)	0.352	-2.18 (6.88)	-26.22 to 4.52	0.14
	EM	-0.60 (0.28)	0.034	21.39 (13.06)	0.104	77.89 (46.57)	0.097	-12.87 (12.64)	-50.70 to 1.74	0.11

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		a (SE)	р	b (SE)	р	c' (SE)	р	ab (SE)	95% CI	R <sup>2</sup>
Environment	CC	-1.20 (0.38)	0.002	26.58 (14.10)	0.062	103.78 (61.40)	0.094	-31.84 (18.19)	-77.65 to -5.62	0.12
	BCF	-0.88 (0.31)	0.005	18.87 (12.49)	0.133	59.42 (48.92)	0.226	-16.54 (11.39)	-47.39 to -0.78	0.14
	EM	-1.25 (.32)	<0.001	22.91 (11.53)	0.049	92.22 (48.28)	0.058	-28.57 (15.46)	-69.42 to -5.84	0.11
Social support	CC	-0.85 (0.61)	0.170	24.51 (8.59)	0.005	91.03 (58.21)	0.121	-20.79 (19.06)	-76.65 to 2.95	0.16
	BCF	-0.34 (0.51)	0.501	18.67 (7.41)	0.013	48.68 (46.95)	0.302	-6.37 (11.29)	-40.32 to 9.27	0.17
	EM	-1.04 (0.48)	0.033	23.75 (7.46)	0.002	87.85 (45.71)	0.057	-24.66 (16.51)	-71.98 to -2.51	0.14
Intention	CC	0.41 (0.26)	0.112	65.36 (20.36)	0.002	41.42 (57.65)	0.474	26.78 (19.38)	-2.92 to 77.43	0.18
	BCF	0.34 (0.21)	0.105	52.46 (17.92)	0.004	21.17 (46.87)	0.652	17.78 (13.17)	-1.88 to 52.37	0.18
	EM	0.39 (0.20)	0.052	64.67 (17.70)	<0.001	34.40 (44.82)	0.444	25.38 (15.81)	1.83 to 63.92	0.17
Planning	CC	2.22 (1.33)	0.098	9.22 (4.01)	0.023	49.80 (59.09)	0.401	20.47 (15.02)	0.36 to 65.52	0.14
	BCF	1.73 (1.11)	0.121	9.21 (3.35)	0.007	24.65 (46.99)	0.601	15.98 (12.01)	-2.04 to 45.61	0.17
	EM	1.99 (1.04)	0.056	9.44 (3.51)	0.008	43.70 (45.88)	0.342	18.80 (12.29)	2.14 to 54.07	0.13
Behavioral mediators										
Sleep Quality	CC	-1.31 (0.49)	0.008	-8.00 (11.12)	0.473	56.54 (61.46)	0.359	10.52 (14.97)	-13.43 to 48.36	0.10
	BCF	-0.88 (0.40)	0.030	-15.56 (9.38)	0.099	26.41 (48.04)	0.583	13.74 (10.82)	-0.17 to 43.31	0.15

Results from mediation analyses based on complete cases (CC), baseline carried forward (BCF) and expectation maximisation (EM)

		a (SE)	р	b (SE)	р	c' (SE)	р	ab (SE)	95% CI	R <sup>2</sup>
	EM	-1.35 (0.40)	0.001	-7.61 (9.17)	0.408	52.19 (47.91)	0.278	10.25 (13.26)	-12.89 to 40.83	0.09
DV = PSQI										
Psychosocial Mediators										
Self-efficacy	CC	-0.14 (0.74)	0.848	-0.02 (0.06)	0.714	-1.22 (0.49)	0.014	0.00 (0.05)	-0.08 to 0.15	0.44
	BCF	-0.10 (0.64)	0.876	0.02 (0.05)	0.686	-0.78 (0.40)	0.054	0.00 (0.04)	-0.10 to 0.05	0.50
	EM	-0.48 (0.66)	0.472	-0.04 (0.05)	0.396	-1.25 (0.40)	0.002	0.02 (0.06)	-0.04 to 0.22	0.36
Perceived capability	CC	-0.74 (.85)	0.389	-0.10 (0.05)	0.060	-1.19 (0.48)	0.015	0.07 (0.10)	-0.05 to 0.49	0.46
	BCF	-0.71 (0.71)	0.318	-0.08 (0.04)	0.084	-0.78 (0.40)	0.051	0.06 (0.08)	-0.03 to 0.31	0.52
	EM	-0.71 (0.71)	0.322	-0.10 (0.04)	0.030	-1.26 (0.40)	0.002	0.07 (0.10)	-0.04 to 0.36	0.38
Outcome expectations	CC	0.18 (1.51)	0.903	0.04 (0.03)	0.205	-1.14 (0.50)	0.024	0.01 (0.08)	-0.12 to 0.23	0.44
	BCF	0.33 (1.19)	0.784	0.02 (0.03)	0.378	-0.80 (0.40)	0.049	0.01 (0.05)	-0.06 to 0.19	0.51
	EM	-1.24 (1.22)	0.313	0.06 (0.03)	0.029	-1.22 (0.40)	0.003	-0.07 (0.09)	-0.34 to 0.04	0.36
Outcome expectancies	CC	0.44 (0.75)	0.552	0.04 (0.06)	0.539	-1.22 (0.50)	0.015	0.02 (0.06)	-0.04 to 0.26	0.43
	BCF	0.37 (0.61)	0.551	0.03 (0.05)	0.629	-0.87 (0.40)	0.034	0.01 (0.04)	-0.04 to 0.17	0.50
	EM	-0.03 (0.61)	0.959	0.05 (0.05)	0.329	-1.30 (0.40)	0.002	0.00 (0.05)	-0.12 to 0.08	0.36

Results from mediation analyses based on complete cases (CC), baseline carried forward (BCF) and expectation maximisation (EM)

Results from mediation analyses based on complete cases (CC), baseline carried forward (BCF) and expectation maximisation (EM)

		a (SE)	р	b (SE)	р	c' (SE)	р	ab (SE)	95% CI	R <sup>2</sup>
Environment	CC	-0.04 (0.08)	0.655	0.10 (0.54)	0.015	-1.24 (0.50)	0.015	0.00 (0.05)	-0.15 to 0.07	0.42
	BCF	-0.02 (0.07)	0.802	0.13 (0.49)	0.796	-0.84 (0.41)	0.040	0.00 (0.04)	-0.10 to 0.06	0.50
	EM	0.02 (0.07)	0.758	-0.23 (0.44)	0.607	-1.31 (0.41)	0.002	-0.01 (0.04)	-0.13 to 0.05	0.34
Social support	CC	0.07 (1.10)	0.951	0.06 (0.04)	0.165	-1.21 (0.49)	0.014	0.00 (0.08)	-0.14 to 0.20	0.44
	BCF	0.31 (0.88)	0.725	0.08 (0.04)	0.031	-0.92 (0.39)	0.022	0.02 (0.08)	-0.11 to 0.22	0.52
	EM	-0.79 (0.91)	0.386	0.05 (0.04)	0.138	-1.31 (0.40)	0.001	-0.04 (0.07)	-0.27 to 0.04	0.37
Intention	CC	1.20 (1.57)	0.448	0.02 (0.03)	0.588	-1.28 (0.50)	0.011	0.02 (0.06)	-0.05 to 0.24	0.42
	BCF	1.14 (1.28)	0.375	0.03 (0.03)	0.211	-0.89 (0.40)	0.028	0.04 (0.06)	-0.04 to 0.25	0.50
	EM	0.58 (1.27)	0.650	0.02 (0.03)	0.515	-1.32 (0.41)	0.001	0.01 (0.05)	-0.04 to 0.17	0.34
Planning	CC	0.18 (2.41)	0.942	-0.02 (0.02)	0.423	-1.26 (0.49)	0.012	0.00 (0.07)	-0.18 to 0.11	0.43
	BCF	-0.63 (1.95)	0.749	-0.02 (0.02)	0.359	-0.87 (0.40)	0.032	0.01 (0.05)	-0.05 to 0.19	0.50
	EM	0.21 (1.97)	0.916	-0.01 (0.02)	0.524	-1.31 (0.40)	0.001	0.00 (0.05)	-0.14 to 0.07	0.35
Behavioural mediators										
MVPA	CC	67.06 (59.57)	0.263	-0.001 (0.001)	0.473	-1.28 (0.49)	0.011	-0.04 (0.07)	-0.29 to 0.04	0.43
	BCF	40.15 (47.58)	0.400	-0.001 (0.001)	0.099	-0.84 (0.40)	0.039	-0.05 (0.06)	-0.25 to 0.04	0.50

Results from mediation analyses based on complete cases (CC), baseline carried forward (BCF) and expectation maximisation (EM)

		a (SE)	р	b (SE)	р	c' (SE)	р	ab (SE)	95% CI	R <sup>2</sup>
	EM	62.44 (46.24)	0.179	-0.001 (0.001)	0.408	-1.31 (0.41)	0.002	-0.04 (0.06)	-0.23 to 0.04	0.35
SHI	CC	-1.41 (0.69)	0.042	0.13 (0.06)	0.050	-1.05 (0.49)	0.036	-0.18 (0.15)	-0.62 to -0.003	0.44
	BCF	-1.14 (0.60)	0.060	0.15 (0.05)	0.005	-0.69 (0.40)	0.083	-0.17 (0.11)	-0.46 to -0.01	0.52
	EM	-2.26 (0.71)	0.002	0.11 (0.04)	0.020	-1.08 (0.41)	0.009	-0.24 (0.13)	-0.58 to -0.05	0.37
DV = SHI										
<b>Psychosocial Mediators</b>										
Self-efficacy	CC	-0.40 (0.80)	0.617	-0.03 (0.09)	0.753	-1.69 (0.76)	0.028	0.01 (0.13)	-0.17 to 0.46	0.60
	BCF	-0.09 (0.64)	0.892	0.00 (0.08)	0.999	-1.07 (0.61)	0.078	0.00 (0.10)	-0.19 to 0.25	0.71
	EM	-0.47 (0.66)	0.477	-0.14 (0.09)	0.104	-2.25 (0.71)	0.002	0.07 (0.14)	-0.10 to 0.55	0.42
Perceived capability	CC	-0.91 (0.88)	0.301	-0.14 (0.08)	0.075	-1.80 (0.76)	0.019	0.13 (0.19)	-0.10 to 0.73	0.61
	BCF	-0.67 (0.70)	0.343	-0.12 (0.07)	0.081	-1.17 (0.60)	0.055	0.08 (0.14)	-0.10 to 0.54	0.72
	EM	-0.68 (0.71)	0.341	-0.24 (0.08)	0.003	-2.37 (0.70)	0.001	0.16 (0.19)	-0.13 to 0.66	0.44
Outcome expectations	CC	-0.19 (1.53)	0.900	0.00 (0.05)	0.962	-1.82 (0.77)	0.020	0.00 (0.08)	-0.16 to 0.18	0.60
	BCF	0.31 (1.20)	0.796	0.00 (0.04)	0.973	-1.17 (0.61)	0.056	0.00 (0.06)	-0.14 to 0.12	0.71
	EM	-1.24 (1.23)	0.314	-0.03 (0.05)	0.517	-2.32 (0.72)	0.002	0.04 (0.10)	-0.06 to 0.39	0.41

		a (SE)	р	b (SE)	р	c' (SE)	р	ab (SE)	95% CI	R <sup>2</sup>
Outcome expectancies	CC	0.18 (0.76)	0.814	0.02 (0.09)	0.842	-1.86 (0.74)	0.014	0.00 (0.08)	-0.12 to 0.22	0.62
	BCF	0.36 (0.61)	0.556	0.05 (0.08)	0.492	-1.19 (0.59)	0.046	0.02 (0.08)	-0.06 to 0.32	0.72
	EM	-0.04 (0.61)	0.951	-0.04 (0.09)	0.640	-2.30 (0.71)	0.001	0.00 (0.07)	-0.12 to 0.18	0.42
Environment (PND score)	CC	-0.03 (0.08)	0.733	-0.03 (0.82)	0.974	-1.67 (0.76)	0.030	0.00 (0.09)	-0.15 to 0.22	0.60
	BCF	-0.02 (0.07)	0.802	0.18 (0.73)	0.807	-1.10 (0.61)	0.072	0.00 (0.07)	-0.17 to 0.12	0.71
	EM	0.02 (0.07)	0.754	-0.85 (0.78)	0.276	-2.19 (0.71)	0.003	-0.02 (0.09)	-0.35 to 0.08	0.41
Social support	CC	-0.17 (0.11)	0.882	-0.02 (0.06)	0.723	-1.82 (0.75)	0.017	0.00 (0.09)	-0.15 to 0.23	0.61
	BCF	0.31 (0.88)	0.723	0.01 (0.05)	0.797	-1.11 (0.60)	0.065	0.00 (0.06)	-0.08 to 0.21	0.72
	EM	-0.79 (0.90)	0.385	-0.06 (0.06)	0.304	-2.27 (0.70)	0.002	0.05 (0.10)	-0.06 to 0.41	0.42
Intention	CC	0.83 (1.60)	0.604	0.01 (0.04)	0.802	-1.74 (0.75)	0.022	0.01 (0.08)	-0.08 to 0.27	0.61
	BCF	1.14 (1.28)	0.376	0.03 (0.04)	0.502	-1.12 (0.60)	0.065	0.03 (0.08)	-0.06 to 0.30	0.72
	EM	0.57 (1.27)	0.652	-0.02 (0.04)	0.651	-2.21 (0.71)	0.002	-0.01 (0.07)	-0.21 to 0.08	0.41
Planning	CC	-0.26 (2.44)	0.916	-0.00 (0.03)	0.874	-1.72 (0.76)	0.025	0.00 (0.081)	-0.17 to 0.18	0.60
	BCF	-0.63 (1.95)	0.746	-0.01 (0.02)	0.715	-1.14 (0.60)	0.060	0.01 (0.07)	-0.10 to 0.18	0.71
	EM	0.21 (1.97)	0.913	-0.02 (0.03)	0.471	-2.25 (0.71)	0.002	0.00 (0.08)	-0.21 to 0.13	0.41

Results from mediation analyses based on complete cases (CC), baseline carried forward (BCF) and expectation maximisation (EM)

*Note.*  $CC = Complete case analysis; BCF = missing values replaced using baseline carried forward; EM = missing values imputed using estimation maximization; <math>(100*R^2) = \%$  variance explained; numbers in bold font indicate a statistically significant effect.

## Table 7.S2

	Comple	ete cases	Baseline car	ried forward	Expectation	maximisation
	IG (n = 59)	WLC (n = 66)	IG (n = 80)	WLC (n = 80)	IG (n = 80)	WLC (n = 80)
Outcomes						
Physical activity	363.9 (348.80)	312.4 (336.34)	316.12 (323.66)	290.8 (315.86)	363.9 (298.86)	312.4 (305.09)
Sleep quality	6.7 (3.81)	8.0 (3.16)	7.5 (3.85)	8.4 (3.20)	6.7 (3.26)	8.0 (2.85)
Sleep hygiene	29.7 (6.37)	32.0 (6.52)	30.7 (7.21)	31.9 (6.81)	29.7 (5.46)	32.0 (5.87)
Mediators						
Physical Activity						
Self-efficacy	14.3 (9.08)	17.2 (8.91)	15.5 (9.17)	17.3 (8.42)	14.3 (7.78)	17.3 (8.03)
Behavioural capability	6.1 (3.19)	6.5 (2.63)	6.3 (3.02)	6.3 (2.87)	6.1 (2.73)	6.6 (2.38)
Outcome expectations	17.3 (4.79)	18.2 (3.66)	17.3 (4.77)	17.9 (4.06)	17.3 (4.10)	18.2 (3.30)
Outcome expectancies	12.3 (2.59)	13.0 (1.97)	12.6 (2.53)	12.9 (2.09)	12.3 (2.22)	13.0 (1.77)
Environment	7.8 (2.88)	8.8 (2.73)	8.2 (2.80)	8.7 (2.78)	7.8 (2.47)	8.8 (2.46)
Social support	5.8 (3.72)	6.7 (3.66)	6.3 (3.78)	6.5 (3.71)	5.7 (3.19)	6.7 (3.30)
Intention	4.4 (1.47)	4.0 (1.55)	4.5 (1.51)	4.1 (1.51)	4.4 (1.26)	4.0 (1.39)
Planning	12.7 (7.52)	10.8 (7.92)	12.1 (7.78)	10.5 (8.04)	12.7 (6.44)	10.9 (7.16)

Mean (SD) values of outcome and mediator variables at 3 months based on complete case, baseline carried forward and imputed data

Sleep

Self-efficacy	23.5 (4.87)	23.4 (5.74)	24.0 (5.64)	23.2 (5.60)	23.5 (4.17)	23.4 (5.17)
Behavioural capability	26.0 (5.75)	26.1 (5.43)	26.0 (5.73)	25.7 (5.46)	26.0 (4.93)	26.1 (4.89)
Outcome expectations	40.9 (9.45)	43.0 (10.27)	41.4 (10.03)	42.6 (10.00)	40.8 (8.09)	43.0 (9.24)
Outcome expectancies	20.4 (4.43)	20.5 (5.20)	20.5 (4.80)	20.3 (5.15)	20.4 (3.80)	20.5 (4.68)

# Table 7.S2

Mean (SD) values of outcome and mediator variables at 3 months based on complete case, baseline carried forward and imputed data

	Comple	te cases	Baseline ca	rried forward	Expectation maximisation		
	IG (n = 59)	WLC (n = 66)	IG (n = 80)	WLC (n = 80)	IG (n = 80)	WLC $(n = 80)$	
Environment	4.0 (0.75)	3.9 (0.83)	4.0 (0.71)	3.9 (0.78)	4.0 (0.65)	3.9 (0.75)	
Social support	24.5 (6.70)	25.1 (8.16)	25.8 (6.81)	25.2 (7.83)	24.5 (5.75)	25.1 (7.35)	
Intention	42.5 (7.70)	41.6 (11.22)	43.5 (8.10)	41.9 (10.77)	42.5 (6.59)	41.6 (10.10)	
Planning	28.0 (15.26)	27.9 (16.26)	27.2 (16.40)	28.1 (15.74)	28.0 (13.07)	28.0 (14.64)	

# **CHAPTER 8. DISCUSSION**

The Primary Aim of this thesis was to test the efficacy of a novel m-health intervention, the Synergy Study, to improve adults' physical activity and sleep quality in combination. To support the development and evaluation of this intervention, this thesis also had three Secondary Aims:

- to synthesise the evidence from sleep interventions to improve sleep health in adults without a clinically diagnosed sleep disorder and to describe the components and strategies used in these interventions;
- 2. to develop an instrument to assess the psychosocial determinants of sleep hygiene practice and examine its psychometric properties; and,
- 3. to examine a range of psychosocial and behavioural mediators of intervention efficacy in the Synergy Study.

Chapter 1 introduced the overall rationale for this thesis. Chapter 2 highlighted the health benefits of physical activity and sleep, the paucity of findings from studies that concurrently addressed physical activity and sleep health (specifically in sub-clinical populations) as well as the potential mechanisms that contribute to the efficacy of such interventions. Chapters 3 through 7 described a series of individual studies, each of which related to one of the overarching aims specified above. Each of the chapters provided a detailed study rationale and description of methods, a presentation and discussion of results including associated strengths and limitations. Consequently, Chapter 8 provides a study-by-study summary inclusive of the strengths and limitations of each study and provides practice recommendations and directions for future research in the context of the broader literature. The final section of this chapter lists the main implications that arise from this body of work, followed by concluding remarks.

# 8.1. Systematic review and meta-analysis

#### 8.1.1 Study aim and rationale

A systematic review and meta-analysis of cognitive and behavioural interventions to improve sleep health in adults without sleep disorders was conducted to address the lack of evidence on the effectiveness of sleep interventions in this population group (Secondary Aim 1). The study was presented in Chapter 3.

#### 8.1.2 Study summary

From 18,009 identified studies, only a small number (n = 11) targeted poor sleep health in adults without clinical sleep disorders. The 11 studies provided data from over 1000 participants, most of whom identified as otherwise healthy students or working individuals. The studies were conducted in developed countries (e.g., Germany, UK and USA) and varied substantially with regards to sample size, intervention components, study duration and mode of delivery. Only two of the 11 studies used a remote mode of delivery (online programme). Attrition rates were low (12–16%) and none of the studies reported any adverse events. Studies assessed intervention efficacy at 2–10 weeks, with few (n = 3) reporting longer term follow-ups (3–24 weeks post intervention).

Random-effects models were used to meta-analyse data that were extracted from the selected studies. Seven of the included studies assessed overall sleep health (PSQI) as an outcome, and interventions produced significant medium-sized improvements in overall sleep quality (g = -0.54). The studies were also effective for improving subjective sleep quality (g = -0.21) and sleep duration (g = -0.32). No significant intervention effects were found for any of the other outcomes that were pooled (i.e., sleep onset latency, sleep efficiency, sleep disturbance, use of sleep medication and daytime dysfunction). The small number of studies (n = 3) that reported results from long-term follow-up assessments were consistent in that they showed sleep quality (PSQI) continued to improve after the interventions had ended. The pooled estimate for overall sleep quality was significantly moderated by baseline sleep quality, with greater improvements seen in those who reported poorer sleep quality at baseline, which is commonly observed [1,2]. None of the other pre-specified moderators (i.e., number of intervention components, participant age, primary intervention focus) were statistically significant. With an average of four intervention components per study, frequently used components were relaxation, stimulus control, sleep hygiene and exercise. The level of detail in the reporting of behaviour change techniques (BCTs) used in these interventions was too limited to draw definitive conclusions on the impact of individual BCTs. The most frequently reported BCTs however, were providing instructions on how to perform the behaviour, providing information on where and when to perform the behaviour and action planning. These results provided evidence that supports the use of cognitive and behavioural interventions to improve sleep health in adults without a clinically diagnosed sleep disorder.

This systematic review and meta-analysis had several strengths. It appears to be the first synthesis of evidence on this topic specific to sub-clinical population groups. The search strategy used was comprehensive and spanned four major databases, which maximised the breadth of literature considered for inclusion in this review. It also sought to extract and synthesise intervention strategies (BCTs) using established frameworks [3] and identified that studies need to improve the reporting of intervention strategies. Moreover, the reviewers achieved excellent levels of agreement for all phases of screening, study selection and for the assessment of study quality. Some of the factors that limited the generalisability of findings from this review were the exclusion of studies published in languages other than English and synthesis of a small number of studies that had high levels of heterogeneity (e.g., study design, intervention components). Generalisability of included studies was also limited by the homogeneous study samples recruited and poor reporting of intervention characteristics. The conclusions should be interpreted in light of these limitations.

#### 8.1.3 Recommendations and future research

A systematic review of internet-delivered CBT-I interventions to treat insomnia highly recommended the development of accessible low-cost treatments, given the high prevalence of sleep problems in the adult population [4]. This review suggested the relative effectiveness of individual components that comprise CBT-I should be examined to identify scalable treatment options for chronic insomnia [4]. Although most of the interventions identified in Chapter 3 appear suitable for administration either in face-to-face format or using m-health, it is not known if sub-clinical population groups require full CBT-I or if comparable benefits could be achieved from partial CBT-I. Thus, examining the relative effectiveness of individual components would also be useful in a sub-clinical context.

This systematic review with meta-analysis underlined the importance of interventions that specifically target adults with poor sleep health, who did not have clinical sleep disorders, and showed that such interventions yield significant improvements in sleep health. Future interventions however, should aim to further enhance intervention efficacy to achieve healthy post-intervention levels of sleep (i.e., PSQI <5), which the majority of included studies did not achieve. The intervention components identified in this review do not require to be delivered by a clinician, and are suitable for implementation in the form of m-health interventions to increase accessibility and reduce costs associated with treatment, which are

known limitations of face-to-face interventions [5,6]. Inclusion of a cost-effectiveness analysis in future research could provide useful information in this context.

Although physical activity is known to improve sleep health [7,8], many of the reviewed studies appeared to promote physical activity without providing specific strategies to help participants actually engage in and maintain their physical activity levels. It is likely that without these specific strategies, meaningful improvements in physical activity are less likely to occur [9]. Hence, there is reason to believe that some interventions yield little to no effect on sleep health from simply promoting regular exercise. Therefore, additional studies are needed that actively target physical activity using evidence-based strategies, rather than leaving it up to participants to select and implement their own strategies [9]. Further research is also required to determine the amount, types and/or frequency of physical activity that is needed (dose-response) to stimulate meaningful changes in sleep health [10].

Based on what was reported in the studies included in the review, the implementation of strategies (e.g., types of BCTs) was in some parts consistent with previous BCT audits of interventions [11,12]. However, the types of BCTs most frequently reported in the review (i.e., providing instructions on how to perform the behaviour, providing information on where and when to perform the behaviour and action planning) were notably different to those strategies most commonly identified in interventions targeting physical activity or diet (i.e., goal-setting, self-monitoring, feedback) [13]. It is possible this was due to the choice of implemented intervention components (e.g., stress management techniques), which may have been more suited to strategies pertaining to knowledge and capability, rather than intention and volition. Moreover, none of the studies used m-health systems including smartphone apps, for which it is typical to include efficacious BCTs such as goal-setting and self-monitoring [14-16]. With up to 16 BCTs per study, many of the included studies reported using a relatively large number of BCTs. Interventions that use a larger number of BCTs are known to be more effective at improving single behaviours compared to those using fewer BCTs ( $\beta = 0.36$ , p < 0.001) [17]. However, the evidence also indicates this may not translate to multiple behaviour interventions (e.g., PA and diet) [17]. A meta-analysis that examined the *active ingredients* of 224 behaviour change interventions found that it is the clustered incorporation of theoretically aligned BCTs (irrespective of the overarching theoretical model) that determines intervention effectiveness [18]. As noted, several of the BCTs did indeed align with the overall

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intervention approach; however, given the large number of BCTs reported in some of the included studies, some of them may not have been as strongly aligned with the intervention approach. As reported for a considerable number of physical activity interventions, the use of combinations of BCTs that are not meaningful was shown to have a negative influence on intervention effectiveness [19]. This suggests that future interventions should be carefully conceptualised using harmonised clusters of BCTs, rather than aiming to incorporate as many BCTs as possible.

It needs to be acknowledged that the partially inadequate and ambiguous reporting of the synthesised interventions may have resulted in an overview of BCTs that does not truly reflect the strategies that were operationalised, which is a well-known issue [20,21]. The future reporting of components and strategies used in interventions therefore needs to be improved and this may be achieved by utilising established taxonomies and frameworks to guide the selection and detailed descriptions of interventions [22]. Given the scarcity of evidence from studies that specifically target sub-clinical population groups, additional studies are needed to further investigate which strategies are most important in changing cognitions and behaviours to promote good sleep health. More evidence from studies that use an m-health approach may further elucidate the full potential of this mode of delivery in a sleep context, in particular with regard to scalability. Additionally, there is a need for studies that recruit more diverse samples, have a longer duration and also assess the maintenance of changes in the longer term (e.g., >10 weeks). Taken together, this knowledge will help determine which interventions are most effective at improving sleep health in the wider population.

# 8.2 Instrument development and psychometric evaluation

#### 8.2.1 Study aim and rationale

This study aimed to develop a set of scales to assess the psychosocial determinants of sleep hygiene and examine the psychometric properties of the scales. This work addressed the lack of available instruments to assess these factors in a sleep context (Secondary Aim 2). The study was presented in Chapter 4 of this thesis.

#### 8.2.2 Study summary

A total of seven scales were developed assessing the following pre-specified psychosocial constructs: self-efficacy, perceived behavioural capability, outcome expectations, outcome expectancies, social support, intention and planning. Each scale contained nine items and each item assessed a different component of sleep hygiene (e.g., avoiding caffeinated beverages in the late afternoon or right before bedtime, exercising regularly, reducing stress levels). Altogether, the seven scales contained a total of 63 items. The scales' unidimensionality was assessed using principal component analyses (PCA), internal consistency was assessed using Cronbach's alpha and test-retest reliability was assessed using intra-class coefficients.

The scales generally had unidimensional component structures, good to excellent internal consistency ( $\alpha = 0.76-0.92$ ) and good to excellent test-retest reliability (ICC = 0.61-0.84). The instrument developed in this study assessed the psychosocial determinants of sleep hygiene practice with acceptable validity and reliability and the values observed for construct validity, internal consistency and test-retest reliability were consistent with those that are typically observed for instruments assessing psychosocial determinants of health behaviour [23-25].

Previous research appears to have used items that only assess a small number of constructs at a time, and likewise, only include a subset of sleep hygiene domains [25]. Thus, the instrument presented in this thesis is, by comparison, more comprehensive. However, some limitations need to be noted. The items were adapted from existing items that were used to assess psychosocial determinants of other health behaviours (i.e., physical activity and diet), rather than using alternative scale development methods that develop entirely new items [26]. This may have limited the coherence and applicability of items to some degree [27]. However, the effect of this was not apparent in the scales' internal consistency, which ranged from  $\alpha = 0.76$  to 0.92.

The lack of previously developed and comparably extensive instruments could be attributed to the degree of variability in the relevance (e.g., perceived importance, current practices) participants associate with different sleep hygiene recommendations, combined with a high level of specificity in the wording required for sleep hygiene recommendations to be appropriate. For example, a given behaviour (e.g., drinking

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caffeinated beverages) does not necessarily have to be fully avoided, but should be limited to certain hours of the day (i.e., not within six hours before going to bed) to reduce its negative effect on sleep [28,29]. It is acknowledged that it was not possible to overcome all of these challenges in developing this instrument. To enhance content validity, the items asking participants about their thoughts and feelings about smoking in relation to sleep were omitted from the analyses, as only a very small proportion (7.4%) of participants were smokers. Hence, it might be useful to work towards developing an instrument that allows for individual preferences (e.g., use of skip logic if a person does not smoke or consume caffeinated beverages), and similarly, each sleep hygiene recommendation should be tailored to an individuals' needs and preferences when used as part of treatment [28]. Notably, the findings from this study showed comparable mean values across all scales between the two samples that were used, despite one sample having anticipated commencing an intervention, while the other sample merely served the purpose of a test-retest study population. This indicates that participants' level of readiness to commencing an intervention had little impact on the performance of the scales.

#### 8.2.3 Recommendations and future research

The overall psychometric qualities established in this study suggest the scales may be useful in understanding the role of psychosocial determinants in the context of sleep hygiene practice, including examining such factors as mechanisms of behaviour change (i.e., mediators of intervention efficacy). An improved understanding of these factors can help further enhance interventions by targeting factors that are most likely to contribute to the success of an intervention [30]. However, studies using larger samples are required to confirm the overall validity and reliability of the scales and address issues such as scale unidimensionality.

The developed scales assessed factors at both the individual level and the bedroom environment, however there is evidence that sleep is also influenced by factors at the wider environmental level (i.e., socioeconomic disparities, urban design) [31,32]. As such, it may be useful to develop measures to assess factors at these broader levels, as seen in previous research on physical activity and sedentary behaviour (i.e., studies on neighbourhood and workplace level) [33-35]. Further, it would be useful to examine the interaction between determinants at different levels (e.g., individual level determinants

such as sociodemographics and environmental level determinants such as characteristics related to urban design, such as traffic or noise). This could provide important insights into the complex interplay of determinants as seen for physical activity [36,37].

# **8.3 Evaluation of intervention efficacy (Study outcomes)**

#### 8.3.1 Study aim and rationale

After the development of the Synergy Study, its efficacy was evaluated in a randomised waitlist-controlled trial (Primary Aim) including a sample of insufficiently physically active adults with poor sleep health, but without diagnosed sleep disorders. This trial addressed the paucity of studies that have targeted physical activity and sleep in combination using an m-health intervention. The study rationale, development and methods of the intervention were described in Chapter 5. The main outcomes of the study were presented in Chapter 6. In addition to a summary of the findings reported in Chapter 6, this section also presents supplementary, previously unpublished process data that are intended to support the overall conclusions made herein.

#### 8.3.2 Study summary

The Synergy Study was a novel, theory-based m-health intervention that concurrently targeted adult physical activity and sleep health, both of which are recognised public health priorities [38–40]. The intervention promoted behaviour change through the use of BCTs that were selected to complement each other and aligned with the theoretical framework. This included educational resources, goal-setting, self-monitoring, and feedback strategies, which were supplemented by personalised support (i.e., weekly reports, tool sheets, prompts) for 12 weeks. Moderate-and-vigorous intensity physical activity (MVPA) and sleep quality (PSQI) were specified as co-primary outcomes.

The Synergy Study yielded improvements in a number of outcomes related to physical activity and sleep health. At three months (primary endpoint), a baseline-adjusted between-group difference in MVPA of 109 minutes favoured the intervention but was not statistically significant. However, significantly more participants in the intervention group engaged in  $\geq 2$  days/week of resistance training and a larger proportion of participants in the intervention group met guidelines for the weekly amount of aerobic exercise and resistance training. The significant improvements in resistance training,

which on their own confer unique health benefits [41], can be considered an encouraging result. Moreover, participants in the intervention group reported significantly greater improvements in overall sleep quality, subjective sleep quality, sleep onset latency, wake time variability, sleep hygiene practice and insomnia severity, than participants in the waitlist-control group. Taken together, these findings indicate that a combined physical activity and sleep intervention yields short-term (i.e., three to six months) improvements in multiple outcomes.

The research outputs from the Synergy Study have added important findings to the evidence base. The trial addressed some of the important limitations of previous physical activity and sleep interventions (as summarised in Chapter 2), in that it:

- recruited adults who reported poor sleep health, but did not have a diagnosed sleep disorder;
- incorporated multiple theory- and evidence-based components; and,
- used a mode of delivery (m-health) with a high level of accessibility, which allowed for inclusion of participants in rural and very remote areas, who tend to have poor access to health services [42].

The Synergy Study specifically excluded individuals with clinically diagnosed sleep problems. However, baseline scores on the Insomnia Severity Index indicated that 9.4% reported non-significant symptoms, 63.1% reported symptoms below the threshold and 27.5% reported symptoms of clinical severity. Eligibility screening omitted participants with doctor-diagnosed sleep disorders. However, this finding suggests future studies should also screen for potentially undiagnosed disorders. Due to the logistical and financial restraints associated with conducting the trial as part of a PhD, this was not done in the current study. Intervention group participants reported reduced insomnia symptom severity and between-group differences were statistically significant at three months (d =0.57) and at six months (d = 0.69). At six months, the difference between groups was 2.9 points, which is similar to the estimates (MD = 3.2 points) reported in a systematic review and meta-analysis of exercise interventions to improve sleep quality in chronic insomniacs [8]. However, for samples with chronic insomnia (i.e., more severe symptoms), it is reasonable to expect improvements of a magnitude larger than what would be observed in sub-clinical population groups. Given the average baseline symptom severity below the clinical threshold, the magnitude of change observed in the

Synergy Study emphasises the benefit of a combined intervention that targets physical activity and sleep health simultaneously and provides specific strategies for both behaviours. This was further supported by the moderate-to-large effect size (d = 0.74) for daytime sleepiness at six months, which is an important indicator of improved sleep health [43].

The majority of sleep hygiene interventions merely provide educational content (i.e., information about the importance of sleep hygiene and what it is comprised of), which tends to have limited efficacy [44]. To address this, the Synergy Study not only provided information on why and how to be active/improve sleep health, but also asked participants to set individual goals and self-monitor the number of sleep hygiene goals accomplished on a daily basis. This component proved efficacious as shown by statistically significant between-group differences and medium-sized effects (d = 0.42) for the sleep hygiene outcome.

Stress management is known to be an effective intervention to improve sleep health [45,46]. Physical activity combined with the stress management techniques provided in the Synergy Study may have contributed to reductions in perceived stress levels, which in turn may have contributed to improvements in sleep quality [47,48]. Thus, it is important for interventions that target sleep health to provide specific strategies supporting participants in managing stress. Although not statistically significant, the systematic review and meta-analysis of cognitive and behavioural interventions (Chapter 3) to improve sleep health showed that interventions with the primary objective to reduce stress to elicit changes in sleep health reported smaller improvements in sleep quality (g = -0.42) relative to interventions, which had placed their focus on improving sleep by way of multi-component strategies, one of which may have been stress management (g = -0.70). Consistent with this, Synergy used a multi-component approach and demonstrated medium-size differences in stress symptom severity in favour of the intervention group at three and six months.

As part of the development phase for the Synergy Study, modifications to an existing mobile app were made using process data and participant feedback available from a pilot study [49]. Participants were advised to work towards overarching goals as per national guidelines (15 min/week of MVPA and two days of resistance training and 7–9h of sleep per night). However, one of the major app modifications was that feedback was generated

in relation to individually set goals, rather than using a single standardised reference value. This was operationalised in the app using a traffic light feature, which half of participants (49%) agreed was useful. Interestingly, when participants were asked which aspect of the intervention they liked best, only 34% selected the autonomy of being able to do as much or as little as they can do/like to do. However, due to the format of this question, this did not necessarily indicate that participants would have preferred a less autonomous format, due to other aspects having been perceived as similarly important (i.e., being able to log activity and sleep to track progress over time: 31%; using a pedometer: 14%; receiving reminders/prompts: 12%; other aspects: 9%). The evidence endorses the use of personalised goals and a non-restrictive approach to how participants reach their goals (i.e., activity types based on personal preference) [50]. This may in turn foster motivation and produce greater improvements in the target behaviour.

Self-monitoring was one of the key strategies used to promote behaviour change in the Synergy Study. Participants received pedometers to self-monitor their steps and were asked to record their daily step count in the app. However, participants still had to recall and manually enter minutes of moderate- and vigorous-intensity physical activity and resistance training, sleep and wake times into the app, select a sleep quality rating and the sleep hygiene items practiced on the previous day. There is some evidence to support the use of so-called wearables (e.g., Fitbit) for automated activity tracking [51]. However, the validity of commercially available wearables to estimate sleep has been questioned [52]. Further, due to cost and feasibility, it was decided participants would not receive wearables to self-monitor their behaviours. In comparison, the use of pedometers provides better accuracy and is associated with significant improvements in physical activity [13,53]. Interestingly, during semi-structured interviews with participants (n = 8; unpublished data), half of interviewees indicated they would have preferred having a device (e.g., Fitbit) that automatically enters data into the app for them. This preference was more common amongst younger participants, who also indicated being aware that commercially available systems are capable of automatic data synchronisation and this was perceived as a convenient feature that also reduces issues related to recall. Automated data entry may be associated with a lower participant burden. However, the intervention group as a whole (n = 59) indicated they did not find the manual data entry procedures too time-consuming or overly burdensome (i.e., 70% agreed it did not take much time to

use the app to track behaviours). This may indicate that manual data entry in m-health interventions is acceptable to participants.

The BCTs (i.e., goal-setting, action planning, self-monitoring and feedback) that were operationalised in the Synergy Study are known to be effective in the short term when implemented in this specific combination [54-56]. However, it is possible that the maintenance of improvements after the three-month time point required different strategies than those provided. This includes strategies that are known to stimulate habit formation, such as the promotion of positive emotions (including rewards), personal satisfaction, self-determination and the ability to apply coping strategies [57]. An intervention design that provides intermittent bolstering or gradually intensifies over a longer period of time may encourage the maintenance of behaviour change [58]. Although the primary objective of the Synergy Study was to test intervention efficacy at three months, the long-term maintenance of behavioural improvement needs to be addressed in future studies. It also needs to be acknowledged the Synergy Study primarily focussed on behaviour change techniques that relate to processes at the intrapersonal level. Additional factors at the wider social, environmental and organisational levels that were unaccounted for may have acted as barriers, regardless of an individual's strong intentions to pursue their personal goals.

The evaluation of app usage (total number of days on which data were logged and average time to non-usage attrition) showed that participants indicated the app had good usability and this may have contributed to app usage with averages exceeding 30 days for both cumulative usage and time to non-usage attrition (no periods of non-usage lasting longer than 14 consecutive days). However, no formal analyses were conducted that examined how different patterns of app usage affected behaviour change and if this differed between physical activity and sleep. Previous web-and app-based physical activity studies have provided evidence for a linear relationship between study duration and non-usage attrition, and show that large proportions of participants abandon data entry in such studies (e.g., >75% after two months) [59,60]. Nonetheless, there are no published data to demonstrate the optimal length of an app-based intervention in relation to behaviour change in general. This is an area of interest in m-health and further knowledge on the role of usage, engagement and behaviour change will be key to optimising these interventions.

A limitation of the Synergy Study was that the generalisability of findings is confined to the predominantly middle-aged females of relatively high socio-economic status, who self-selected to take part in the study in response to online advertising. The underrepresentation of male participants is a commonly reported limitation in health behaviour interventions [61,62]. It is possible that specific recruitment strategies as well as tailored content and information are required to attract more males to take part in trials that target modifiable risk behaviours (i.e., physical activity, poor sleep). Population data show that levels of physical inactivity and poor sleep health are high in those with poor socioeconomic status [63,64]. However, mobile phone ownership tends to be high across all population groups, regardless of socioeconomic status [65], potentially making an intervention like the Synergy Study an accessible solution for individuals with low socioeconomic status.

Dropout rates between baseline and three months were within the anticipated range (25%) and none of the study participants reported adverse events as a result of participating in the trial. In comparison, average attrition rates in sleep-only interventions, as reported in the systematic review (Chapter 3), are much lower (12–16%). However, the studies that were included in the systematic review on average had a shorter duration (5 weeks) than the Synergy Study (12 weeks) and a shorter study duration is commonly associated with lower participant dropout rates [66,67]. In comparison, physical activity interventions with a duration similar to that of the Synergy Study report average attrition rates of 20– 25% [68,69]. This could also indicate some underlying differences that are unique to each behaviour, which may have influenced the attrition rate observed in the Synergy Study. In addition, all except for two of the synthesised studies were delivered face-to-face, and attrition levels are known to be higher in technology-based studies [68,70]. These factors may also explain the substantially greater amount of loss to follow-up at the six-month time point (44%). Alternatively, it could be that the length of the online surveys in addition to the lack of personal contact during assessments contributed to low response rates [71,72]. Future studies may be able to reduce loss-to-follow-up at secondary time points and beyond by reducing survey length or by making additional reminder contacts (e.g., telephone).

The use of self-report measures had unique implications for both co-primary outcomes in the Synergy Study. For minutes of moderate-to-vigorous intensity physical activity (measured using the Active Australia Survey [73]), a statistically significant difference between groups was not detected. This was in part due to relatively high levels of selfreported physical activity at baseline, and larger than expected variation in activity levels at three months (M = 177.63; SD = 208.31), which may have reduced the power to detect significant group differences. Despite the strict cut-offs used for participant eligibility (i.e., <90 min/week), the observed baseline levels of physical activity indicated participants on average were sufficiently physically active (i.e., >150 min/week). This discrepancy, although noted in previous studies using similar measures [74,75], is undesirable and was likely due to the different measures that were used for each process. That is, a single-item measure was used for screening purposes, whereas the instrument (Active Australia Questionnaire) used for baseline assessments consisted of multiple items and sub-domains including recreational walking/transport, moderate-intensity physical activity (e.g., swimming/golfing) and vigorous-intensity activity (e.g., cycling/jogging). It is possible that the number of items in an instrument has an influence on the cumulative total of reported physical activity, with more items leading to higher total values. To reduce the risk of participants making substantial changes independent of their participation in the trial prior to baseline, the time window between participant screening and baseline assessments was intentionally kept to a minimum. Given the average between those time points was 2.3 days (range = 0-10 days), it is more likely that baseline activity was a matter of low instrument accuracy at eligibility screening. This issue seems inherent to subjective measures as shown in studies that report low-tomoderate correlations between self-reported and objectively measured physical activity (M = 0.37 [SD 0.25]; range = -0.71 to 0.98) [76].

More accurate measures of physical activity are necessary to fulfil screening protocols and to warrant the evaluation of intervention efficacy based on the outcome measures used. Objective measurement may help overcome issues such as over-reporting, whilst also capturing different intensity levels of physical activity (e.g., light, moderate, vigorous) as well as the timing and patterns of physical activity a person engages in [77,78]. Further, this level of detail in the data could potentially offer valuable insights into how changes in physical activity influence sleep, and vice versa. However, objective measurement also has its limitations, including the application of cut-points to determine different physical activity levels (i.e., intensity), which can lead to misclassification errors [77,79]. In addition, currently available devices are unable to accurately assess resistance training [78]. The accuracy of estimates also depends on participants wearing the devices as any physical activity that is accumulated when an accelerometer is not worn (e.g., contact sports, swimming) is not recorded, and their costs (e.g., AU\$ 300–400 per unit) may can be problematic in small scale studies [80]. On the other hand, the use of the Pittsburgh Sleep Quality Index (PSQI) to assess the second co-primary outcome of sleep quality had advantages over objective measures (i.e., accelerometry, polysomnography). Especially in combination with other subjective measures, such as the Insomnia Severity Index that is frequently used in clinical sleep research, the PSQI is a cost-effective and reliable instrument which gives an account of multiple dimensions of sleep health. The PSQI does not require to be administered by trained staff, which is the case for polysomnographic assessment, and it also captures the perceived restorative effect of sleep, which objective assessment is not capable of doing [43,81]. Additionally, given its known robustness and extensive validation [81], the PSQI seems suitable for use in future trials.

#### **8.3.3 Process outcomes**

Due to time constraints, this thesis did not include a formal process evaluation study for the Synergy Study. Therefore, the following section will comment on a number of aspects (e.g., fidelity, participant satisfaction) that complement the efficacy outcomes presented in Chapter 6. These data were collected (via online survey and semi-structured interviews) from participants in the intervention group (n = 59) at the three-month time point.

#### Intervention fidelity

The remote design and delivery of intervention content via email allowed for maximal standardisation between participants. Continuous process monitoring and the scheduling of messages according to protocol ensured the intervention was delivered as intended. No adjustments had to be made to any of the processes that were planned, and the time frames selected for individual tasks (i.e., weekly summary, weekly facts) appeared appropriate and feasible. However, to reduce the overall burden on the research team given the total study duration, future studies in larger samples should aim to automate some of the processes that occur repetitively, such as the weekly summary report. No complaints were received that would have led to the conclusion that the intensity at which components

were delivered was perceived as excessive. Based on the successful implementation of all processes as per protocol, the Synergy Study can be considered suitable for administration to otherwise healthy adults, who report insufficient physical activity and poor sleep health, but do not have a diagnosed sleep disorder.

During the recruitment phase, it was noted a lot of interest was expressed by shift workers. However, any individuals who indicated working nightshifts or rotating shifts were excluded, as the strategies provided in the Synergy Study did not specifically address the unique challenges of shift work, particularly with regards to sleep. Future studies may explore to what extent the intervention and its contents require to be modified to suit the needs of a shift work population. This may require additional strategies that facilitate circadian adaptation, such as the regulation of food intake, napping routines and bright light exposure [82]. Likewise, individuals with more severe sleep problems may find an intervention like the Synergy Study insufficiently effective and there is a risk that individuals whose sleep problems are driven by excessive cognitive arousal (worry and rumination), rather than maladaptive practices (i.e., poor sleep hygiene) may find that strategies such as goal-setting and self-monitoring of sleep to feed into repetitive negative thought processes and thus, experience a perpetual worsening of their sleep problems [83].

#### Acceptability, usability and satisfaction

To examine the acceptability of the Synergy Study, participants in the intervention group (n = 80) were asked a number of questions regarding their reasons for participation in the study and what their experience was like. The most commonly selected reasons for choosing an online programme were ease of use (39%) and convenience (29%), both of which can be considered important aspects with regards to potential future scale-up. These perceptions were likely due to the study requiring no visits to a research centre and participants not having to commit to any scheduled appointments, other than the online surveys at three and six months. As reported in previous studies utilising smartphone technology, it is possible that perceptions relating to ease of use were directly related to participants' level of experience with and the resulting level of confidence in using a mobile app [84]. Participants in the Synergy Study reported high levels of internet self-efficacy scores (M = 46.8 [SD = 9.65]) out of a possible maximum score of 56, where higher scores indicate higher levels of internet self-efficacy). Thus, it is possible that

participants who are less confident with the use of smartphone apps are less likely to enrol in an m-health intervention due to concerns about ease of use.

The majority of participants (70%) agreed the app was useful in helping keep track of behaviours (physical activity and sleep). This may have been facilitated by the userfriendly app interface (indicated by 81%), with 93% of participants also stating that learning to use the app was easy. During semi-structured interviews, participants (n = 8)were asked to rate on a scale from zero to 10 (where higher ratings indicate greater satisfaction) to what extent the study met their expectations. With an average rating of seven points, the overall perception of the intervention was positive. However, less than half (49%) of participants indicated the app, which was a key intervention component, was useful in helping them change their behaviours. It is possible that this contributed to non-usage attrition, as participants did not observe the changes they anticipated. Previous research has highlighted that misalignments between participants' outcome expectancies/expectations and the outcomes the intervention is likely to produce can affect adherence rates as well as the magnitude of behaviour change achieved [85]. Therefore, future studies should explore additional strategies that help participants reconsider to what extent personal expectations are realistic and achievable and how likely the intervention is to meet these expectations.

The Balanced mobile app was considered the main intervention component. However, the extent to which participants utilised the app more or less than other components of the intervention (i.e., handbook, tool sheets, reports) and how this affected behaviour change, was not captured. Only 37% said they would like to keep using the app in the future. A plausible explanation for this is that the novelty factor of using the app was short-lived and that different strategies may have been required to encourage long-term use (e.g., chat function, social interaction with other participants, leader boards). As suggested in a systematic review, features that promote interaction and competition with others is associated with positive behaviour change [86]. These features are also frequently utilised in commercially available apps [87,88]; however, no definitive guidance is available that is based on user preferences in addition to the magnitude of behaviour change associated with specific features (BCTs). Given the duration of the intervention, participants may have felt confident that the information and strategies provided were sufficient to make changes without needing to log data on a daily basis or

at all. After the 6-month assessments, 21% (n = 17) of waitlist-control group participants logged enough data (i.e., one or more entries for at least one behavior) to receive at least one weekly summary report. However, it is possible they may have utilised other components, such as the participant handbook or tool sheets, which was not formally assessed. Therefore, the proportion of app users in the waitlist group may not give a full account of intervention uptake and overall engagement.

#### Intervention costs

No formal cost-effectiveness analysis was undertaken. Expenses associated with recruitment through social media advertising, newspaper and magazine editorials totalled approximately AU\$ 10,000, of which AU\$ 8,900 was spent on Facebook advertising through which 100% of the sample were recruited. Exclusive of the remaining advertising costs (e.g., magazine editorials), this equates to approximately AU\$ 56 per enrolled participant, which is higher than that reported in other studies [89]. There is a need to optimise recruitment strategies in future studies that seek to recruit larger samples. The use of different media (beyond Facebook) to reach potential participants may be useful. Further, the cost of app development should not be underestimated. Albeit a modification to an existing app, the total cost of the app development to date exceeds AU\$ 85,000 and researchers should be aware that funds are needed to cover the costs of ongoing app maintenance (e.g., device/software compatibility).

#### 8.3.4 Recommendations and future research

The above findings indicate that individuals participating in m-health behaviour change interventions value easy to use apps that allow for autonomous engagement and individual goal-setting. Although app usage data from the Synergy Study showed satisfactory levels of engagement, future studies should also analyse different app usage patterns in relation to behaviour change, and seek to introduce specific features (e.g., prompts, feedback) that foster patterns of engagement that maximise behaviour over time [90].

The systematic review presented in Chapter 3 showed a pooled effect of medium size for sleep quality (Hedge's g = g -0.54. [95% CI] -0.89 to -0.19, p < 0.01). The effect size for sleep quality observed in the Synergy Study was of similar size (d = 0.48). However, this effect size was lower than that used for the purpose of power calculations (d = 0.65),

which assumed a synergistic effect between physical activity and sleep, and this may have been overestimated. The outcomes reported from the Synergy Study provide initial support for the efficacy of an m-health intervention approach in a broader population; though further studies are needed to confirm this. Moreover, further multi-arm trials including a control arm are also needed. For example, in this two-arm randomised waitlist-controlled trial, it was not possible to show if improvements in physical activity have an additional effect on changes in sleep quality, as this would have required a separate group that received a sleep only intervention. Studies are underway to address this [91].

Process data from the Synergy Study indicate that improving both behaviours in combination is more of a priority to people than improving just one behaviour (when asked, 49% of participants said the main reason for enrolling was *to improve both behaviours together*, only 10% (PA) and 12% (sleep) said their reason for participation was *to improve a single behaviour*). This underpins the need for additional multibehaviour interventions, which are known to produce greater health outcomes than single behaviour interventions [92]. Further, practitioners are encouraged to promote physical activity and sleep health concurrently and utilise this as a pathway to address the high prevalence of both, insufficient physical activity and poor sleep health in the adult population.

Additional studies are needed to explore how interventions can successfully recruit more individuals of low socioeconomic status and if the content of multi-health behaviour interventions is perceived as useful and effective by these individuals. As shown by a study on the influence of socioeconomic status on the adoption, usage and usability, participants with lower socioeconomic status rate the usability of smartphone (i.e., iPhone) applications lower compared to those with higher socioeconomic status and also exhibit unique patterns of usage [93]. Thus, a greater diversity in sample characteristics may also demand additional modifications to acknowledge the above-mentioned differences and to ensure high levels of usage and usability.

Recruitment avenues other than social media may help reduce advertising costs and also reduce potential biases associated with recruitment through Facebook alone [94]. Future studies are encouraged to conduct formal cost-effectiveness evaluations to facilitate comparison between m-health interventions and other delivery modes, such as those

including face-to-face contact. Furthermore, it appears there are very little data on the cost-effectiveness of multi-behaviour interventions and none from studies that have combined physical activity and sleep [95]. Given the evidence for substantial reductions in medical costs for every additional health behaviour (i.e., risk factor) that is successfully intervened with [96], more information pertaining to cost in relation to outcomes could further support the use of m-health interventions targeting multiple behaviours.

A large proportion of empirical trials are efficacy trials, with fewer studies examining the effectiveness of an intervention in real-world settings or focussing on the scalability of a programme [97]. Future studies should examine the effectiveness of the intervention when delivered at scale. To test effectiveness and to increase the intervention's potential for scalability, it is necessary to determine if it is possible to use fully automated processes to reduce the need for researchers to manually analyse user data, generate feedback, send weekly reports and prompts. Further, studies should also test if individual intervention components can be removed to further increase programme scalability, without to compromise on its effectiveness. Alternatively, it would be interesting to examine if the findings from the Synergy Study can be replicated in specific population groups (e.g., shift workers, co-morbid individuals), which may be tested in future studies. This however requires a systematic approach to intervention adaptation, which can be structured using established frameworks [98].

# 8.4 Explanatory evaluation of intervention efficacy (Mediation)

#### 8.4.1 Study aim and rationale

The potential mechanisms of behaviour change in the Synergy Study were assessed to address the lack of evidence on mediators of intervention efficacy in multiple-behaviour interventions (Secondary Aim 3). The findings from this study were reported in Chapter 7.

#### 8.4.2 Study summary

A range of behavioural and psychosocial mediators of physical activity (MVPA), sleep quality and sleep hygiene were examined using bias-corrected bootstrapping in single mediator models following the procedures outlined by Preacher and Hayes [99]. Conclusions were based on analyses of imputed data (using Expectation Maximisation). At three months, the estimated between-group difference in MVPA (109 minutes/week) was not statistically significant, but meaningful from a public health perspective, as this could translate to an average participation in an additional 3 days of >30 minutes of MVPA each, which could help a significant proportion of individuals approach the recommended levels of physical activity [100]. This also indicates that within-group changes occurred following the intervention, which supports the merit of examining the potential factors that mediated these changes. The effect of the intervention was statistically significant for both of the specified sleep outcomes (sleep quality and sleep hygiene practices) in the mediation analysis. The psychosocial factors that mediated changes in MVPA were self-efficacy, perceived capability, environment, social support, intention and planning. All of these mediators, except for intention and planning showed inconsistent mediation (suppression) effects. None of the psychosocial factors mediated changes in sleep quality or sleep hygiene. Physical activity and sleep quality did not mediate each other, indicating an absence of a bi-directional effect, but sleep hygiene practices mediated sleep quality.

The strengths and limitations of the Synergy Study as such were outlined in section 8.3.2. Therefore, this section will focus specifically on the strengths and limitations of the methods used to test mediators of intervention efficacy in the Synergy Study.

A large number of studies have examined mediators of physical activity [101], yet very few have investigated which mechanisms play a role in changing sleep health and no previous studies have tested mediators in a combined physical activity and sleep intervention. This study sought to address this gap in the literature. For the future refinement and development of interventions to improve physical activity and sleep health in combination, it is important to determine the mechanisms that operate in such an intervention and if they differ between behaviours. Intervention content and components can be adapted by incorporating this knowledge to better target each behaviour.

Based on the models examining behavioural mediators, there was no evidence for a bidirectional relationship between physical activity and sleep quality. This finding is in contrast to several studies that examined this relationship using cross-sectional as well as longitudinal data [40,102,103]. In addition to the differences in analytical techniques used to examine this relationship, there may have been several other factors that explain this finding. First, it is possible that the magnitude of changes in physical activity participants reported was not sufficient to elicit changes in sleep quality and vice versa. The exact dose of physical activity needed to improve sleep health is unknown. However, some studies suggest that 60 minutes of daily aerobic exercise over the course of several months (i.e., 13 weeks) are required to alter multiple indicators of sleep health [104], while other studies note that much higher levels (i.e., 190 min/week of moderate intensity physical activity) are required [105]. Second, results from cross-sectional studies, which provide much of the evidence for a bi-directional relationship between physical activity and sleep (see Chapter 2, Section 2.3), do not always align with results from prospective studies, which may require a longer time to manifest [106]. In addition, prospective studies tend to use much larger samples [103]; hence, the sample size used in the mediation analyses based on data from the Synergy Study (n = 160) may not have been sufficiently powered for to detect this relationship and other methods such as cross-lagged study designs may be more useful for this purpose [107].

The mediation approach used in this study had several strengths. The study examined a comprehensive range of psychosocial factors based on psychosocial determinants theories (e.g., Social Cognitive Theory), which were operationalised in the Synergy Study. These factors were examined using a specifically developed set of scales that showed satisfactory levels of validity and reliability (as discussed in earlier sections of this chapter). Further, it acknowledged distal and proximal sleep outcomes and used a type of statistical analysis that is well established and can be used to test mediators in the absence of an intervention effect. There is a possibility that researchers have refrained from testing mediation effects in the past where a main intervention effect could not be detected. However, there is growing evidence that supports the notion that an intervention effect is not needed to justify the examination of potential mediators of behaviour change [108].

There were some limitations associated with this study that require discussion. Although the method of bias-corrected bootstrapping was employed, which is generally seen as a powerful method [109], it may have failed to fully account for the amount of variation in the data. Therefore, it is important to determine if these findings can be corroborated using larger datasets, which may increase precision. In addition, it would be interesting to also examine the hypothesised psychosocial mediators in the context of objectively measured outcomes (physical activity and sleep quality), which could provide a less biased account of changes in behaviour. This could in turn affect the observed strength of association between mediators and outcomes [110].

Moreover, the intervention led to a decrease in scores for factors such as self-efficacy, which were expected to increase following the intervention. So-called "suppression effects" have been reported in previous studies that examined mechanisms of behaviour change [111]. One possible explanation for such effects could be that participant's perceptions related to personal capability and control change following initial attempts at changing behaviour, as these appear much harder to sustain than anticipated at the outset [112]. A systematic review and meta-analysis of 180 physical activity interventions highlighted a number of challenges in the context of improving self-efficacy for physical activity and concluded that the extent to which individuals respond to specific strategies may vary for different population groups and that intervention effects on self-efficacy levels were generally small (d = 0.26) [19]. Thus, it is possible that improvements in MVPA would have been greater (and potentially significantly different between groups), had the intervention succeeded at increasing participants' self-efficacy levels. Ultimately, there may be strategies other than the ones implemented in the Synergy Study that foster an increase in self-efficacy. Nonetheless, it needs to be acknowledged that suppression effects can also indicate issues with the instruments used to measure hypothesised mediators [108]. This may suggest an additional limitation of the scales described in Chapter 4.

Although existing models are useful to inform which factors should be targeted to change a given behaviour, to date, there appear to be no theoretical frameworks specific to changing multiple health behaviours in combination and little evidence from studies that have explored this [113]. This further hindered the appraisal of findings from the Synergy Study against existing research, particularly with regard to both sleep outcomes. Moreover, due to sample size restrictions, no models including multiple mediators were considered in the mediation study presented in this thesis and it is possible that this would have resulted in different estimates (i.e., proportion of the effect that is explained by changes in a set of factors, rather than individual factors), especially if the hypothesised mediators are known to be inter-related, as was the case in this study [114]. Finally, this study only examined mediators of short-term intervention efficacy, using data from the immediate post-test at three months and therefore lacks an insight into mechanisms that could potentially play a role in the context of behavioural changes that occur in the longer term. Studies have shown that the mechanisms involved in the initiation of behaviour change may be different from those that contribute to the maintenance of behaviour change [115]. However, in line with the main objective and the primary endpoint of the Synergy Study (i.e., intervention efficacy at three months), the a priori specification of mediators (see Chapter 5) was focused on the initiation of behaviour change and not the maintenance.

#### 8.4.4 Recommendations and future research

Based on the findings from these analyses, researchers are encouraged to implement strategies (BCTs) specific to physical activity that foster intention and facilitate action planning. Future studies should seek to further examine the mediators that showed negative changes in the Synergy Study, as it remains unclear to what extent these factors would influence behaviour change in the absence of a suppression effect.

To identify potential mediators of sleep-related outcomes, studies may also extend their investigations to include constructs from other frameworks that are known to explain health behaviour and behaviour change (e.g., Self-Determination Theory, Theory of Planned Behaviour) [116]. More research is needed to confirm which mechanisms operate across behaviours, and whether specific clusters of mechanisms operate in parallel to change multiple behaviours. While it is important to identify the active mechanisms of an intervention, it is similarly important to determine moderators of intervention efficacy, as it is possible that there are specific subgroups (e.g., age, gender), for whom an intervention is more effective than for others. For example, there may be a difference in how effective a combined physical activity and sleep intervention is for individuals who report very low baseline levels of physical activity as well as severe sleep problems, compared to individuals who report moderate physical activity as well as poor sleep health. Cross-sectional data show the combination of insufficient physical activity and poor sleep health is prevalent in the adult population (28%) [117], which emphasises the need to better understand which mechanisms are key to improving these two behaviours in combination.

# 8.5 Implications for research and practice

The findings from this thesis embody a number of important contributions to the existing literature on m-health interventions and multiple health behaviour change research in the adult population. In light of the strengths and limitations of each study and the need to confirm some of these findings in future studies, as discussed in preceding sections of Chapter 8, the following section lists some of the key implications for research and practice.

# 8.5.1 Impact of the systematic review and meta-analysis of sleep interventions (Chapter 3)

- This synthesis of the evidence can be used to inform both researchers and practitioners who have a specific interest in non-clinical sleep health.
- Researchers are encouraged to improve the amount of detail provided in reports of behaviour change interventions to enhance the quality of evidence from systematic reviews and meta-analyses (i.e., facilitating data extraction and synthesis). This may be achieved by reporting intervention components using established frameworks for BCTs.
- Future studies trialling cognitive and behavioural sleep interventions should focus specifically on adults with poor sleep health, who do not have a clinical sleep disorder to add to the body of evidence on the effectiveness of such interventions.
- Additional studies are needed to shed further light on the feasibility and effectiveness of sleep interventions that are delivered without any face-to-face contact (e.g., m-health design). This could further improve the cost-effectiveness and accessibility of such interventions.
- Long-term studies should also examine whether early intervention targeting the restoration and maintenance of sleep health can help prevent the onset of clinical-level symptoms (e.g., chronic insomnia).
- Practitioners may utilise and promote cognitive and behavioural strategies that destress mind and body to improve overall sleep health in adults without sleep disorders.

# 8.5.2 Impact of the instrument developed to assess the psychosocial determinants of sleep hygiene (Chapter 4)

- The developed instrument provides a novel tool for researchers and practitioners to assess the psychosocial determinants of sleep hygiene
- Future studies should assess the psychosocial determinants of sleep hygiene to tailor intervention content to participants' needs.
- Larger samples are required to validate the psychometric qualities of the instrument and to confirm the component structures of the scales.
- Practitioners may consider the impact of psychosocial determinants when recommending sleep hygiene practices to patients with poor sleep health.

# 8.5.3 Impact of the empirical evaluation of the Synergy Study (Chapter 6)

- Researchers are encouraged to publish detailed study protocols to facilitate replicability and improve transparency.
- The use of effective combinations of behaviour change strategies should be at the core of interventions targeting health behaviours such as physical activity and sleep.
- Automated data entry in place of manual self-monitoring could be explored using existing wearables (e.g., Fitbit) to reduce the burden on participants.
- Future trials should also explore strategies that manipulate engagement with the app over time and investigate the minimum app usage needed to provoke behaviour change.
- The maintenance of behaviour change should be targeted using dedicated intervention strategies and assessed via additional follow-up assessments (i.e., beyond six months).
- Prior to disseminating the Synergy Study at scale, it would be interesting to replicate the intervention to examine its efficacy in more diverse participant groups.
- More automated processes may be used in future trials that reduce the burden on research staff and reduce delivery costs.
- Optimisation phases in the form of comparative effectiveness trials could also be used to identify the key components that make the intervention effective.
- In additional adaptation could involve examining the efficacy of the Synergy Study in specific subgroups of the population that are known to be particularly

physically inactive and also report poor sleep health due to co-morbidities or unique circumstances and needs (e.g., cancer survivors, caretakers).

• Practitioners are encouraged to promote the reduction of physical inactivity and poor sleep health in combination to help combat the joint impact of these behaviours on public health and the associated economic burden.

#### 8.5.4 Impact of the explanatory evaluation of the Synergy Study (Chapter 7)

- Researchers should continue to examine potential mediators of intervention efficacy (i.e., behaviour change), despite the growing body of evidence arguing that mediation analyses infrequently identify mediation effects of substantial magnitude. This may require consideration of theoretical frameworks that have received little attention in the past, development of new behaviour change frameworks and the use of instruments that align with respective frameworks.
- Additional studies are needed that provide a more detailed insight into how different mechanisms operate across behaviours and whether these occur at different levels
- Future trials should ensure that those factors that were shown to play an important role in changing behaviour (e.g., intentions and planning to improve physical activity) are operationalised using evidence-based strategies.

### 8.6 Final summary

Physical inactivity and poor sleep health are highly prevalent in the general adult population. This thesis addressed these two behaviours with a set of unique and important research aims and employed a range of different study designs to address these research aims. The thesis also highlighted further interesting research questions that could not be addressed and need attention in future research. The Synergy Study was a theory-informed trial that used evidence-based strategies to target self-regulation in a group of participants who enrolled in an intervention to improve their physical activity *and* sleep health. The findings presented in this thesis lend strong support for the use of interventions that target physical activity and sleep health in combination for adults who report poor sleep health, but do not have clinically diagnosed sleep disorders. The various outcomes that were improved during the Synergy Study are important determinants of

adults' overall health and well-being. The assessment of psychosocial factors in the context of behaviour change is important and this thesis provided initial evidence that these mechanisms might not operate in the same ways across behaviours. The further utility and scalability of the Synergy Study needs to be established in future studies, given the immense need for global intervention, inclusive of rural and remote areas.

## **References – Chapter 8**

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## Appendices

## **Appendix A: Prospero registration**



## PROSPERO

International prospective register of systematic reviews

Systematic review and meta-analysis of non-pharmacological interventions to improve sleep health in adults Beatrice Murawski, Mitch Duncan

## Citation

Beatrice Murawski, Mitch Duncan. Systematic review and meta-analysis of non-pharmacological interventions to improve sleep health in adults. PROSPERO 2015 CRD42015029642 Available from:

http://www.crd.york.ac.uk/PROSPERO/display\_record.php?ID=CRD4201 5029642

## **Review question**

(1) synthesise evidence from trials that evaluated the efficacy of behavioural interventions targeting improvements in sleep,

(2) describe the use of sleep hygiene recommendations (SHR) and behaviour change techniques (BCT) that are implemented in trials,

(3) examine if the efficacy of sleep interventions is moderated by use of SHR and/or BCT, mode of delivery (individual, group, technology-based), participant characteristics (age, gender, chronic disease, etc.) and outcome measurement (self-report, accelerometer, home-PSG). The review will include changes in any dimension of sleep (duration, sufficiency, quality) and discuss the importance of secondary outcomes (physical activity, quality of life, sleepiness, etc.) in relation to clinical meaningfulness.

## Searches

Electronic database searching will be conducted in: MEDLINE (core), EMBASE, PsycINFO, and CINAHL. Record retrieval will be limited to age groups 18-64 as well as English language full-text. Limitations regarding date of publication will be relaxed to include all records from journal inception until most recent (December 2015). All search strings are devised from one of three term sets: (i) sleep, (ii) intervention, and (iii) study type. The latter will be restricted to being a study design with a minimum of two measurement occasions and one or several comparator conditions. Our full search strategy is provided as supplementary material. We sought advice from the faculty librarian for the development of this strategy. Previous reviews in the field and any publications referenced within the selected records, as well as the reviewers' existing library will complement the electronic database search. Search alerts will be set up to consider relevant contributions that are published while the review is underway.

## Types of study to be included

We will include full reports of any type of experimental study design (randomised controlled trials) as well as quasi-experimental studies (pre-post designs, within-subject designs, matched subject designs, etc.) as long as they included a minimum of two measurement occasions, for which the quantified measures of sleep are comparable.

## Condition or domain being studied

As part of many national and international health agendas, poor sleep has been declared a public health threat and with the aim to educate at a whole population level, public guides to restore or maintain healthy sleep often refer to a set of behavioural recommendations, also known as sleep hygiene. The majority of scientific intervention reports however, remain focused on clinical treatment that requires clinical diagnosis. Non-pharmacological, self-regulatory interventions for improved sleep health in subclinical populations and moreover, at a public health level are not understood well enough, so that initiatives can be made accessible, reliable and sustainable in effectively reducing chronic disease risk, while improving health- related quality of life, overall wellbeing and daytime functioning.

## Participants/population

This review will include studies of adults within the age range of 18-64 years. Studies of populations where subjects were diagnosed with acute or chronic insomnia will be eligible, as we seek to learn from the strategies used to operationalise concepts of behaviour change in clinical sleep research. However, insomnia status will be strictly stratified by primary vs. secondary insomnia with the latter referring to co- morbid sleep difficulty (i.e. due to chronic pain). Secondly, if a measure is available from the report, insomnia

severity will be stratified as per insomnia severity index (ISI) by Morin et al., (2011), or as per Pittsburgh Sleep Quality Index (PSQI) by Buysse et al., (1989).

Interventions for sleep disorders other than insomnia (e.g. those that target sleep apnea, restless legs syndrome, narcolepsy, sleepwalking, etc.) are not eligible for selection, as the underlying cause is better met with different forms of treatment. Finally, studies that tested intervention efficacy in individuals whose condition would not have allowed the occurrence of natural sleep patterns are also excluded. The same applies to shift workers and any individuals whose chronobiology was temporarily or permanently disrupted due to external factors.

## Intervention(s), exposure(s)

The scope of enquiry in this review is subject to multi-parameter study variables and heterogeneous intervention approaches. Nonetheless, we sought to define a range of criteria that would frame a rigorous synthesis and serve the objectives of this undertaking. For the purpose of final refinements and clarification, eligibility criteria were pilot tested on a number of records that were thought to be relevant.

To be eligible, studies will have to employ a minimum of one behavioural strategy as part of the non- pharmacological study arm. Intervention contents include, but are not restricted to psychoeducation, CBT-I (Cognitive Behavioural Therapy for Insomnia), sleep hygiene instructions, mind-body approaches and sleep diaries.

## Comparator(s)/control

Studies will have to report a minimum of one comparator condition. Trial arms where a behavioural program was implemented to be compared against a pharmacological intervention or to balance medication tapering will be eligible and coded, respectively.

## Context

Studies will be excluded, if observation took place in an institutionalised or hospitalised setting (e.g. intensive care) and if sleep was monitored under laboratory conditions (lab-based polysomnography).

## Main outcome(s)

Changes in any parameter of sleep (such as self-reported sleep quality or total sleep time, objectively measured total sleep time, wake-after sleep onset, sleep onset latency, rapid vs. non-rapid eye movement, sleep efficiency, etc.).

#### Timing and effect measures

Changes between baseline to first post-intervention follow-up. If the majority of studies provide a long-term follow-up, the sustainability factor (behaviour maintenance) will be discussed.

#### Additional outcome(s)

Changes in physical activity levels, sleepiness, or quality of life that occur during the intervention period.

#### Timing and effect measures

Changes between baseline to first post-intervention follow-up. If the majority of studies provide a long-term follow-up, the sustainability factor (behaviour maintenance) will be discussed.

## Data extraction (selection and coding)

All of the identified records will be exported to EndNote X7 and de-duplicated. One reviewer will (BM) screen titles and abstracts to exclude inapt records, which will be checked and approved by the second reviewer (MJD). Following full-text retrieval for those retained after screening, both reviewers (BM, MJD) will independently assess each record against pre-specified eligibility criteria. A third reviewer (TBA) will provide mediation, if discussion fails to resolve discrepant interpretations. Where necessary, authors of the selected studies will be contacted to request missing information. Flow of records will adhere to the PRISMA statement. Extracted data will be managed and analysed using CMA (Comprehensive Meta Analysis).

An electronic extraction form (Excel) will be used to collect all the relevant information for synthesis and potential meta-analysis. Both reviewers (BM, MJD) will independently extract and code data of interest against the pre-specified criteria. These were appraised, refined and described a priori to prevent ambiguous interpretation. To further address the stated research questions, a separate coding sheet (Excel) will supplement the extraction form to help quantify intervention features of interest. We will be using the 40-item CALO-RE taxonomy of behavior change techniques (BCT) by Michie and colleagues (2011) to code for the

strategies by which intervention content was operationalised (1 = present; 0 = absent). The items for codable intervention content (1 = present; 0 = absent) will be guided by Irish et al.'s (2015) review of empirically supported sleep hygiene recommendations, which also corresponds with most of the national and international guidelines for sleep health. This list included (1) avoiding caffeine, (2) avoiding nicotine, (3) avoiding alcohol, (4) exercising regularly, but not right before bedtime, (5) managing stress, (6) reducing bedroom noise and/or lighting. (7) regular sleep timing. (8) avoiding daytime naps. Based on the increasing dominance of technological devices in the home setting, we decided to extend this list and consider (9) reducing technology use as well as (10) maintaining comfort (via temperature, garments, linen, scents, etc.). A unique identifier number will be assigned to selected records. Data extraction per se will include: (i) meta- data: author name, year of publication, title, DOI, source, export date, extraction date, corresponding author & affiliation, publication type, full-text availability, study type, (ii) demographics & design: mean age (+SD and range) at baseline, gender, ethnicity, education, employment status, health status, veteran status, insomnia severity, insomnia type, setting type, context, population type, intervention design, number of study arms, incentive to participate, n enrolled, n allocated to intervention/control, n lost to follow-up, n included in analyses, (iii) outcomes: changes in sleep (parameters), outcome measures (tool/instruments employed), secondary measures (i.e. activity, sleepiness), study aim, study design, variables of interest, total study duration, intervention period, (iv) mode of delivery: frequency of contact, duration per one contact, timing of contact, level of tailoring, theoretical basis, administration (sequential

vs. simultaneous), programme scope (multi- vs. single health behaviour intervention), format (one-to-one vs. group-based), provider, medium of contact and (v) Results: OR, RR, CI and p-values for binary outcome data; mean differences, confidence intervals for continuous outcome data. Adverse events will be noted and summarised from those studies that reported such outcomes.

## Risk of bias (quality) assessment

Study quality and risk of bias will be assessed using Downs & Black's (1998) checklist. This tool subdivides quality appraisal into five sections: reporting (10 items), external validity (3 items), internal validity - bias (7 items), internal validity - confounding (6 items) and power (1 item).

## Strategy for data synthesis

Provided that risk of bias and heterogeneity fall within the anticipated margins (assessed through chi2 testing), extracted data will be meta-analysed. A narrative synthesis will be prioritised otherwise. If data pooling is deemed feasible, meta-analyses will be conducted using standardised mean differences (incl. 95% CI) to calculate a weighted average. This procedure may have to be restricted to the most prevalent sleep parameters (i.e sleep quality and total sleep time) and to those studies that were RCTs. A random effects model will be employed to allow for between-study variability.

## Analysis of subgroups or subsets

Subgroups will be analysed to explore moderator effects in sleep interventions conducted in the adult population.

Primarily, the model for intervention effectiveness will be extended to produce estimates for the effect of:

(i) use of behaviour change techniques

(ii) type of sleep hygiene recommendation,

(iii) mode of delivery, and/or

(iv) type of outcome measure (subjective vs. objective assessment).

Subsequently, subject-specific strata will help explore the effect of participant health status, BMI/weight, age, sex, and education. To avoid over-specification, the listed covariates will only be considered, if sufficient data can be obtained for the majority of clusters.

## Contact details for further information

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### Anticipated or actual start date

11 December 2015

Anticipated completion date 12 December 2016

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This work is supported by a Future Leader Fellowship (ID 100029) from the National Heart Foundation of Australia awarded to MJD

Conflicts of interest None known

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Country Australia

Stage of review Review completed and published

#### Details of final report/publication(s)

This review was published in Sleep Medicine Reviews 40 (2018) 160-169 https://www.ScienceDirect.com/science/article/pii/S1087079217301661

Subject index terms status Subject indexing assigned by CRD

Subject index terms Adult; Humans; Sleep

Date of registration in PROSPERO 08 December 2015

Date of publication of this version 03 April 2019

Versions 08 December 2015 03 April 2019

#### PROSPERO

This information has been provided by the named contact for this review. CRD has accepted this information in good faith and registered the review in PROSPERO. CRD bears no responsibility or liability for the content of this registration record, any associated files or external websites.

## **Appendix B: Ethics approval Synergy Study**

#### HUMAN RESEARCH ETHICS COMMITTEE



#### Notification of Expedited Approval

To Chief Investigator or Project Supervisor:	Associate Professor Mitch Duncan
Cc Co-investigators / Research Students:	Professor Ronald Plotnikoff Miss Beatrice Murawski Mrs Anna Rayward
Re Protocol:	Efficacy of a theory-based intervention to improve physical activity and sleep behaviour in adults
Date:	26-Sep-2016
Reference No:	H-2016-0181
Date of Initial Approval:	26-Sep-2016

Thank you for your **Response to Conditional Approval (minor amendments)** submission to the Human Research Ethics Committee (HREC) seeking approval in relation to the above protocol.

Your submission was considered under Expedited review by the Ethics Administrator.

#### I am pleased to advise that the decision on your submission is Approved effective 26-Sep-2016.

In approving this protocol, the Human Research Ethics Committee (HREC) is of the opinion that the project complies with the provisions contained in the National Statement on Ethical Conduct in Human Research, 2007, and the requirements within this University relating to human research.

Approval will remain valid subject to the submission, and satisfactory assessment, of annual progress reports. If the approval of an External HREC has been "noted" the approval period is as determined by that HREC.

The full Committee will be asked to ratify this decision at its next scheduled meeting. A formal *Certificate of Approval* will be available upon request. Your approval number is **H-2016-0181**.

If the research requires the use of an Information Statement, ensure this number is inserted at the relevant point in the Complaints paragraph prior to distribution to potential participants You may then proceed with the research.

#### **Conditions of Approval**

This approval has been granted subject to you complying with the requirements for *Monitoring of Progress, Reporting of Adverse Events,* and *Variations to the Approved Protocol* as <u>detailed below</u>.

PLEASE NOTE:

In the case where the HREC has "noted" the approval of an External HREC, progress reports and reports of adverse events are to be submitted to the External HREC only. In the case of Variations to the approved protocol, or a Renewal of approval, you will apply to the External HREC for approval in the first instance and then Register that approval with the University's HREC.

• Monitoring of Progress

Other than above, the University is obliged to monitor the progress of research projects involving human participants to ensure that they are conducted according to the protocol as approved by the HREC. A progress report is required on an annual basis. Continuation of your HREC approval for this project is conditional upon receipt, and satisfactory assessment, of annual progress reports. You will be advised when a report is due.

#### • Reporting of Adverse Events

- 1. It is the responsibility of the person first named on this Approval Advice to report adverse events.
- 2. Adverse events, however minor, must be recorded by the investigator as observed by the investigator or as volunteered by a participant in the research. Full details are to be documented, whether or not the investigator, or his/her deputies, consider the event to be related to the research substance or procedure.
- 3. Serious or unforeseen adverse events that occur during the research or within six (6) months of completion of the research, must be reported by the person first named on the Approval Advice to the (HREC) by way of the Adverse Event Report form (via RIMS at <u>https://rims.newcastle.edu.au/login.asp</u>) within 72 hours of the occurrence of the event or the investigator receiving advice of the event.
- 4. Serious adverse events are defined as:
  - Causing death, life threatening or serious disability.
  - Causing or prolonging hospitalisation.
  - Overdoses, cancers, congenital abnormalities, tissue damage, whether or not they are judged to be caused by the investigational agent or procedure.
  - Causing psycho-social and/or financial harm. This covers everything from perceived invasion of privacy, breach of confidentiality, or the diminution of social reputation, to the creation of psychological fears and trauma
  - o Any other event which might affect the continued ethical acceptability of the project.

#### 5. Reports of adverse events must include:

- Participant's study identification number;
- date of birth;
- date of entry into the study;
- treatment arm (if applicable);
- date of event;
- details of event;
- the investigator's opinion as to whether the event is related to the research procedures; and
- action taken in response to the event.
- 6. Adverse events which do not fall within the definition of serious or unexpected, including those reported from other sites involved in the research, are to be reported in detail at the time of the annual progress report to the HREC.

#### • Variations to approved protocol

If you wish to change, or deviate from, the approved protocol, you will need to submit an *Application for Variation to Approved Human Research* (via RIMS at <u>https://rims.newcastle.edu.au/login.asp</u>). Variations may include, but are not limited to, changes or additions to investigators, study design, study population, number of participants, methods of recruitment, or participant information/consent documentation. **Variations must be approved by the (HREC) before they are implemented** except when Registering an approval of a variation from an external HREC which has been designated the lead HREC, in which case you may proceed as soon as you receive an acknowledgement of your Registration.

#### Linkage of ethics approval to a new Grant

HREC approvals cannot be assigned to a new grant or award (ie those that were not identified on the application for ethics approval) without confirmation of the approval from the Human Research Ethics Officer on behalf of the HREC.

Best wishes for a successful project.

Professor Allyson Holbrook Chair, Human Research Ethics Committee

For communications and enquiries: Human Research Ethics Administration

Research Services Research Integrity Unit NIER, Block C The University of Newcastle Callaghan NSW 2308 T +61 2 492 17894 <u>Human-Ethics@newcastle.edu.au</u>

RIMS website - https://RIMS.newcastle.edu.au/login.asp

#### Linked University of Newcastle administered funding:

Funding body	Funding project title	First named investigator	Grant Ref
National Heart Foundation of Australia/Future	Reducing population level CVD risk by improving physical	Duncan, Mitch	G1400694
Leader Fellowship(**)	activity, sitting and sleep behaviours		

## Appendix C: Ethics approval test-retest study

#### HUMAN RESEARCH ETHICS COMMITTEE



#### Notification of Expedited Approval

To Chief Investigator or Project Supervisor:	Associate Professor Mitch Duncan
Cc Co-investigators / Research Students:	Miss Beatrice Murawski Professor Ronald Plotnikoff
Re Protocol:	Test-retest reliability of a scale assessing social cognitive mechanisms relating to sleep hygiene behaviours.
Date:	13-Feb-2018
Reference No:	H-2018-0012
Date of Initial Approval:	13-Feb-2018

Thank you for your **Response to Conditional Approval (minor amendments)** submission to the Human Research Ethics Committee (HREC) seeking approval in relation to the above protocol.

Your submission was considered under Expedited review by the Ethics Administrator.

I am pleased to advise that the decision on your submission is Approved effective 13-Feb-2018.

In approving this protocol, the Human Research Ethics Committee (HREC) is of the opinion that the project complies with the provisions contained in the National Statement on Ethical Conduct in Human Research, 2007, and the requirements within this University relating to human research.

Approval will remain valid subject to the submission, and satisfactory assessment, of annual progress reports. If the approval of an External HREC has been "noted" the approval period is as determined by that HREC.

The full Committee will be asked to ratify this decision at its next scheduled meeting. A formal *Certificate of Approval* will be available upon request. Your approval number is **H-2018-0012**.

## If the research requires the use of an Information Statement, ensure this number is inserted at the relevant point in the Complaints paragraph prior to distribution to potential participants You may then proceed with the research.

For Noting

Information Statement

Please indicate how participants can choose to enter the draw and make it clear that both surveys need to be completed.

Please include the signature of the student researcher at the end of the document as well as the signature of the CI.

#### **Conditions of Approval**

This approval has been granted subject to you complying with the requirements for *Monitoring of Progress*, *Reporting of Adverse Events*, and *Variations to the Approved Protocol* as <u>detailed below</u>.

#### PLEASE NOTE:

In the case where the HREC has "noted" the approval of an External HREC, progress reports and reports of adverse events are to be submitted to the External HREC only. In the case of Variations to the approved protocol, or a Renewal of approval, you will apply to the External HREC for approval in the first instance and then Register that approval with the

University's HREC.

#### • Monitoring of Progress

Other than above, the University is obliged to monitor the progress of research projects involving human participants to ensure that they are conducted according to the protocol as approved by the HREC. A progress report is required on an annual basis. Continuation of your HREC approval for this project is conditional upon receipt, and satisfactory assessment, of annual progress reports. You will be advised when a report is due.

#### • Reporting of Adverse Events

- 1. It is the responsibility of the person first named on this Approval Advice to report adverse events.
- Adverse events, however minor, must be recorded by the investigator as observed by the investigator or as volunteered by a participant in the research. Full details are to be documented, whether or not the investigator, or his/her deputies, consider the event to be related to the research substance or procedure.
- 3. Serious or unforeseen adverse events that occur during the research or within six (6) months of completion of the research, must be reported by the person first named on the Approval Advice to the (HREC) by way of the Adverse Event Report form (via RIMS at <u>https://rims.newcastle.edu.au/login.asp</u>) within 72 hours of the occurrence of the event or the investigator receiving advice of the event.
- 4. Serious adverse events are defined as:
  - Causing death, life threatening or serious disability.
  - Causing or prolonging hospitalisation.
     Overdeses cancers concentral apportalities tissue damage whether or not they appeared to the second secon
  - Overdoses, cancers, congenital abnormalities, tissue damage, whether or not they are judged to be caused by the investigational agent or procedure.
  - Causing psycho-social and/or financial harm. This covers everything from perceived invasion of privacy, breach of confidentiality, or the diminution of social reputation, to the creation of psychological fears and trauma.
  - Any other event which might affect the continued ethical acceptability of the project.

#### 5. Reports of adverse events must include:

- Participant's study identification number;
  - date of birth;
  - date of entry into the study;
  - treatment arm (if applicable);
  - date of event;
  - details of event;
  - the investigator's opinion as to whether the event is related to the research procedures; and
  - o action taken in response to the event.
- 6. Adverse events which do not fall within the definition of serious or unexpected, including those reported from other sites involved in the research, are to be reported in detail at the time of the annual progress report to the HREC.

#### • Variations to approved protocol

If you wish to change, or deviate from, the approved protocol, you will need to submit an *Application for Variation to Approved Human Research* (via RIMS at <a href="https://rims.newcastle.edu.au/login.asp">https://rims.newcastle.edu.au/login.asp</a>). Variations may include, but are not limited to, changes or additions to investigators, study design, study population, number of participants, methods of recruitment, or participant information/consent documentation. **Variations must be approved by the (HREC) before they are implemented** except when Registering an approval of a variation from an external HREC which has been designated the lead HREC, in which case you may proceed as soon as you receive an acknowledgement of your Registration.

#### Linkage of ethics approval to a new Grant

HREC approvals cannot be assigned to a new grant or award (ie those that were not identified on the application for ethics

approval) without confirmation of the approval from the Human Research Ethics Officer on behalf of the HREC.

Best wishes for a successful project.

Associate Professor Helen Warren-Forward Chair, Human Research Ethics Committee

For communications and enquiries: Human Research Ethics Administration

Research & Innovation Services Research Integrity Unit The University of Newcastle Callaghan NSW 2308 T +61 2 492 17894 <u>Human-Ethics@newcastle.edu.au</u>

Funding body

RIMS website - https://RIMS.newcastle.edu.au/login.asp

Linked University of Newcastle administered funding:

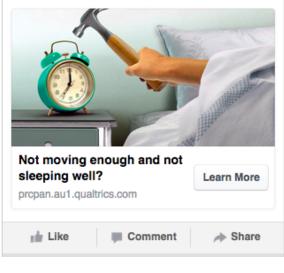
Funding project title

First named investigator Grant Ref

## Appendix D: Facebook recruitment Synergy Study

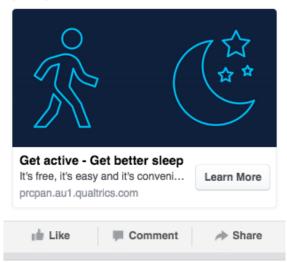


Being more active and getting good sleep can lower the risk of developing chronic conditions such as type-2 diabetes or heart disease and improve energy levels, productivity, mental health and weight management... More



The Synergy Study Sponsored · ©

Join a free University-led research program designed to increase physical activity and improve sleep health using the latest scientific evidence. No visits to the research centre required, Synergy provides you with a mobile app and personalised support. Click on 'Learn more' now to see if you are eligible to participate.



## **Appendix E: Advertorial Synergy Study**



# **NEED MORE ENERGY? WANT BETTER SLEEP?**

## MANY AUSTRALIAN ADULTS ARE NOT SATISFIED WITH THEIR SLEEP AND DO NOT GET ENOUGH PHYSICAL ACTIVITY.

When was the last time you woke up feeling refreshed and ready to tackle your day? How many times has being tired stopped you from meeting with friends or fitting in that much needed walk or workout?

A new research study combines the latest scientific evidence and a custom-built app including personalised support to help you get more active and sleep better. Join up from any location and benefit from the convenient design of the programme.

### BOTH FACTORS PLAY A KEY ROLE FOR LIFELONG HEALTH & WELLBEING.

Getting enough physical activity and sleep not only makes you feel energised and functional, it also supports weight management and reduces your chronic disease risk by up to 80%. To achieve this, the national guidelines recommend at least 150 minutes of moderate-intensity physical activity per week and 7-9 h of good quality sleep per night.

#### PHYSICAL ACTIVITY AND GOOD SLEEP ARE A GREAT MATCH

Both behaviours on their own contribute to health and well-being, but they also boost each other. So, more active people tend to have better sleep, and people with better sleep are more active through the day.

Our new study uses simple strategies to help you set your own goals, track your progress and improve both behaviours at the same time.

## KEEPING TRACK OF DAILY ACHIEVEMENTS IS A HIGHLY EFFFECTIVE STRATEGY

Synergy provides participants with a free pedometer, personalised feedback and a comprehensive handbook to make behaviour change easy.

## WE ARE NOW RECRUITING PARTICIPANTS

We invite both men and women, aged 18 to 55 who are physically inactive and who have poor sleep - additional criteria apply.

## >>> Click here to see if you are eligible



## **Appendix F: Information statement Synergy Study**



Associate Professor Mitch Duncan Priority Research Centre for Physical Activity and Nutrition & School of Medicine and Public Health University of Newcastle Callaghan, NSW, Australia, 2308 (02) 4921 7805 <u>Mitch.Duncan@newcastle.edu.au</u>

## Information Statement for the Research Project: "*Efficacy of a theory-based mobile intervention to improve physical activity and sleep behaviour in adults: A randomised waitlist-controlled trial*" Document Version 2; dated 05/09/16

You are invited to participate in the research project identified above which is being conducted by Associate Prof Mitch Duncan, Ms Beatrice Murawski, Dr Anna Rayward and Prof Ron Plotnikoff. These researchers are from the University of Newcastle, Priority Research Centre in Physical Activity and Nutrition. The study is funded by a *Future Leader Fellowship* (ID 100029) from the National Heart Foundation of Australia awarded to Associate Professor Mitch Duncan.

Why is the research being done? The purpose of this project is to examine the efficacy of a mobile device intervention or 'app', to improve the physical activity and sleep behaviours of Australian adults. We will also examine different factors that make the intervention more or less effective (e.g., how much you use the app, or your age) and the impact of the intervention on your health and wellbeing. The intervention will allow participants to keep track of their physical activity and sleep behaviours each day for a total time period of three months and will actively encourage them to make changes to daily routines to improve these behaviours. The content provided in the app will include the information and instructions needed to track and record these behaviours. The research team will provide assistance via email or phone, as required.

**Who can participate in the research?** We are seeking adults aged 18-55 years, living in Australia, who have access to an Apple or Android device (smartphone or tablet) with Internet access, who have a BMI between 18.5 and 35. Participants are required to currently perform less than 150 minutes of physical activity per week and report poor sleeping patterns.

If you have a medically diagnosed sleep disorder, are currently taking sleep medications, have a condition meaning you are unable to change your physical activity and sleep behaviours, work shift work (night shifts or rotating shifts), are planning to travel to a destination with a shift in time zone by more than 3 hours, or are currently using an app or activity tracker to monitor your physical activity or sleep, then unfortunately you will not be eligible to participate in this study.

#### What would you be asked to do?

If you agree to participate, you will be asked to:

- 1. Complete a screening questionnaire to determine your eligibility to participate in the study.
- 2. Wear a pedometer: this is a waist-worn device that measures the number of steps you take and will be provided to you. You will not have to return this device and you may continue to use it in the future, if you wish to do so. We, the study provider will carry the full costs associated with the purchase and shipping of these devices.
- **3.** Use the app to record your daily step count & any other physical activity as well as your sleep patterns and sleep hygiene behaviours.
- **4. Provide a mobile number and email address** to receive reminders, prompts and additional support, which is part of the intervention package and helps you make changes (see statement below for any concerns about data protection).
- 5. Complete a number of short tasks that help you improve both physical activity and sleep: this includes setting your own goals, creating an action plan and learning to manage time and stress.
- 6. Participate in a telephone interview: You may be asked to participate in an interview with the research team about your experience in the study including what you liked, disliked, and what you expected the program to do.
- 7. Complete 3 online surveys (approx. 45 minutes) asking about your physical activity and sleep behaviours, general health and wellbeing and attitudes towards physical and sleep.

What choice do you have? Participation in this research is entirely your choice. Only those people who give informed consent online will be included in the project. You do this by checking the box during registration that you accept the terms and conditions (listed below). Whether or not you decide to participate, your decision will not disadvantage you. If you do decide to participate, you may withdraw from the project at any time without giving a reason and you will have the option to withdraw any data that identifies you.

**How much time will it take?** The entire intervention project will be delivered remotely, which means that you are not required to visit a research centre. The surveys you will be asked to complete online will take approximately 45 minutes each. Recording your activities (physical activity and sleep) on the mobile device app will take approximately 2-5 minutes each day and you will be asked to do this on a daily basis for a period of 3 consecutive months. However, you can use the app as much or as little as you like and stop using it whenever you like, but our system is designed to be supportive and will prompt you to re-engage with the app via SMS/email (max. number of reminders per month = 3). We also provide you with additional information on relaxation techniques or stress management – if you choose to do these it may take 10-20 minutes per day, but how frequently or how long you do them for is your choice. If you are selected to take part in a telephone interview, this will last for between 15-30 minutes.

Which study groups can I be allocated to? There will be two study groups in this project and you will be randomly allocated to one of these two groups. One of the two groups will receive the mobile device-based intervention package immediately, including access to the app to provide an electronic platform for you to self-monitor your physical activity and sleep, set and change your goals, view feedback and to acquire the necessary knowledge to get started and keep going with behavioural changes. In addition, a personalised support system using email and text message prompts or reminders will help you make progress. The second group will serve as a waitlist control group. Should you be allocated to this group, we will ask you not to make any changes to your usual physical activity and sleep habits. Following your participation in a further online survey after 6 months, you will receive the full program.

What are the risks and benefits of participating? You are being asked to increase your activity levels and modify your sleeping behaviours. Increases in physical activity may cause some muscle soreness, however this is not expected to be long lasting or severe in nature. Your participation in this research may give rise to risks that are beyond the reasonable control of the University. The research will involve encouraging you to engage in physical activity and this can present a risk to your health and safety. If you have any doubts about your physical condition or your ability to safely perform physical activity, we recommend you obtain medical guidance from

your doctor prior to participating and never disregard any medical advice given to you because of information provided in our study.

We cannot and do not promise that you will receive any benefits from participating in this study. However, the desired outcomes of this research are increased physical activity levels and improved sleep behaviours, which may contribute to improved wellbeing, and reduced risk of developing diseases such as diabetes and heart disease. At assessment points 1, 2 and 3 you will be entered into a draw to win 1 of 5 gift cards (\$50 value per gift card) as a gesture of our appreciation for your participation in the study.

Any personal risks associated with this research project have been considered and measures have been taken to minimise these risks to the utmost. We ask any participant who feels concerned about undertaking the above-mentioned tasks to contact either the research team or the University of Newcastle Human Research Ethics Committee using the details provided on this information sheet.

Some of the questions we ask in the surveys are of a sensitive nature. If you find these questions distressing or upsetting we encourage you to contact one of the following organisations to discuss this.

- Lifeline. Phone: 13 11 14. Website: <u>www.lifeline.org.au/</u>
- BeyondBlue. Phone: 1300 22 4686. Website: www.beyondblue.org.au/
- Blackdog Institute. Website: http://www.blackdoginstitute.org.au/

**How will your privacy be protected?** All data collected during the study will be stored on password-protected computers and networks. This data would include, but is not limited to, deidentification records of data entered into the app and information on how you used the app. This information includes the information you manually enter for your physical activity and sleep behaviours. This information will be accessible by the research team only and those people the research team engages to do maintenance work on the app. This is required so that we can keep the app working properly.

De-identified data will be kept for a minimum of five years after the last publication from this data at the University of Newcastle, after which time any paperwork will be shredded and electronic data deleted. Any transmission of data between the app and any servers uses industry standard security protocols to protect your information.

**How will the information collected be used?** In any publication or report, information will be provided in such a way that you cannot be identified. We plan to publish the results in scientific literature, provide reports to interested parties, and present the results at scientific conferences and other meetings. Information collected as part of this study may also be used for student theses and dissertations.

What do you need to do to participate? Please read this Information Statement and be sure you understand its contents. If there is anything you do not understand, or you have questions, contact the researchers. If you would like to participate, please indicate that you are giving your informed consent (online), agree with our terms & conditions (listed below) and complete the online survey at INSERT URL HERE. If you are eligible to participate we will contact you (phone/email) to arrange an induction. At this appointment we will explain the study and answer any questions you may have. If you are not eligible we will contact you (phone/email) to advise you of this and answer any questions you have.

**Further information** If you would like further information please contact Ms Beatrice Murawski via email at <u>beatrice.murawski@newcastle.edu.au</u> or on +61 (0) 2 4921 2067.

#### Research Team:

#### **Associate Professor Mitch Duncan**

Priority Research Centre for Physical Activity and Nutrition, School of Medicine & Public Health, Faculty of Health & Medicine, University of Newcastle

### **Beatrice Murawski**

Priority Research Centre for Physical Activity and Nutrition, School of Medicine & Public Health, Faculty of Health & Medicine, University of Newcastle

#### **Dr Anna Rayward**

Priority Research Centre for Physical Activity and Nutrition, School of Medicine & Public Health, Faculty of Health & Medicine, University of Newcastle

#### Professor Ron Plotnikoff

Priority Research Centre for Physical Activity and Nutrition, School of Education, Faculty of Education & Arts, University of Newcastle

Thank you for considering this invitation.

Associate Prof Mitch Duncan (Future Leaders Fellow)

**Complaints about this research** This project has been approved by the University's Human Research Ethics Committee, Approval No. H-2016-0181. Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, to the Human Research Ethics Officer, Research Office, The Chancellery, The University of Newcastle, University Drive, Callaghan NSW 2308, Australia, telephone (02) 49216333, email <u>Human-Ethics@newcastle.edu.au</u>.

#### Terms and Conditions

The Balanced app is funded by the University of Newcastle, Australia and National Heart Foundation of Australia (ID 100029 & ID 100629) and designed by Headjam Inc; these parties are referred to as the "participants". The term "Balanced Platform" refers to the Balanced app (Balanced), website (<u>www.balanced.org.au</u>) and any database or other material associated with the app and/or website. The terms "you" and "user" shall refer to all individuals and entities that access or otherwise use the Balanced Platform.

The materials presented in the Balanced Platform are presented as an information source only. The Participants make no representations and provide no warranties in relation to the Balanced Platform including no warranty as to suitability or fitness for use for any purpose and the Participants disclaim all liability associated with your access or use of the Balanced Platform. The Balanced Platform is provided solely on the basis that users are responsible for making their own assessment of the matters presented therein. Users are advised to verify any statements and information and to rely upon their own enquiries (including seeking appropriate medical advice) before relying or taking any action based on the Balanced Platform.

By registering with the Balanced Platform, using the Balanced Platform and agreeing to these terms and conditions you are consenting to the following and releasing the participants in respect of any liability associated with your use of the Balanced Platform:

- I understand that any information and advice is directed towards adults, and not children
- I understand information in the Balanced Platform does not constitute professional or medical advice and should not be relied upon as such. Before making changes to their behaviours users should seek medical advice to ensure that the changes are appropriate to their personal situation and health. The Participants accept no responsibility for any injury or adverse health consequences that may occur as a result of use of the Balanced Platform.
- As a user I understand that I should never disregard the advice provided to me by a health professional or medical practitioner because of information provided in the Balanced Platform.
- I understand that any advice contained in the Balanced Platform is not professional or medical advice and should not be relied on as such and that I should obtain my own medical or other professional advice before relying upon or taking any action based on the Balanced Platform.
- Formal advice from appropriately qualified practitioners should be sought in regard to the Balanced Platform including making changes to any behaviour or lifestyle choice.
- I understand that I use the Balanced Platform at my own risk and any modifications to my behaviour or lifestyle based on the Balanced Platform or otherwise are performed at my own risk.
- I understand that any data (including my usage patterns of the Balanced Platform) I enter into the Balanced Platform (including data transmitted to the Balanced Platform by third party sources) will be stored and used for research and evaluation purposes including scientific publications and presentations, student theses and dissertations and reports and I expressly consent to such use without the requirement to obtain my further consent or to notify me upon each occasion of use (Research Use). The University of Newcastle Human Research Ethics Committee has approved this research H-2016-0181.
- I understand that any presentation of these data will be done in a way that does not allow my identity to be disclosed.
- I understand that any changes to my behaviours or lifestyle, such as increasing the amount of physical activity performed has the potential to cause injury, muscle soreness or other unintended consequences.
- I understand that I am being asked to increase my physical activity levels and make changes to my sleep behaviours and that I am not aware of any condition that means making these changes will adversely affect my health. The participants recommend you seek medical advice before relying upon or taking any action based on the Balanced Platform.
- I understand that reasonable attempts will be made to keep my data secured.

- I understand that my data will not be made available to any third party not associated with the Balanced Platform research team without my permission. This does not apply to Research Use described above.
- The Balanced Platform, the participants and any individual or organisation associated with it is not responsible for or accountable for any adverse events or unintended consequences associated with use of the Balanced Platform or changes I make to my behaviour.
- The participants do not guarantee or warrant that any particular results, including weight loss, reduced cardiovascular risk, or increased cardiovascular fitness, will occur as a result of use of the Balanced Platform.
- My use or non-use of the Balanced Platform is completely voluntary, I can stop at any time for any reason this will not prejudice my relationship with any individual or organisation associated with the Balanced Platform or any of the participants.
- I understand that my use of the Balanced Platform may require I share my login and access details for third parties programs and products in order to use some features of the Platform.
- I understand that to use some features of the Balanced Platform I grant the Balanced Platform permission to access my data held by third parties and to record this data in to the Balanced Platform.
- I understand that every attempt is made to ensure the information provided in the Balanced Platform is accurate.
- The Participants, the Balanced Platform any individuals or organisations associated with it are not responsible for any costs I incur when using the Balanced Platform in any State, Territory or Country.
- The Balanced Platform, the Participants and any individuals or organisations associated with it are not responsible for any damage to my device/s or loss of data associated with using or caused by the Balanced Platform or by the interaction of the Balanced Platform with any software, application, hardware, device or similar
- To the maximum extent permitted by applicable Law, the operation of Part 4 of the Civil Liability Act 2002 (NSW) is excluded in relation to any and all rights, obligations and liabilities arising under or in relation to your use of the Balanced Platform.
- The Balanced Platform and the participants are not liable for, and no measure of damages will, under any circumstances, include, special, indirect, consequential, incidental or punitive damages or economic loss, loss of profits, revenue, goodwill, bargain, anticipated savings or loss or corruption of data, whether in an action in contract, tort (including without limitation negligence and product liability), statute or otherwise, whether or not such loss or damage was foreseeable and even if advised of the possibility of the loss or damage.
- In no way shall any of the Participants or the Balanced Platform be liable (including liability for negligence) for any damages (including without limitation, direct, indirect, punitive, special or consequential) whatsoever arising out of my use of, access to or inability to use or access the Balanced Platform or any web site linked or associated with the Balanced Platform.
- I understand that I may be contacted by individuals or groups on behalf of the Balanced Platform or by Balanced to invite me to participate in research. My participation in this research is completely voluntary and my participation or non-participant will not prejudice me or my relationships with the Participants in any way.
- The Participants in Balanced project make no guarantee that the information in the Balanced Platform is free of infection by computer viruses or other contamination.
- The links offered from the Balanced Platform are provided for the interest of users.
- The links have been added because content was determined by the Participants as relevant to the Balanced Platform functions and operations. Provision of these links does not constitute endorsement, non-endorsement or support by the Participants. The content found by using these links is not created, controlled or approved by the Participants in the Balanced Platform and no responsibility is taken for the consequences of viewing or using such content.
- The Participants in the Balanced Platform do not guarantee that they will provide uninterrupted access at all times to this app, site or any web sites linked to this site. Any questions can be sent to <u>Balanced-Study@newcastle.edu.au</u> or <u>HumanEthics@newcastle.edu.au</u>

## **Appendix G: Consent form Synergy Study**



# A University-led research study to improve your physical activity and sleep health.

Click >> NEXT to find out more and see if you are eligible.

## **Start of Block: Info**

The Synergy Study offers a free, University-led program that aims to test the effectiveness of a specifically developed intervention to improve your physical activity and sleep behaviours using a mobile app and message-based support.

The following link provides a copy of our Information Statement and we ask you to read the statement prior to giving your online consent for participation in the study:

>>> click here to download the information statement

If you have read the Information Statement and you have no further questions regarding your participation, please proceed to give your consent to participate. If you would like to have any questions answered before deciding, if you wish participate in the study, please contact the research team.

Thank you.

BEATRICE MURAWSKI – PROJECT LEADER BSc (Sport Performance & Coaching) | MSc (Medical Science) | PhD Candidate (Behavioural Sciences) at the Priority Research Centre for Physical Activity & Nutrition School of Medicine & Public Health, Faculty of Health and Medicine The University of Newcastle (UON), University Drive, Callaghan NSW 2308 T: +61 (0) 2 4921 2067 E: synergystudy@newcastle.edu.au **End of Block: Info** 

**Start of Block: Consent** 

I have read the Information Statement and understand the requirements of my participation in the study, and I hereby provide my consent to participate. I also understand that:

- The project will be conducted as described in the Information Statement, a copy of which I have retained;
- I will be randomly assigned to one of two groups either the intervention group or a waitlist control group, which will receive a program identical to that of the intervention group following the 6-month assessment;
- I can withdraw from the project at any time and do not have to give any reason for withdrawing;
- my personal information will remain confidential to the researchers; and
- I have had the opportunity to have questions answered to my satisfaction.

As per description in the Information Statement, I consent to:

- measure/recall the time spent each day/night performing physical activity and sleeping;
- use the mobile device app to log this information;
- provide a mobile number, postal address and/or email address for the purpose of receiving support prompts, reminders and study materials from the research team; complete a number of short tasks that may help me improve both my physical activity and sleep behaviours;
- complete a short questionnaire to determine, whether I am eligible to take part and complete an assessment survey before the study starts, then 3 months and 6 months after that; and
- participate in a short telephone interview about my experience in the study, regardless of whether I completed the intervention or decided to withdraw.
   Do you agree to participate in this research project?
- Yes, I agree to participate. (1)
- No, I do not wish to give my consent. (2)

Please enter your full name below (Format: FIRST NAME LAST NAME)

After you have provided your full name, we will ask some questions about your physical activity and sleep habits, any chronic conditions as well as some basic demographics.

Enter your name and click >> NEXT to proceed

**End of Block: Consent** 

## Appendix H: Baseline survey items Synergy Study

## **Survey Flow**

Welcome (1 Question) **Demographics** (7 Questions) **Residence** (3 Questions) Perceived Neighbourhood Disorder (1 Question) Education (1 Question) **Income** (1 Question) **Employment** (6 Questions) **Current Health** (1 Question) Active Australia Questionnaire (11 Questions) Pittsburgh Sleep Quality Index (11 Questions) **QOL** (7 Questions) Mental Wellbeing - DASS21 (22 Questions) Morningness-Eveningness Questionnaire (6 Questions) **Insomnia Severity Index** (8 Questions) **Epworth Sleepiness Scale** (2 Questions) Sleep Timing Questionnaire shortened (10 Questions) Lifestyle factors (8 Questions) **Sleep Hygiene Index** (3 Questions) Workforce Sitting Questionnaire (2 Questions) Social Cognitive Factors - PA (11 Questions) Social Cognitive Factors - Sleep (9 Questions) Shipment info (2 Questions)

Start of Block: Welcome

baseline\_intro1 Welcome to your first assessment.

The following questions aim to explore aspects of your general health & wellbeing, your physical activity levels and sleep habits and the environments you live in.

Your time and patience is much appreciated. Please provide your honest responses.

End of Block: Welcome

**Start of Block: Demographics** 

intro\_base2 We will start this survey with some general questions.

sdem1a Are you:

- Male (1)
- Female (2)

sdem2 What is your current **age**? (Enter years)

sdem3 What is your current marital status?

- Single (1)
- Widowed (2)
- Divorced (3)
- Separated, but not divorced (4)
- Married (5)
- De Facto (6)
- Prefer not to answer (7)

sdem4a What is your **height** in centimetres? (Example: 175)

IMPORTANT: Please enter your height in **metric units** (centimetres) instead of imperial units (foot/inches), for example: 5'7" = 170cm; 5'8" = 173cm; 5'9" = 175cm; 6'0" = 183cm; 6'1" = 185cm

sdem4b What is your current **body weight** in kilograms? (Example: 65)

Display This Question:

If Are you: = Female

sdem1b Are you currently pregnant?

• Yes (1)

• No (2)

**End of Block: Demographics** 

```
Start of Block: Residence
```

sdem11a In which Australian State or Territory do you currently reside?

- Australian Capital Territory (1)
- New South Wales (2)
- Northern Territory (3)
- Queensland (4)
- South Australia (5)
- Tasmania (6)
- Victoria (7)
- Western Australia (8)
- I live outside of Australia (9)

sdem11b Please enter your **postcode** 

sdem12 With which racial or ethnic group(s) do you most identify with?

- □ Caucasian (1)
- □ Aboriginal, Torres Strait Islander and Pacific Islanders (2)
- □ African (3)
- □ Asian (4)
- □ Other/Prefer not to say (5)

**End of Block: Residence** 

Start of Block: Perceived Neighbourhood Disorder

spnd Think about the **order and safety in your neighbourhood**; by this we mean the area **ALL around your home** that you could **walk to in 10-15 minutes**.

For each of the following statements, please **rate your agreement** by choosing the answer that corresponds to how you feel.

	Strongly disagree (1)	Disagree (2)	Neither disagree or agree (3)	Agree (4)	Strongly agree (5)
My neighbourhood is noisy. (spnd_1)	0	0	0	0	0
My neighbourhood is clean. (spnd_2)	0	0	0	0	0
There is a lot of crime in my neighbourhood. (spnd_3)	0	0	0	0	0
My neighbourhood is safe. (spnd_4)	0	0	0	0	0

End of Block: Perceived Neighbourhood Disorder

**Start of Block: Education** 



sdem6 How many **years of education** have you completed in total? (Example: after year 10, you would have completed 11 years of education = 1 year of kindergarten + 6 years of primary education + 4 years of high school)

Enter years \_\_\_\_\_

**End of Block: Education** 

**Start of Block: Income** 

## sdem7 What is your approximate annual individual income (before tax)?

- Less than \$30,000 per year (less than \$2,500 per month) (1)
- \$30,001 \$50,000 per year (\$2,501 \$4,200 per month) (2)
- \$50,001 \$70,000 per year (\$4,201 \$5,800 per month) (3)
- \$70,001 \$100,000 per year (\$5,801 \$8,300 per month) (4)
- \$100,001 \$150,000 per year (\$8,301 \$12,500 per month) (5)
- Don't know/prefer not to answer (6)

End of Block: Income

**Start of Block: Employment** 

## sdem8a Please specify the industry in which you are employed

- Agriculture, forestry & fishing (1)
- Mining (2)
- Manufacturing (3)
- Electricity, gas & water supply (4)
- Construction (5)
- Wholesale trade (6)
- Retail trade (7)
- Accommodation, cafes & restaurants (8)
- Transport & storage (9)
- Communication services (10)
- Finance, property and business services (11)
- Finance & insurance (12)
- Property & business services (13)
- Government administration & defence (14)
- Recreation, personal & other services (15)
- Health & community services (16)
- Education (17)
- Cultural & recreational services (18)
- Personal & other services (19)
- Retired (20)
- Student (21)
- Home duties (22)
- Unemployed (23)
- Unable to work (24)
- Other (specify below) (25)

Skip To: End of Block If Please specify the industry in which you are employed = Retired Skip To: End of Block If Please specify the industry in which you are employed = Student Skip To: End of Block If Please specify the industry in which you are employed = Home duties Skip To: End of Block If Please specify the industry in which you are employed = Unemployed Skip To: End of Block If Please specify the industry in which you are employed = Unemployed skip To: End of Block If Please specify the industry in which you are employed = Unemployed skip To: End of Block If Please specify the industry in which you are employed = Unable to work sdem8b Please indicate the **level at which you work** (if you have more than one job, consider the highest of levels you work in out of all your jobs)

- Manager & administrator (1)
- Professional (2)
- Associate/Para-professional (3)
- Tradesperson (4)
- o Clerk (5)
- Salesperson & personal service worker (6)
- Plant & machine operators/drivers (7)
- Advanced clerical & service worker (8)
- Intermediate clerical & service worker (9)
- Intermediate production & transport worker (10)
- Elementary clerical, sales & service worker (11)
- Labourer & related worker (12)
- Retired (13)
- Student (14)
- Home duties (15)
- Unemployed (16)
- Unable to work (17)
- Other (specify below) (18)

sdem9a Thinking about your job, in the last week, how many days did you work?

	enter a number
days per week (1)	▼ 0 (0 7)

sdem9b How would you describe your working hours?

- Only during the day (allowing you to keep normal bedtimes during the night, approximately between 5am and 10pm) (1)
- Only during the afternoon/evening (no later than 10pm) (2)
- Only during the night/early morning hours (not allowing you to keep normal bedtimes during the night, approximately between 10pm and 5am) (3)
- Rotating shifts (if any shifts on your roster include night work or require you to shift your sleep times, e.g. between the hours of 10pm and 5am) (4)
- Not working (5)

\_\_\_\_\_

sdem9c In the last week, how many hours did you work on an average working day?

(Enter hours and minutes separately, e.g., 7 hours 30 minutes)

	hours	minutes
enter hours and minutes per day	▼ 0 (0 24)	▼ 00 (0 45)

sdem10 On a scale from **0 to 10**, where 0 is the worst **job performance** anyone could have at their job and 10 is the performance of a top worker, how would you rate your overall performance on the days you worked **during the past 4 weeks** (28 days)?

					4-w	veek ra	ating				
	0	1	2	3	4	5	6	7	8	9	10
job performance	0	0	0	0	0	0	0	0	0	0	0

**End of Block: Employment** 

**Start of Block: Current Health** 

sdem5a Have you ever been **told by a doctor** that you have any of the following **chronic health problems**? (Multiple options possible).

- Arthritis (1)
- Asthma (2)
- Cancer (3)
- Cerebrovascular disease (stroke) (4)
- Chronic obstructive pulmonary disease (emphysema) (5)
- Coronary heart disease (heart attack, angina) (6)
- Type 1 Diabetes (7)
- Type 2 Diabetes (8)
- High blood pressure (9)
- High Cholesterol (14)
- Irritable Bowel Syndrome (13)
- Kidney disease (10)
- Osteoporosis (12)
- Depression (11)
- Anxiety (17)
- Other health problems (please describe): (15)
- Chronic Insomnia (18)
- Restless Legs Syndrome (19)
- Sleep Apnoea (20)
- Other sleep disorders (please describe): (21)
- None of the above (16)

**End of Block: Current Health** 

Start of Block: Active Australia Questionnaire

saaq\_intro The next questions are about any physical activities that you may have done in the last week.

saaq1 In the last week, **how many times** have you **walked continuously, for at least 10 minutes**, for recreation, exercise or to get to or from places?

▼ 0 ... 25

saaq2 What do you estimate was the **total time that you spent walking** in this way in the **last week**? In hours and/or minutes

	Hours	Minutes
Enter Hours and Minutes	▼ 0 (0 14)	▼ 0 (0 50)

saaq3 In the last week, **how many times** did you do any **vigorous gardening or heavy work** around the yard, which made you **breathe harder or puff and pant**?

▼ 0 (0) ... 25 (25)

saaq4 What do you estimate was the **total time that you spent doing vigorous gardening or heavy work** around the yard in the last week? In hours and/or minutes

	Hours	Minutes
Enter Hours and Minutes	▼ 0 (1 14)	▼ 0 (1 50)

saaq5 In the next questions, exclude household chores, gardening or yardwork.

In the last week, **how many times** did you do any **vigorous physical activity**, which made you **breathe harder or puff and pant**? (e.g., jogging, cycling, aerobics, competitive tennis)

▼ 0 25)			

saaq6 What do you estimate was the **total time that you spent doing this vigorous physical activity** in the last week? In hours and/or minutes

	Hours	Minutes
Enter Hours and Minutes	▼ 0 (1 14)	▼ 0 (1 50)

saaq7 In the last week, **how many times** did you do any **other more moderate physical activities** that you have not already mentioned?

▼ 0 25						
saaq8 What do you estimate activities in the last week? In		spent doing these				
activities in the last week! If	activities in the last week? In nours and/or minutes					
	Hours	Minutes				
Enter Hours and Minutes	▼ 0 (1 14)	▼ 0 (1 50)				
saaq9_rt In the last week, on <b>strengthening activities</b> (inc		•				
Enter number of days						
▼ 0 7						
saaq10_rt What do you estim strengthening activities (inc	-					
Enter hours and minutes						
	Hours	Minutes				
Enter Hours and Minutes	▼ 0 (0 20)	▼ 0 (0 50)				
End of Block: Active Austra	lia Questionnaire					

Start of Block: Pittsburgh Sleep Quality Index

psqi\_intro The following questions relate to your **usual sleep habits during the past month only**.

Your answers should indicate the most accurate reply for the **majority of days and nights** in the past month.

spsqi1 During the past month, when have you usually gone to bed at night?

	hours	minutes	am or pm
enter your usual bedtime	▼ 00 (0 12)	▼ 00 (0 59 )	▼ pm (0 am (1)

spsqi2 During the past month, about **how long (in minutes) did it usually take you to fall asleep** each night?

\_ \_ \_ \_ \_ \_ \_ \_ \_ \_

	hours	minutes
enter a time	▼ 0 (0 4)	▼ 00 (0 55)

spsqi3 During the past month, when have you **usually gotten up** in the morning? (enter your usual time of getting up)

	hours	minutes	am or pm	
enter your usual wake time	▼ 00 (0 12)	▼ 00 (0 59)	▼ am (1 pm (2)	

spsqi4 During the past month, **how many hours of actual sleep did you get** at night? (This may be different than the number of hours you spend in bed)

	hours	minutes
enter amount of sleep	▼ 0 (0 24)	▼ 00 (0 55)
enter amount of sleep	▼ 0 (0 24)	▼ 00 (0 55)

spsqi5 For each of the following questions, choose the one best response. Please answer all the questions.

## During the past month, how often have you had trouble sleeping because you...

	Not during the past month (1)	Less than once a week (2)	Once or twice a week (3)	Three or more times a week (4)
cannot get to sleep within 30 minutes. (spsqi5_1)	0	0	0	0
wake up in the middle of the night or early morning. (spsqi5_2)	0	0	0	0
have to get up to use the bathroom. (spsqi5_3)	0	0	0	0
cannot breathe comfortably. (spsqi5_4)	0	0	0	0
cough or snore loudly. (spsqi5_5)	0	0	0	0
feel too cold. (spsqi5_6)	0	0	0	0
feel too hot. (spsqi5_7)	0	0	0	0
had bad dreams. (spsqi5_8)	0	0	0	0
have pain. (spsqi5_9)	0	0	0	0
other reason(s), please describe and indicate how often during the past month you have had trouble sleeping because of this (spsqi5_10)	Ο	0	0	0

spsqi6 During the past month, how would you rate your sleep quality overall?

- very bad (1)
- o fairly bad (2)
- o fairly good (3)
- very good (4)

spsqi7 During the past month...

	Not during the past month (1)	Less than once a week (2)	Once or twice a week (3)	Three or more times a week (4)
how often have you taken medicine (prescribed or "over the counter") to help you sleep? (spsqi7_1)	0	0	0	0
how often have you had trouble staying awake while driving, eating meals, or engaging in social activity? (spsqi7_2)	0	0	0	0

spsqi8 During the past month, **how much of a problem** has it been for you to keep up enough **enthusiasm** to get things done?

- No problem at all (1)
- Only a very slight problem (2)
- Somewhat of a problem (3)
- A very big problem (4)

spsqi9 Do you have a **bed partner** or **roommate**?

- No bed partner or roommate (1)
- Partner/roommate in other room (2)
- Partner in same room, but not same bed (3)
- Partner in same bed (4)

Skip To: End of Block If Do you have a bed partner or roommate? = No bed partner or roommate

	number of days
loud snoring. (spsqi10_1)	▼ 0 (0 31)
long pauses between breaths while asleep. (spsqi10_2)	▼ 0 (0 31)
legs twitching or jerking while you sleep. (spsqi10_3)	▼ 0 (0 31)
episodes of disorientation or confusion during sleep. (spsqi10_4)	▼ 0 (0 31)
other restlessness while you sleep (please describe and enter the number of days this was observed): (spsqi10_5)	▼ 0 (0 31)

spsqi10 If you have a roommate or bed partner, **ask him/her how often in the past month** you have had...

## End of Block: Pittsburgh Sleep Quality Index

Start of Block: QOL

sqol1 In general, would you say your health is:

- Excellent (1)
- Very good (2)
- Good (3)
- Fair (4)
- Poor (5)

sqol3 The following items are about activities you might do during a typical day. **Does your health now limit you** in these activities? If so, how much?

	Yes, limited a lot (1)	Yes, limited a little (2)	No, not limited at all (3)
Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf sports. (sqol3_2)	0	0	0
Climbing several flights of stairs. (sqol3_4)	0	0	0

sqol4 During the **past 4 weeks**, have you had any of the following **problems with your work** or other regular daily activities **as a result of physical health**?

	Yes (1)	No (2)
Accomplished less than you would like. (sqol4_2)	0	0
Were limited in the kind of work or other activities. (sqol4_3)	0	0

sqol5 During the **past 4 weeks**, have you had any of the following **problems with your work** or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

	Yes (1)	No (2)
Accomplished less than you would like. (sqol5_2)	0	0
Did work or activities less carefully than usual. (sqol5_3)	0	0

sqol8 During the **past 4 weeks**, how much **did pain interfere with your normal work** (including both work outside the home and housework)?

- Not at all (1)
- A little bit (2)
- Moderately (3)
- Quite a bit (4)
- Extremely (5)

sqol9 These questions are about **how you have been feeling** during the **past 4 weeks**. For each question, please give the **one answer** that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks...

	All of the time (1)	Most of the time (2)	A good bit of the time (3)	Some of the time (4)	A little bit of the time (5)	None of the time (6)
Did you feel full of pep (sqol9_1)	0	0	0	0	0	0
Have you felt calm and peaceful? (sqol9_2)	0	0	0	0	0	0
Did you have a lot of energy? (sqol9_3)	0	0	0	0	0	0
Have you felt downhearted and blue? (sqol9_4)	0	0	0	0	0	0
Did you feel worn out? (sqol9_5)	0	0	0	0	0	0
Did you feel tired? (sqol9_6)	0	0	0	0	0	0

sqol10 During the **past 4 weeks**, how much of the time has your physical health or emotional problems interfered with your **social activities** (like visiting friends, relatives, etc.)?

- All of the time (1)
- Most of the time (2)
- Some of the time (3)
- A little of the time (4)
- None of the time (5)

**End of Block: QOL** 

Start of Block: Mental Wellbeing - DASS21

sdass\_intro Please read each statement and choose a response, which indicates how much the statement applied to you over **the past week.** There are no right or wrong answers. Do not spend too much time on any statement.

#### sdass1 I found it hard to wind down

- Did not apply to me at all NEVER (1)
- Applied to me to some degree, or some of the time SOMETIMES (2)
- Applied to me to a considerable degree, or a good part of the time OFTEN (3)
- Applied to me very much, or most of the time ALWAYS (4)

sdass2 I was aware of dryness of my mouth

- Did not apply to me at all NEVER (1)
- Applied to me to some degree, or some of the time SOMETIMES (2)
- Applied to me to a considerable degree, or a good part of the time OFTEN (3)
- Applied to me very much, or most of the time ALWAYS (4)

### sdass3 I couldn't seem to experience any positive feeling at all

- Did not apply to me at all NEVER (1)
- Applied to me to some degree, or some of the time SOMETIMES (2)
- Applied to me to a considerable degree, or a good part of the time OFTEN (3)
- Applied to me very much, or most of the time ALWAYS (4)

sdass4 I experienced **breathing difficulty** (e.g., excessively rapid breathing, breathlessness in the absence of physical exertion)

- Did not apply to me at all NEVER (1)
- Applied to me to some degree, or some of the time SOMETIMES (2)
- Applied to me to a considerable degree, or a good part of the time OFTEN (3)
- Applied to me very much, or most of the time ALWAYS (4)

sdass5 I found it difficult to work up the **initiative** to do things

- Did not apply to me at all NEVER (1)
- Applied to me to some degree, or some of the time SOMETIMES (2)
- Applied to me to a considerable degree, or a good part of the time OFTEN (3)
- Applied to me very much, or most of the time ALWAYS (4)

sdass6 I tended to **over-react** to situations

- Did not apply to me at all NEVER (1)
- Applied to me to some degree, or some of the time SOMETIMES (2)
- Applied to me to a considerable degree, or a good part of the time OFTEN (3)
- Applied to me very much, or most of the time ALWAYS (4)

sdass7 I experienced trembling (e.g., in the hands)

- Did not apply to me at all NEVER (1)
- Applied to me to some degree, or some of the time SOMETIMES (2)
- Applied to me to a considerable degree, or a good part of the time OFTEN (3)
- Applied to me very much, or most of the time ALWAYS (4)

### sdass8 I felt that I was using a lot of nervous energy

- Did not apply to me at all NEVER (1)
- Applied to me to some degree, or some of the time SOMETIMES (2)
- Applied to me to a considerable degree, or a good part of the time OFTEN (3)
- Applied to me very much, or most of the time ALWAYS (4)

sdass9 I was worried about situations in which I might **panic** and **make a fool of myself** 

- Did not apply to me at all NEVER (1)
- Applied to me to some degree, or some of the time SOMETIMES (2)
- Applied to me to a considerable degree, or a good part of the time OFTEN (3)
- Applied to me very much, or most of the time ALWAYS (4)

## sdass10 | felt that | had nothing to look forward to

- Did not apply to me at all NEVER (1)
- Applied to me to some degree, or some of the time SOMETIMES (2)
- Applied to me to a considerable degree, or a good part of the time OFTEN (3)
- Applied to me very much, or most of the time ALWAYS (4)

# sdass11 I found myself getting agitated

- Did not apply to me at all NEVER (1)
- Applied to me to some degree, or some of the time SOMETIMES (2)
- Applied to me to a considerable degree, or a good part of the time OFTEN (3)
- Applied to me very much, or most of the time ALWAYS (4)

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### sdass12 I found it **difficult to relax**

- Did not apply to me at all NEVER (1)
- Applied to me to some degree, or some of the time SOMETIMES (2)
- Applied to me to a considerable degree, or a good part of the time OFTEN (3)
- Applied to me very much, or most of the time ALWAYS (4)

- sdass13 I felt down-hearted and blue
  - Did not apply to me at all NEVER (1)
  - Applied to me to some degree, or some of the time SOMETIMES (2)
  - Applied to me to a considerable degree, or a good part of the time OFTEN (3)
  - Applied to me very much, or most of the time ALWAYS (4)

sdass14 I was **intolerant** of anything that kept me from getting on with what I was doing

- Did not apply to me at all NEVER (1)
- Applied to me to some degree, or some of the time SOMETIMES (2)
- Applied to me to a considerable degree, or a good part of the time OFTEN (3)
- Applied to me very much, or most of the time ALWAYS (4)

### sdass15 I felt I was close to panic

- Did not apply to me at all NEVER (1)
- Applied to me to some degree, or some of the time SOMETIMES (2)
- Applied to me to a considerable degree, or a good part of the time OFTEN (3)
- Applied to me very much, or most of the time ALWAYS (4)

### sdass16 I was unable to become enthusiastic about anything

- Did not apply to me at all NEVER (1)
- Applied to me to some degree, or some of the time SOMETIMES (2)
- Applied to me to a considerable degree, or a good part of the time OFTEN (3)
- Applied to me very much, or most of the time ALWAYS (4)

sdass17 I felt I wasn't worth as much as a person

- Did not apply to me at all NEVER (1)
- Applied to me to some degree, or some of the time SOMETIMES (2)
- Applied to me to a considerable degree, or a good part of the time OFTEN (3)
- Applied to me very much, or most of the time ALWAYS (4)

sdass18 I felt that I was rather touchy

- Did not apply to me at all NEVER (1)
- Applied to me to some degree, or some of the time SOMETIMES (2)
- Applied to me to a considerable degree, or a good part of the time OFTEN (3)
- Applied to me very much, or most of the time ALWAYS (4)

sdass19 I was aware of the action of my **heart** in the absence of physical exertion (e.g., increased sense of heart rate increase, heart missing a beat)

- Did not apply to me at all NEVER (1)
- Applied to me to some degree, or some of the time SOMETIMES (2)
- Applied to me to a considerable degree, or a good part of the time OFTEN (3)
- Applied to me very much, or most of the time ALWAYS (4)

sdass20 I felt scared without any good reason

- Did not apply to me at all NEVER (1)
- Applied to me to some degree, or some of the time SOMETIMES (2)
- Applied to me to a considerable degree, or a good part of the time OFTEN (3)
- Applied to me very much, or most of the time ALWAYS (4)

sdass21 I felt that life was meaningless

- Did not apply to me at all NEVER (1)
- Applied to me to some degree, or some of the time SOMETIMES (2)
- Applied to me to a considerable degree, or a good part of the time OFTEN (3)
- Applied to me very much, or most of the time ALWAYS (4)

End of Block: Mental Wellbeing - DASS21

Start of Block: Perceived Neighbourhood Disorder

spnd Think about the **order and safety in your neighbourhood**; by this we mean the area **ALL around your home** that you could **walk to in 10-15 minutes**.

For each of the following statements, please **rate your agreement** by choosing the answer that corresponds to how you feel.

	Strongly disagree (1)	Disagree (2)	Neither disagree or agree (3)	Agree (4)	Strongly agree (5)
My neighbourhood is noisy. (spnd_1)	0	0	0	0	0
My neighbourhood is clean. (spnd_2)	0	0	0	0	0
There is a lot of crime in my neighbourhood. (spnd_3)	0	0	0	0	0
My neighbourhood is safe. (spnd_4)	0	0	0	0	0

End of Block: Perceived Neighbourhood Disorder

Start of Block: Morningness-Eveningness Questionnaire

smeq\_intro For each of the following questions, please select the answer that best indicates **how you have felt in recent weeks** (last 30 days).

smeq1 At what time would you get up if you were entirely free to plan your day?

- $\circ$  5:00 AM 6:30 AM (05:00 06:30h) (1)
- $\circ$  6:30 AM 7:45 AM (06:30 07:45h) (2)
- 7:45 AM 9:45 AM (07:45 09:45h) (3)
- 9:45 AM 11:00 AM (09:45 11:00h) (4)
- 11:00 AM 12 noon (11:00 12:00h) (5)

smeq2 During the first half hour after you wake up in the morning, how do you feel?

- Very tired (1)
- Fairly tired (2)
- Fairly refreshed (3)
- Very refreshed (4)

smeq3 At what time in the evening do you feel tired, and, as a result, in need of sleep?

- 8:00 PM 9:00 PM (20:00 21:00h) (1)
- 9:00 PM 10:15 PM (21:00 22:15h) (2)
- 10:15 PM 12:30 AM (22:15 00:30h) (3)
- 12:30 AM 1:45 AM (00:30 01:45h) (4)
- 1:45 AM 3:00 AM (01:45 03:00h) (5)

smeq4 At approximately what time of day do you usually feel your best?

- 5:00 AM 8:00 AM (05:00 08:00h) (1)
- 8:00 AM 10:00 AM (08:00 10:00h) (2)
- 10:00 AM 5:00 PM (10:00 17:00h) (3)
- 5:00 PM 10:00 PM (17:00 22:00h) (4)
- 10:00 PM 5:00 AM (22:00 05:00h) (5)

smeq5 One hears about "**morning types**" and "**evening types**". Which one of these types do you consider yourself to be?

- Definitely a morning type (1)
- Rather a morning type than an evening type (2)
- Rather an evening type than a morning type (3)
- Definitely an evening type (4)

End of Block: Morningness-Eveningness Questionnaire

**Start of Block: Insomnia Severity Index** 

sisi\_intro We will now ask you a number of questions about your sleep health.

Please rate the current (i.e., last 2 weeks) severity of your insomnia problem(s):

\_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_

sisi1 Difficulty falling asleep

- None (1)
- Mild (2)
- Moderate (3)
- Severe (4)
- Very severe (5)

sisi2 Difficulty staying asleep

- None (1)
- Mild (2)
- Moderate (3)
- Severe (4)
- Very severe (5)

sisi3 Problems waking up too early

- None (1)
- Mild (2)
- Moderate (3)
- Severe (4)
- Very severe (5)

sisi4 How satisfied/dissatisfied are you with your current sleep pattern?

- Very satisfied (1)
- o Satisfied (2)
- Moderately satisfied (3)
- Dissatisfied (4)
- Very dissatisfied (5)

sisi5 How **noticeable to others** do you think your sleep problem is in terms of **impairing the quality of your life**?

- Not at all noticeable (1)
- A little (2)
- Somewhat (3)
- Much (4)
- Very much noticeable (5)

sisi6 How worried/distressed are you about your current sleep problem?

- Not at all worried (1)
- A little (2)
- Somewhat (3)
- Much (4)
- Very much worried (5)

sisi7 To what extent do you consider your sleep problem to **interfere with your daily functioning** (e.g., daytime fatigue, mood, ability to function at work/daily chores, concentration, memory, mood, etc.) currently?

- Not at all interfering (1)
- A little (2)
- Somewhat (3)
- Much (4)
- Very much interfering (5)

End of Block: Insomnia Severity Index

Start of Block: Epworth Sleepiness Scale

sess1 How **Sleepy** Are You? **How likely are you to doze off or fall asleep** in the following situations? You should **rate your chances** of dozing off, not just feeling tired. Even if you have not done some of these things recently try to determine how they would have **affected** you.

	No chance of dozing (1)	Slight chance of dozing (2)	Moderate chance of dozing (3)	High chance of dozing (4)
Sitting and reading. (sess1_1)	0	0	0	0
Watching TV. (sess1_2)	0	0	0	0
Sitting inactive in a public place (e.g., a theatre or a meeting). (sess1_3)	0	0	0	0
As a passenger in a car for an hour without a break. (sess1_4)	0	0	0	0

For each situation, decide what the chances are of you dozing off.

	No chance of dozing (5)	Slight chance of dozing (6)	Moderate chance of dozing (7)	High chance of dozing (8)
Lying down to rest in the afternoon when circumstances permit. (sess1_5)	0	0	0	0
Sitting and talking to someone. (sess1_6)	0	0	0	0
Sitting quietly after a lunch without alcohol. (sess1_7)	0	0	0	0
In a car, while stopped for a few minutes in traffic. (sess1_8)	0	0	0	0

### sess1 For each situation, decide what the chances are of you dozing off.

End of Block: Epworth Sleepiness Scale

Start of Block: Sleep Timing Questionnaire\_shortened

sstq\_intro The following questions ask you about **when** you normally sleep. We are interested in getting as accurate a picture as we can of the times when you normally go to bed and get up.

Please think carefully before giving your answers and be as accurate and as specific as you can be. Please answer in terms of recent "**normal average week**", not one in which you traveled, vacationed or had a family crisis.

sstq1 Please think of **GOOD NIGHT** time as the time at which you are finally **in bed and trying to fall asleep**.

On the **night before a work day or school day**, what time is your **usual** GOOD NIGHT time?

	Hours	Minutes	PM/AM
Enter time	▼ 00 (0 11)	▼ 00 (0 59)	▼ PM (0 AM (1)

sstq2 **How stable** (i.e., similar each night) are your GOOD NIGHT times **before a work or school day**?

Choose one answer.

- 0-15 minutes (1)
- o 16-30 minutes (2)
- o 31-45 minutes (3)
- 46-60 minutes (4)
- o 61-75 minutes (5)
- o 76-90 minutes (6)
- 91-105 minutes (7)
- 106-120 minutes (8)
- 2-3 hours (9)
- o 3-4 hours (10)
- o over 4 hours (11)

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sstq3 On a night before a day off (e.g., a weekend), what is your <b>usual</b> GOOD NIGHT
time?

	Hours	Minutes	PM/AM
Enter time	▼ 00 (0 11)	▼ 00 (0 59)	▼ PM (0 AM (1)

sstq4 **How stable** (i.e., similar each night) are your GOOD NIGHT times **on a night before a day off** (e.g., a weekend)?

Choose one answer.

- 0-15 minutes (1)
- 16-30 minutes (2)
- o 31-45 minutes (3)
- o 46-60 minutes (4)
- o 61-75 minutes (5)
- o 76-90 minutes (6)
- 91-105 minutes (7)
- 106-120 minutes (8)
- 2-3 hours (9)
- o 3-4 hours (10)
- o over 4 hours (11)

 sstq5 Please think of a **GOOD MORNING** time as the time at which you finally get out of bed and start your day.

Before a work day or school day, what time is your usual GOOD MORNING time?

	Hours	Minutes	AM/PM
Enter time	▼ 00 ( 12)	▼ 00 (0 59)	▼ AM (0 PM (2)

sstq6 **How stable** (i.e., similar each day) are your GOOD MORNING times **before a work day or school day**?

Choose one answer.

- 0-15 minutes (1)
- o 16-30 minutes (2)
- o 31-45 minutes (3)
- 46-60 minutes (4)
- o 61-75 minutes (5)
- o 76-90 minutes (6)
- 91-105 minutes (7)
- 106-120 minutes (8)
- 2-3 hours (9)
- o 3-4 hours (10)
- o over 4 hours (11)

\_\_\_\_\_

	Hours	Minutes	AM/PM
Enter time	▼ 00 (1 12)	▼ 00 (1 59)	▼ AM (1 PM (2)

sstq7 Before a day off (e.g., a weekend), what is your usual GOOD MORNING time?

sstq8 **How stable** (i.e., similar each day) are your GOOD MORNING times **before a day off** (e.g., a weekend)?

Choose one answer.

- 0-15 minutes (1)
- 16-30 minutes (2)
- o 31-45 minutes (3)
- 46-60 minutes (4)
- o 61-75 minutes (5)
- o 76-90 minutes (6)
- 91-105 minutes (7)
- 106-120 minutes (8)
- 2-3 hours (9)
- o 3-4 hours (10)
- o over 4 hours (11)

sstq9 The last question is about how much **sleep you lose to unwanted wakefulness**:

On most nights, how much sleep do you lose, on average, from waking up during the night (e.g., to go to the bathroom)?

	hours	minutes
enter hours and minutes	▼ 0 (0 8)	▼ 00 (0 55)

End of Block: Sleep Timing Questionnaire

**Start of Block: Lifestyle factors** 

slifestyle1 How often do you have a drink containing alcohol?

- Never (1)
- Monthly or less (2)
- 2-4 times a month (3)
- $\circ$  2-3 times a week (4)
- 4 or more times a week (5)

Skip To: slifestyle5 If How often do you have a drink containing alcohol? = Never

slifestyle2 How many standard drinks containing alcohol do you have on a typical day?

None (0)
1 or 2 (1)
3 or 4 (2)
5 or 6 (3)
7 to 9 (4)
10 or more (5)

slifestyle3 How often do you have six or more drinks on one occasion?

- Never (1)
- Less than monthly (2)
- Monthly (3)
- Weekly (4)
- Daily or almost daily (5)

slifestyle4 How often do you have a drink containing alcohol close to bedtime?

- Never (1)
- Monthly or less (2)
- 2-4 times a month (3)
- $\circ$  2-3 times a week (4)
- 4 or more times a week (5)

slifestyle5 **How often** do you have a **drink containing caffeine**?

- Never (1)
- Monthly or less (2)
- 2-4 times a month (3)
- $\circ$  2-3 times a week (4)
- 4 or more times a week (5)

Skip To: slifestyle8 If How often do you have a drink containing caffeine? = Never

slifestyle6 **How many drinks containing caffeine** do you have on **a typical day**? (eg. tea, coffee, Coca-Cola, Pepsi, Red Bull, Mother, etc.)

▼ 0 ... 20

slifestyle7 How often do you have a drink containing caffeine close to bedtime?

- Never (1)
- Monthly or less (2)
- 2-4 times a month (3)
- $\circ$  2-3 times a week (4)
- 4 or more times a week (5)

slifestyle8 Do you **currently smoke cigarettes** or any other tobacco products **on a daily basis**?

- Yes (1)
- No (2)

**End of Block: Lifestyle factors** 

**Start of Block: Sleep Hygiene Index** 

	Never (1)	Rarely (2)	Sometimes (3)	Frequently (4)	Always (5)
I take daytime naps lasting two or more hours too close to bedtime. (sshi1_1)	0	0	0	0	0
l go to bed at different times from day to day. (sshi1_2)	0	0	0	0	0
l get out of bed at different times from day to day. (sshi1_3)	0	0	0	0	0
l exercise to the point of sweating within 1 h of going to bed. (sshi1_4)	0	0	0	0	0
I stay in bed longer than I should two or three times a week. (sshi1_5)	0	0	0	0	0

sshi1 For the following items, please indicate how frequently you do each of them.

	Never (1)	Rarely (2)	Sometimes (3)	Frequently (8)	Always (9)
I use alcohol, tobacco, or caffeine within 4 h of going to bed or after going to bed. (sshi1_6)	0	0	0	0	0
I do something that may wake me up before bedtime (for example: play video games, use the internet, or clean). (sshi1_7)	0	0	0	0	0
l go to bed feeling stressed, angry, upset, or nervous. (sshi1_8)	0	0	0	0	0
l use my bed for things other than sleeping or sex (for example: watch television, read, eat, or study). (sshi1_9)	0	0	0	0	0
I sleep on an uncomfortable bed (for example: poor mattress or pillow, too much or not enough blankets). (sshi1_10)	0	0	0	0	0

sshi1 For the following items, please indicate how frequently you do each of them.

	Never (1)	Rarely (2)	Sometimes (3)	Frequently (4)	Always (5)
I sleep in an uncomfortable bedroom (for example: too bright, too stuffy, too hot, too cold, or too noisy). (sshi1_11)	0	0	0	0	0
I do important work before bedtime (for example: pay bills, schedule, or study). (sshi1_12)	0	0	0	0	0
I think, plan, or worry when I am bed. (sshi1_13)	0	0	0	0	0
l drink a lot of alcohol or coffee close to bedtime. (sshi1_14)	0	0	0	0	0
l smoke. (sshi1_15)	0	0	0	0	0

sshi1 For the following items, please indicate how frequently you do each of them.

End of Block: Sleep Hygiene Index

Start of Block: Workforce Sitting Questionnaire

swfsq1 During the **last 7 days**, please estimate **how much time** (in hours and minutes) you usually spend **sitting** in each of the following activities on a **working day**.

	hours	minutes
For transport (e.g., in car, bus, train, etc.) (swfsq1_1)	▼ 00 (0 24)	▼ 00 (0 55)
At work (e.g., sitting at a desk or using a computer) (swfsq1_2)	▼ 00 (0 24)	▼ 00 (0 55)
Watching TV (swfsq1_3)	▼ 00 (0 24)	▼ 00 (0 55)
Using a computer at home (e.g., email, games, information, chatting) (swfsq1_4)	▼ 00 (0 24)	▼ 00 (0 55)
Other leisure activities (e.g., socialising, movies, etc., but not including computer use or TV) (swfsq1_5)	▼ 00 (0 24)	▼ 00 (0 55)

swfsq2 During the **last 7 days**, please estimate **how much time** (hours and minutes) you usually spend **sitting** in each of the following activities on a **non-working day**.

	hours	minutes
For transport (e.g., in car, bus, train, etc.) (swfsq2_1)	▼ 00 (0 24)	▼ 00 (0 55)
At work (e.g., sitting at a desk or using a computer) (swfsq2_2)	▼ 00 (0 24)	▼ 00 (0 55)
Watching TV (swfsq2_3)	▼ 00 (0 24)	▼ 00 (0 55)
Using a computer at home (e.g., email, games, information, chatting) (swfsq2_4)	▼ 00 (0 24)	▼ 00 (0 55)
Other leisure activities (e.g., socialising, movies, etc., but not including computer use or TV) (swfsq2_5)	▼ 00 (0 24)	▼ 00 (0 55)

End of Block: Workforce Sitting Questionnaire

Start of Block: Social Cognitive Factors - PA

ssct\_pa\_intro Regular physical activity is defined as doing at least **150 minutes of moderate intensity physical activity each week**. Moderate intensity can be described as any type of aerobic activity performed at a level where a person begins to lightly sweat, but can still carry on a conversation. This may feel different from one person to another.

The next questions ask you **how confident** you are about doing regular physical activity **over the next 3 months** in different circumstances. For each question, choose the one response that best matches your answer.

	Not at all confident (1)	A little confident (2)	Moderately confident (3)	Very confident (4)	Extremely confident (5)
l am a little tired. (ssct_pa1_1)	0	0	0	0	0
I am in a bad mood or feeling depressed. (ssct_pa1_2)	0	0	0	0	0
l have to do it by myself. (ssct_pa1_3)	0	0	0	0	0
when it becomes boring. (ssct_pa1_4)	0	0	0	0	0
when I can't notice any improvements in my fitness. (ssct_pa1_5)	0	0	0	0	0
when I have many other demands on my time. (ssct_pa1_6)	0	0	0	0	0
when I feel a little stiff and sore. (ssct_pa1_7)	0	0	0	0	0
when the weather is bad. (ssct_pa1_8)	0	0	0	0	0
when I have to get up early, even on weekends. (ssct_pa1_9)	0	0	0	0	0
when I am on vacation. (ssct_pa1_10)	0	0	0	0	0

ssct\_pa1 I am confident that I can participate in regular physical activity, when...

ssct\_pa2 The following questions ask **how confident** you are about performing **specific tasks.** Rate how confident you are that you can perform the following activities **over the next 3 months**.

	Never (1)	Seldom (2)	Occasionally (3)	Often (4)	Always (5)
I can run or jog for 10 minutes without stopping. (ssct_pa2_1)	0	0	0	0	0
I can climb 3 flights of stairs without stopping. (ssct_pa2_2)	0	0	0	0	0
I can exercise for 20 minutes at a level hard enough to cause a large increase in my breathing and heart rate. (ssct_pa2_3)	0	0	0	0	0

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ssct\_pa3 The following questions list a number of things, which may or may not **impact your physical activity habits** over the **next 3 months**.

For each question, first indicate **how much you agree** with each statement and then **rate how important** each statement is to you.

	Strongly disagree (1)	Slightly disagree (2)	Neither disagree nor agree (3)	Slightly agree (4)	Strongly agree (5)
reduce my risk for some illnesses and diseases (e.g., heart disease, diabetes, some cancers, etc.). (ssct_pa3_1)	0	0	0	0	0
help me feel better physically. (ssct_pa3_2)	0	0	0	0	0
help me control weight. (ssct_pa3_3)	0	0	0	0	0
help me sleep better. (ssct_pa3_4)	0	0	0	0	0
help me feel more energetic throughout the day. (ssct_pa3_5)	0	0	0	0	0

### Being physically active can...

## ssct\_pa3 How important is...

	Not at all important (6)	Only slightly important (7)	Important (8)	Extremely important (9)
reducing your risk for illness and disease? (ssct_pa3_6)	0	0	0	0
feeling better physically? (ssct_pa3_7)	0	0	0	0
controlling your weight? (ssct_pa3_8)	0	0	0	0
sleeping well? (ssct_pa3_9)	0	0	0	0
feeling more energetic? (ssct_pa3_10)	0	0	0	0

ssct\_pa4 We would like to find out more **information about your local area**. Please select the answer that best describes your local area. Your local area is about a **10-15 minute walk from your home**.

	Strongly disagree (1)	Disagree (2)	Neutral (3)	Agree (4)	Strongly agree (5)
There are sidewalks on most of the streets in my local area. (ssct_pa4_1)	0	0	0	0	0
There are many interesting things to look at while walking my local area. (ssct_pa4_2)	0	0	0	0	0
My local area has several free or low cost recreation facilities, such as parks, walking trails, biking paths, playgrounds, and recreation centres. (ssct_pa4_3)	0	0	0	0	0

ssct\_pa5 How much do you **agree** or **disagree** with each of the following statements? Select the statement that best matches your answer.

Example: If **people in your social network** don't seem to care what you do for activity, select 'strongly disagree'

	Strongly disagree (1)	Moderately disagree (2)	Slightly disagree (3)	Neither disagree nor agree (4)	Slightly agree (5)	Moderately agree (6)	Strongly agree (7)
People in my social network are likely to help me participate in regular physical activity. (ssct_pa5_1)	0	0	0	0	0	0	0
I feel that someone in my social network will provide me with the support I need to get regular physical activity. (ssct_pa5_2)	0	0	0	0	0	0	0

\_\_\_\_\_

Over the next 3 months...

ssct\_pa6 Do you intend to do regular physical activity over the next 3 months?

- 1 No, not really (1)
- o 2 (2)
- o 3 (2)
- 4 Somewhat intend (3)
- o 3 (7)
- o 5 (4)
- 0 6 (5)
- 7 Strongly intend (6)

ssct\_pa7 **How motivated** are you to do regular physical activity **over the next 3 months**?

- 1 Not at all motivated (1)
- o 2 (2)
- 3 Somewhat motivated (3)
- o 4 (4)
- 5 Quite motivated (5)
- o 6 (6)
- 7 Extremely motivated (7)

ssct\_pa8 For the following statements, 'exercise' refers to any vigorous or moderate physical activity, which makes you breathe harder or puff and pant (e.g., jogging, cycling, aerobics, competitive tennis, gentle swimming, social tennis, golf, etc.) For each of the following statements please rate your level of agreement, by selecting the answer that best corresponds to how you feel.

### Exercise is something...

	Strongly disagree (1)	Disagree (2)	Somewhat disagree (3)	Neither disagree nor agree (4)	Somewhat agree (5)	Agree (6)	Strongly agree (7)
l do automatically. (ssct_pa8_1)	0	0	0	0	0	0	0
I do without having to consciously remember. (ssct_pa8_2)	0	0	0	0	0	0	0
l do without thinking. (ssct_pa8_3)	0	0	0	0	0	0	0
I start doing before I realise I am doing it. (ssct_pa8_4)	0	0	0	0	0	0	0

ssct\_pa9 Next, we are going to ask you about your **planning related to** being physically active **over the next 3 months**.

## I have made plans concerning...

	No plans						Detailed plans
	1	2	3	4	5	6	7
"when" I am going to be physically active over the next 3 months. (ssct_pa9_1)	0	0	0	0	0	0	0
"where" I am going to be physically active over the next 3 months. (ssct_pa9_2)	0	0	0	0	0	0	0
"what kind" of physical activity I am going to do over the next 3 months. (ssct_pa9_3)	0	0	0	0	0	0	0
"how" I am going to get to a place to engage in regular physical activity over the next month months. (ssct_pa9_4)	0	Ο	0	Ο	0	0	0

End of Block: Social Cognitive Factors - PA

Start of Block: Social Cognitive Factors - Sleep

ssct\_sl1 The following questions relate to some **general daytime routines** and what you do **before going to bed**. Please indicate your **level of confidence** in engaging in the following behaviours for the general purpose **of keeping your sleep healthy**.

I can...

	Not at all confident (1)	A little confident (2)	Moderately confident (3)	Very confident (4)	Extremely confident (5)
avoid caffeinated beverages (coffee, tea, energy drinks, etc.) right before bedtime. (ssct_sl1_1)	0	0	0	0	0
avoid nicotine right before bedtime. (ssct_sl1_2)	0	0	0	0	0
avoid alcohol right before bedtime. (ssct_sl1_3)	0	0	0	0	0
exercise on a regular basis. (ssct_sl1_4)	0	0	0	0	0
reduce my stress levels. (ssct_sl1_5)	0	0	0	0	0
reduce the impact of noise and nuisance in my bedroom. (ssct_sl1_6)	0	0	0	0	0
keep my sleep/wake times consistent. (ssct_sl1_7)	0	0	0	0	0
avoid taking daytime naps. (ssct_sl1_8)	0	0	0	0	0
avoid using technological devices (e.g., phone, TV, laptop, etc.) right before bedtime or in bed. (ssct_sl1_9)	0	0	0	0	0

ssct\_sl2 The following sections ask how **confident** you are about making specific **choices**. Rate how **confident** you are that you can **make the following choices** over the **next 3 months**.

## Whenever I have the opportunity to...

	Never (1)	Rarely (2)	Sometimes (3)	Often (4)	Always (5)
drink coffee/tea or energy drinks right before bedtime, I know how to avoid them. (ssct_sl2_1)	0	0	0	0	0
smoke a cigarette right before bedtime, I know how to avoid it. (ssct_sl2_2)	0	0	0	0	0
drink alcohol right before bedtime, I know how to avoid it. (ssct_sl2_3)	0	0	0	0	0
do some exercise, I know how to make it happen. (ssct_sl2_4)	0	0	0	0	0
reduce my stress levels, I know how to relax and unwind. (ssct_sl2_5)	0	0	0	0	0
minimise the impact of noise and nuisance in my bedroom, I know how to remove all sources of noise or block them out. (ssct_sl2_6)	0	0	0	0	0
set my own sleep and wake times, I know how to keep them consistent. (ssct_sl2_7)	0	0	0	0	0
take a daytime nap, I know how to avoid it. (ssct_sl2_8)	0	0	0	0	0
use technological devices right before bedtime or in bed, I know how to avoid or remove them. (ssct_sl2_9)	0	0	0	0	0

ssct\_sl3\_intro The following questions list a number of things, which may or may not **impact your sleep-related habits** over the **next 3 months**.

For each question, first indicate **how much you agree** with each statement and then rate **how important** each statement is to you. **For me...** 

	Strongly disagree (1)	Disagree (2)	Slightly disagree (3)	Neither disagree nor agree (4)	Slightly agree (5)	Agree (6)	Strongly agree (7)
avoiding caffeine/tea or energy drinks would help me sleep better. (ssct_sl3_1)	0	0	0	0	0	0	0
avoiding nicotine would help me sleep better. (ssct_sl3_2)	0	0	0	0	0	0	0
avoiding alcohol would help me sleep better. (ssct_sl3_3)	0	0	0	0	0	0	0
exercising regularly would help me sleep better. (ssct_sl3_4)	0	0	0	0	0	0	0
reducing my stress levels would help me sleep better. (ssct_sl3_5)	0	0	0	0	0	0	0
reducing the impact of noise and nuisance in my bedroom would help me sleep better. (ssct_sl3_6)	0	0	0	0	0	0	0
keeping consistent sleep/wake times would help me sleep better. (ssct_sl3_7)	0	0	0	0	0	0	0
avoiding daytime naps would help me sleep better. (ssct_sl3_8)	0	0	0	0	0	0	0

avoiding the use of technological devices right before bedtime or in bed would help me sleep better. (ssct_sl3_9)	0	0	0	0	0	0	0

## ssct\_sl3 How important is it to ...

	Not at all important (10)	Only slightly important ()	Important (12)	Extremely important (13)
avoid caffeine/tea or energy drinks to sleep well? (ssct_sl3_10)	0	0	0	0
avoid nicotine to sleep well? (ssct_sl3_11)	0	0	0	0
avoid alcohol to sleep well? (ssct_sl3_12)	0	0	0	0
exercise regularly to sleep well? (ssct_sl3_13)	0	0	0	0
reduce stress to sleep well? (ssct_sl3_14)	0	0	0	0
reduce bedroom noise and nuisance to sleep well? (ssct_sl3_15)	0	0	0	0
keep sleep/wake times consistent to sleep well? (ssct_sl3_16)	0	0	0	0
avoid daytime naps to sleep well? (ssct_sl3_17)	0	0	0	0
avoid technological devices right before bedtime or in bed to sleep well? (ssct_sl3_18)	0	0	0	0

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ssct\_sl4 Now, referring to your **friends, family members, partner or your housemates**, please indicate your level of **agreement** with the following statements:

## Most people who are important to me would encourage me to...

	Strongly disagree (1)	Disagree (2)	Neither disagree nor agree (3)	Agree (4)	Strongly agree (5)
avoid caffeine. (ssct_sl5_1)	0	0	0	0	0
avoid nicotine. (ssct_sl5_2)	0	0	0	0	0
avoid alcohol. (ssct_sl5_3)	0	0	0	0	0
exercise regularly. (ssct_sl5_4)	0	0	0	0	0
reduce my stress levels. (ssct_sl5_5)	0	0	0	0	0
reduce the impact of noise and nuisance in my bedroom. (ssct_sl5_6)	0	0	0	0	0
keep my sleep and wake times consistent or keep the same schedule as me. (ssct_sl5_7)	0	0	0	0	0
avoid taking daytime naps. (ssct_sl5_8)	0	0	0	0	0
avoid the use of technological devices right before bedtime or in bed and not use them either when they are in the same bedroom/bed. (ssct_sl5_9)	0	0	0	0	0

	No, not really			Somewhat intend			Strongly intend
	1	2	3	4	5	6	7
avoid caffeine, especially right before bedtime. (ssct_sl6_1)	0	0	0	0	0	0	0
avoid nicotine, especially right before bedtime. (ssct_sl6_2)	0	0	0	0	0	0	0
avoid alcohol, especially right before bedtime. (ssct_sl6_3)	0	0	0	0	0	0	0
be more physically active. (ssct_sl6_4)	0	0	0	0	0	0	0
reduce my stress levels. (ssct_sl6_5)	0	0	0	0	0	0	0
keep my bedroom free of noise and nuisance. (ssct_sl6_6)	0	0	0	0	0	0	0
keep my sleep and wake times more consistent. (ssct_sl6_7)	0	0	0	0	0	0	0
take fewer daytime naps. (ssct_sl6_8)	0	0	0	0	0	0	0
avoid using technological devices, especially right before bedtime or in bed. (ssct_sl6_9)	0	0	0	0	0	0	0

ssct\_sl5 Please indicate to what extent **you intend** to engage in the following behaviours over the **next 3 months**. I intend to...

	Strongly disagree (1)	Disagree (2)	Somewhat disagree (3)	Neither disagree nor agree (4)	Somewhat agree (5)	Agree (6)	Strongly agree ()
Avoiding caffeine. (ssct_sl7_1)	0	0	0	0	0	0	0
Avoiding nicotine. (ssct_sl7_2)	0	0	0	0	0	0	0
Avoiding alcohol. (ssct_sl7_3)	0	0	0	0	0	0	0
Regular exercise. (ssct_sl7_4)	0	0	0	0	0	0	0
Reducing my stress levels. (ssct_sl7_5)	0	0	0	0	0	0	0
Reducing the impact of noise and nuisance in my bedroom. (ssct_sl7_6)	0	0	0	0	0	0	0
Keeping my sleep and wake times consistent. (ssct_sl7_7)	0	0	0	0	0	0	0
Avoiding daytime naps. (ssct_sl7_8)	0	0	0	0	0	0	0
Avoiding technological devices in my bedroom or in bed. (ssct_sl7_9)	0	0	0	0	0	0	0

ssct\_sl6 Next, please rate to what extent each of the following behaviours is something you do automatically. Example: "Avoiding caffeine is something I do automatically.

	No plans						Detailed plans
	1	2	3	4	5	6	7
avoid caffeine. (ssct_sl8_1)	0	0	0	0	0	0	0
avoid nicotine. (ssct_sl8_2)	0	0	0	0	0	0	0
avoid alcohol. (ssct_sl8_3)	0	0	0	0	0	0	0
exercise regularly. (ssct_sl8_4)	0	0	0	0	0	0	0
reduce my stress levels. (ssct_sl8_5)	0	0	0	0	0	0	0
minimise the impact of noise and nuisance in my bedroom. (ssct_sl8_6)	0	0	0	0	0	0	0
keep my sleep and wake times consistent. (ssct_sl8_7)	0	0	0	0	0	0	0
avoid daytime naps. (ssct_sl8_8)	0	0	0	0	0	0	0
avoid using technological devices right before bedtime or in bed. (ssct_sl8_9)	0	0	0	0	0	0	0

ssct\_sl7 Next, we are going to ask you about your **planning related to sleep over the next 3 months**. I have planned where, when and how I will...

End of Block: Social Cognitive Factors - Sleep

### **Start of Block: Shipment info**

## Congratulations.

You have now completed your baseline assessment. This will automatically enter you into the first out of three draws for **1 of 5 Woolworths eGift certificates worth \$50**.

As a next step, we will randomly allocate you to one of two groups. To introduce you to your 12-week intervention, we will send you a participant handbook including all further instructions and access details for the mobile app we have developed for you.

Please note: We need a full address to be able to ship your welcome package.

If you get allocated to **Group 1**, you will receive your package within the next few days and commence your program.

If you get allocated to **Group 2**, which is our wait-list control group, this package will be sent in approximately 6 months from now, after you have completed your third and last assessment.

We will contact you shortly to inform you about the group you have been allocated to. Please enter your full address below so that we can dispatch your study materials as soon as possible.

## Thank you.

\_\_\_\_\_

### postal\_address Enter your postal address

- Street Number (2) \_\_\_\_\_\_
- City/Town/Suburb (3)
- State (5) \_\_\_\_\_\_
- Additional information (c/o), add if applicable, or type "N/A" (6)

**End of Block: Shipment info** 

## Appendix I: Eligibility survey test-retest study

## FORM D - ONLINE ELIGIBILITY SCREENING

Administered via Qualtrics Total number of items: 14 *Version 1; 17/10/17* 

## Thank you for consenting to participate in this study.

The following questions will help us determine if you are eligible to participate in our study. Please provide your honest responses.

## qdem1a

Are you:

- Male (1)
- Female (2)
- Indeterminate, unspecified, intersex (3)

Display next question, if qdem1 (Are you:) = 'Female'

## qdem1b

Are you currently pregnant or have you given birth in the past 12 months?

- Yes (1)
- No (2)

### qdem2

What is your current age? (Enter years)

### qdem3a

What is your height in centimetres? (Example: 175)

## **IMPORTANT:**

Please enter your height in metric units (centimetres) instead of imperial units (foot/inches), for example: 5'7'' = 170cm; 5'8'' = 173cm; 5'9'' = 175cm; 6'0'' = 183cm; 6'1'' = 185cm

## qdem3b

What is your current body weight in kilograms? (example: 65 kg)

## info\_dem3c

Based on the height and weight you have entered, we calculated a body mass index (BMI) of: \${e://Field/output}

## qemp4a

How would you describe your usual working hours?

- Only during the day (1)
- Only during the afternoon/evening (2)
- Only during the night/early morning hours (3)
- Rotating shifts (if your usual work requires you to rotate between days and nights)
   (4)
- Not working (5)

## qemp4b

Do you frequently travel (once a month or more often) across time zones involving a change in time by 3 or more hours?

- Yes (1)
- No (2)

## qupa1

As a rule, do you do at least half an hour per day (30 min/day) of moderate or vigorous exercise (such as walking or a sport) on 3 or more days a week?

- Yes (1)
- No (2)

## qusleep1a

During the past month, how would you rate your sleep quality overall?

- Very good (1)
- Fairly good (2)
- Fairly bad (3)
- Very bad (4)

## qusleep1b

During the past month, how many hours of actual sleep did you get at night? (This may be different than the number of hours you spend in bed). Enter hours and minutes.

## qusleep2

Have you ever been told by a doctor that you have any of the following chronic sleep problems? (multiple responses possible)

## IMPORTANT:

If you have suffered from any of the listed conditions in the past (e.g., during your childhood), but you no longer experience any symptoms or chronic problems, please select 'none'.

If you experience some symptoms, but you are not sure about the cause and you have not been told by a doctor that you have any of the listed chronic sleep problems, also select 'none'.

If you are unsure about your answer and you wish to discuss this with our research team, please select 'other' and we will contact you for further clarification.

- Obstructive Sleep Apnoea (1)
- Restless Legs Syndrome (2)
- Insomnia (3)
- Other (please specify) (4) \_\_\_\_\_
- None (5)

## qusleep3

Are you currently taking any medication to help you sleep?

If you are taking prescription medicines or any over-the-counter pharmaceuticals specifically formulated to induce sleep, please select 'yes'.

If you are taking any herbal remedies, such as lavender or valerian, please select 'no'.

- Yes (1)
- No (2)
- Not sure (please explain) (3)

## qappuser2

Do you currently use an app or activity tracker (wristband, watch, clip, etc.) to monitor your sleep patterns?

If you have used smartphone apps or tracking devices in the past, but you are no longer using them, please select 'no'.

- Yes (1)
- No (2)

## qcontact2a

Do you currently reside in Australia?

- Yes (1)
- No (2)

## qcontact2b

Please enter your postcode:

Next, we ask you to provide your contact details, so that we can remind you when your second survey is due and send you information related to your participation as well as your \$20 eGift certificate as a token of appreciation for your participation.

## qcontact1a

Please enter your first name only (at this stage, we do not require a surname).

**qcontact3a** Please enter your Email address.

### qcontact3b

Please enter your phone number (numbers only).

## End of survey message 1 (if participant is eligible)

Thank you for taking our online survey and showing interest in the study.

We hereby confirm: you are eligible to participate.

Please proceed right through to your first assessment. This will take approximately xxx minutes to complete. You will be reminded in time for your second assessment, which will be due one week after you completed this first assessment.

If you have any further questions, please get in touch.

Please click >>> NEXT to start with your first assessment.

## End of survey message 2 (if participant is *ineligible*)

Thank you for taking our online survey and showing interest in the study.

We hereby confirm: you are not eligible to participate.

If you wish to use a public version of our mobile app to learn more about a variety of health behaviours,

please visit the App Store: https://itunes.apple.com/au/app/balanced/id990154592?mt=8

or the Google Play Store: <u>https://play.google.com/store/apps/details?id=au.com.headjam.balanced&hl=en</u>

for a free download of the Balanced app. Alternatively, search "Balanced Headjam" to locate our app. Balanced is a multi-health behaviour app, the public version of which is not linked to this study.

If you have any further questions, please get in touch with the study team.

## Appendix J. Facebook recruitment test-retest study



Like For Comment

## Appendix K: Information statement test-retest study



Associate Professor Mitch Duncan Priority Research Centre for Physical Activity and Nutrition School of Medicine and Public Health University of Newcastle Callaghan, NSW, Australia, 2308 (02) 4921 7805 <u>Mitch.Duncan@newcastle.edu.au</u>

### Information Statement for the Research Project: "Test-retest reliability of a scale assessing social cognitive mechanisms relating to sleep hygiene behaviours." Document Version 2; 01/02/18

You are invited to participate in the research project identified above which is being conducted by Associate Prof Mitch Duncan, Ms Beatrice Murawski and Prof Ronald Plotnikoff. These researchers are from the University of Newcastle, Priority Research Centre in Physical Activity and Nutrition. This project forms part of a series of studies that contribute to the doctoral thesis of Ms Beatrice Murawski, who is a student researcher at the University of Newcastle.

The study is funded by a *Future Leader Fellowship* (ID 100029) from the National Heart Foundation of Australia awarded to Associate Professor Mitch Duncan.

Why is the research being done? Healthy sleep plays an important role in the maintenance of overall health and wellbeing. It helps you restore and recover both physically and mentally. However, large proportions of adults worldwide report problems with their sleep health, including inadequate or dissatisfactory levels of sleep duration and sleep quality, all of which can have an impact on daytime functioning, productivity and many other aspects of health and wellbeing.

These problems can be addressed through targeted and effective, yet wide reaching intervention programmes. To further refine such interventions, it is crucial to better understand what determines how people engage in behaviours that promote good sleep health. The current evidence recommends practising a set of so-called sleep hygiene behaviours, which include abstaining from any substances that have a stimulant effect prior to going to bed, keeping sleep and wake times consistent and creating a calm and comfortable sleep environment.

The purpose of this study is to learn more about how people think and feel in relation to practising good sleep hygiene to allow good sleep to occur. A part of this study is to test the performance (reliability) of our survey when asking people on multiple occasions. Participants in this study will be asked to answer our survey twice (1 week apart) to provide us with the data necessary to test our survey reliability.

**Who can participate in the research?** We are seeking adults aged 18-55 years, living in Australia, who have a BMI between 18.5 and 35. Participants are required to currently perform less than 90 minutes of physical activity per week and report poor sleeping patterns. If you have

a medically diagnosed sleep disorder, are currently taking sleep medications, are pregnant or have given birth in the last 12 months, work shift work (night shifts or rotating shifts), frequently travel to a destination with a shift in time zone by more than 3 hours, then unfortunately you will not be eligible to participate in this study.

#### What would you be asked to do?

If you agree to participate, you will be asked to:

- 1. Complete a screening questionnaire to determine your eligibility to participate in the study.
- 2. Provide a mobile number and Email address to receive reminder messages with your survey links.
- **3. Complete 2 online surveys 1 week apart** (approx. 20-30 minutes each) that ask about your perceptions, thoughts and attitudes relating to sleep hygiene.

What choice do you have? Participation in this research is entirely your choice. Only those people who give informed consent online will be included in the project. You do this by checking the box during registration that you accept the terms and conditions (listed below). Whether or not you decide to participate, your decision will not disadvantage you. If you do decide to participate, you may withdraw from the project at any time without giving a reason and you will have the option to withdraw any data that identifies you.

**How much time will it take?** Both surveys will be administered entirely remotely, which means that you are not required to visit a research centre. The surveys you will be asked to complete online will take approximately 20-30 minutes each. The research team will provide assistance via Email or phone, as required.

What are the risks and benefits of participating? Any personal risks associated with this research project have been considered and measures have been taken to minimise these risks to the utmost. We ask any participant who feels concerned about undertaking the abovementioned tasks to contact either the research team or the University of Newcastle Human Research Ethics Committee using the details provided on this information sheet.

During each of the two online assessments, you are being asked to provide your personal perceptions, thoughts, plans and habits relating to your engagement in behaviours that have an influence on sleep health. Prior to inviting you to participate in our study, we will ask some basic demographic questions (e.g., age, gender, height, weight, etc.) that help us determine your eligibility. Some of the questions we ask in the surveys may be perceived as being of a sensitive nature. If you find these questions distressing or upsetting, we encourage you to contact either of the following organisations to discuss this.

Lifeline	Phone: 13 11 14	Website: www.lifeline.org.au/
BeyondBlue	Phone: 1300 22 4686	Website: www.beyondblue.org.au/
BlackDog Institute		Website: http://www.blackdoginstitute.org.au/

We cannot and do not promise that you will receive any benefits from participating in this study. However, the desired outcomes of this research are increased knowledge and awareness relating to the factors that influence your sleep health.

It will be beyond the focus of this study to comment on whether your sleep health requires improvements or not, but once you have completed both online assessments, you will receive free and unrestricted access to the Balanced app, which is an app that was specifically designed by the research team and provides information and instructions on how to improve multiple health behaviours and allows you to track changes in these behaviours over time.

Once all data are collected and analysed (within six months of your participation), we will prepare a plain English summary of study findings and provide you with a copy.

In addition, at the end of your second survey, you will have the option to be entered into a draw to win 1 of 5 \$50 shopping vouchers (1 in 15 chance or better) as a thank you for your time and commitment. Please note, we require you to have completed both surveys to enter our draw.

**How will your privacy be protected?** All data collected during the study will be stored on password-protected computers and networks. This information will be accessible by the research team only and those people the research team engages to assist with statistical analyses. Your data will be de-identified prior to data analysis and de-identified data will be kept for a minimum of five years after the last publication from this data at the University of Newcastle, after which time any paperwork will be shredded and electronic data deleted.

**How will the information collected be used?** In any publication or report, information will be provided in such a way that you cannot be identified. We plan to publish the results in scientific literature, provide reports to interested parties, and present the results at scientific conferences and other meetings. Information collected as part of this study may also be used for student theses and dissertations.

What do you need to do to participate? Please read this Information Statement and be sure you understand its contents. If there is anything you do not understand, or you have questions, please contact the researchers. If you would like to participate, please indicate that you are giving your informed consent (online) and complete our online survey to see if you are eligible to take part. If you are eligible to participate, we will contact you (via phone/Email) to notify you and to provide further instructions. The study team will be available during office hours (via phone/Email) to explain the study and answer any questions you may have. If you are not eligible, we will contact you also (via phone/Email) to advise you of this and answer any questions you have.

**Further information** If you would like further information please contact Ms Beatrice Murawski via Email at <u>beatrice.murawski@newcastle.edu.au</u> or on +61 (02) 4921 2067.

Thank you for considering this invitation,

Associate Professor Mitch Duncan, Chief Investigator (Future Leaders Fellow) Beatrice Murawski Student Researcher

#### Research Team:

#### Associate Professor Mitch J. Duncan – Chief Investigator

Priority Research Centre for Physical Activity and Nutrition, School of Medicine & Public Health, Faculty of Health & Medicine, University of Newcastle

#### Miss Beatrice Murawski – Student Researcher

Priority Research Centre for Physical Activity and Nutrition, School of Medicine & Public Health, Faculty of Health & Medicine, University of Newcastle

#### Professor Ronald C. Plotnikoff – Co-Investigator

Priority Research Centre for Physical Activity and Nutrition, School of Education, Faculty of Education & Arts, University of Newcastle

#### Complaints about this research:

This project has been approved by the University's Human Research Ethics Committee, Approval No. H-2018-0012.

Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, to the Human Research Ethics Officer, Research Services, NIER Precinct, The University of Newcastle, University Drive, Callaghan NSW 2308, Australia, Telephone (02) 4921 6333, Email <u>Human-Ethics@newcastle.edu.au</u>.

## Appendix L: Consent form test-retest study

FORM C - ONLINE CONSENT PROCEDURE Administered via Qualtrics Version 1; 17/10/17

### Welcome

This study aims to explore the reliability of a new questionnaire that will help us learn more about the thoughts and beliefs people have in relation to the practice of sleep hygiene.

Sleep hygiene includes components such as keeping consistent bed and wake times or exercising regularly to promote good sleep, which in turn can contribute to overall health and wellbeing.

To be able to develop these questionnaire items systematically and to determine, if these items enquire exactly about what they are supposed to measure, we need to collect your answers on two separate occasions 7 days apart. This allows us to determine how reliable the instrument is over time. To check if you can participate in the study, we will assess your eligibility using an online survey and if you are eligible, we will provide you with a direct link to the study to be completed online. If you complete both assessments, you will go into the draw for a \$50 shopping voucher where you have a 1 in 5 chance to receive this as a thanks for your time.

The following link provides a copy of our <u>Information Statement</u> and we ask you to read the statement prior to giving your online consent for participation in the study:

### Click here to download information statement

If you have read our Information Statement and you have no further questions regarding your participation, please proceed to give your consent to participate. If you would like to have any questions answered before deciding, if you wish participate in the study, please contact the research team.

### Thank you.

## BEATRICE MURAWSKI – PROJECT LEADER BSc (Sports Performance & Coaching) | MSc (Medical Science) | PhD Candidate (Behavioural Sciences) Priority Research Centre for Physical Activity & Nutrition

School of Medicine & Public Health, Faculty of Health and Medicine The University of Newcastle (UON), University Drive, Callaghan, NSW 2308

T: +61 (0) 2 4921 2067 E: beatrice.murawski@uon.edu.au

## **Consent Form**

I have read the Information Statement and understand the requirements of my participation in the study, and I hereby provide my consent to participate.

## I also understand that:

- The project will be conducted as described in the Information Statement, a copy of which I have retained;
- I will be required to complete two identical surveys on two separate occasions one week apart;
- I can withdraw from the project at any time and do not have to give any reason for withdrawing;
- my personal information will remain confidential to the researchers; and
- I have had the opportunity to have questions answered to my satisfaction.

## As per description in the Information Statement, I consent to:

- completing a short questionnaire to determine, whether I am eligible to take part and
- completing two identical surveys the second of which will be due one week after completing the first survey.

## Do you agree to participate in this research project?

- No, I do not wish to give my consent. (1)
- Yes, I agree to participate. (2)

## End of survey message 1

Please provide your full name below (Format: FIRST NAME LAST NAME)

Next, to assess your eligibility to participate, we will ask some questions about your physical activity and sleep habits, any chronic conditions as well as some basic demographics.

Please enter your name and click >>> NEXT to proceed.

## Appendix M: Survey items test-retest study

## FORM E - ONLINE SURVEYS Administered via Qualtrics

Total number of items per survey: 93 Time points: 2 (1 week apart) *Version 1; 17/10/17* 

## SOCIAL COGNITIVE ITEMS FOR SLEEP HYGIENE Number of items: 72

The following questions relate to some general daytime routines and what you do before going to bed. Please indicate your level of confidence in engaging in the following behaviours for the general purpose of keeping your sleep healthy.

I can...

	Not at all confident (1)	A little confident (2)	Moderately confident (3)	Very confident (4)	Extremely confident (5)
avoid caffeinated beverages (coffee, tea, energy drinks, etc.) right before bedtime. (ssct_sl1_1)	0	0	0	0	0
avoid nicotine right before bedtime. (ssct_sl1_2)	0	0	0	0	0
avoid alcohol right before bedtime. (ssct_sl1_3)	0	0	0	0	0
exercise on a regular basis. (ssct_sl1_4)	0	0	0	0	0
reduce my stress levels. (ssct_sl1_5)	0	0	0	0	0
reduce the impact of noise and nuisance in my bedroom. (ssct_sl1_6)	0	0	0	0	0
keep my sleep/wake times consistent. (ssct_sl1_7)	0	0	0	0	0

avoid taking daytime naps. (ssct_sl1_8)	0	0	0	0	0
avoid using technological devices (e.g., phone, TV, laptop, etc.) right before bedtime or in bed. (ssct_sl1_9)	0	0	0	0	0

The following section asks how confident you are about making specific choices. Please rate how confident you generally feel about making the following choices.

## Whenever I have the opportunity to...

	Never (1)	Rarely (2)	Sometimes (3)	Often (4)	Always (5)
drink coffee/tea or energy drinks right before bedtime, I know how to avoid them. (ssct_sl2_1)	0	0	0	0	0
smoke a cigarette right before bedtime, I know how to avoid it. (ssct_sl2_2)	0	0	0	0	0
drink alcohol right before bedtime, I know how to avoid it. (ssct_sl2_3)	0	0	0	0	0
do some exercise, I know how to make it happen. (ssct_sl2_4)	0	0	0	0	0
reduce my stress levels, I know how to relax and unwind. (ssct_sl2_5)	0	0	0	0	0
minimise the impact of noise and nuisance in my bedroom, I know how to remove all sources of noise or block them out. (ssct_sl2_6)	0	0	0	0	0
set my own sleep and wake times, I know how to keep them consistent. (ssct_sl2_7)	0	0	0	0	0
take a daytime nap, I know how to avoid it. (ssct_sl2_8)	0	0	0	0	0
use technological devices right before bedtime or in bed, I know how to avoid or remove them. (ssct_sl2_9)	0	0	0	0	0

The following questions list a number of things, which may or may not impact your sleep-related habits.

For each question, first indicate how much you agree with each statement and then rate how important each statement is to you.

## For me...

	Strongly disagree (1)	Disagree (2)	Slightly disagree (3)	Neither disagree nor agree (4)	Slightly agree (5)	Agree (6)	Strongly agree (7)
avoiding caffeine/tea or energy drinks would help me sleep better. (ssct_sl3_1)	0	0	0	0	0	0	0
avoiding nicotine would help me sleep better. (ssct_sl3_2)	0	0	0	0	0	0	0
avoiding alcohol would help me sleep better. (ssct_sl3_3)	0	0	0	0	0	0	0
exercising regularly would help me sleep better. (ssct_sl3_4)	0	0	0	0	0	0	0
reducing my stress levels would help me sleep better. (ssct_sl3_5)	0	0	0	0	0	0	0
reducing the impact of noise and	0	0	0	0	0	0	0

nuisance in my bedroom would help me sleep better. (ssct_sl3_6)							
keeping consistent sleep/wake times would help me sleep better. (ssct_sl3_7)	0	0	0	0	0	0	0
avoiding daytime naps would help me sleep better. (ssct_sl3_8)	0	0	0	0	0	0	0
avoiding the use of technological devices right before bedtime or in bed would help me sleep better. (ssct_sl3_9)	Ο	0	Ο	0	0	0	0

## How important is it to...

	Not at all important (1)	Only slightly important (2)	Important (3)	Extremely important (4)
avoid caffeine/tea or energy drinks to sleep well? (ssct_sl3_10)	0	0	0	0
avoid nicotine to sleep well? (ssct_sl3_11)	0	0	0	0
avoid alcohol to sleep well? (ssct_sl3_12)	0	0	0	0
exercise regularly to sleep well? (ssct_sl3_13)	0	0	0	0
reduce stress to sleep well? (ssct_sl3_14)	0	0	0	0
reduce bedroom noise and nuisance to sleep well? (ssct_sl3_15)	0	0	0	0
keep sleep/wake times consistent to sleep well? (ssct_sl3_16)	0	0	0	0
avoid daytime naps to sleep well? (ssct_sl3_17)	0	0	0	0
avoid technological devices right before bedtime or in bed to sleep well? (ssct_sl3_18)	0	0	0	0

Now, referring to your friends, family members, partner or your housemates, please indicate your level of agreement with the following statements:

## Most people who are important to me would encourage me to...

	Strongly disagree (1)	Disagree (2)	Neither disagree nor agree (3)	Agree (4)	Strongly agree (5)
avoid caffeine. (ssct_sl4_1)	0	0	0	0	0
avoid nicotine. (ssct_sl4_2)	0	0	0	0	0
avoid alcohol. (ssct_sl4_3)	0	0	0	0	0
exercise regularly. (ssct_sl4_4)	0	0	0	0	0
reduce my stress levels. (ssct_sl4_5)	0	0	0	0	0
reduce the impact of noise and nuisance in my bedroom. (ssct_sl4_6)	0	0	0	0	0
keep my sleep and wake times consistent or keep the same schedule as me. (ssct_sl4_7)	0	0	0	0	0
avoid taking daytime naps. (ssct_sl4_8)	0	0	0	0	0
avoid the use of technological devices right before bedtime or in bed and not use them either when they are in the same bedroom/bed. (ssct_sl4_9)	0	0	0	0	0

Please indicate to what extent you generally have the intention to engage in the following behaviours.

## I intend to...

	No, not really			Somewhat intend			Strongly intend
	1	2	3	4	5	6	7
avoid caffeine, especially right before bedtime. (ssct_sl5_1)	0	0	0	0	0	0	0
avoid nicotine, especially right before bedtime. (ssct_sl5_2)	0	0	0	0	0	0	0
avoid alcohol, especially right before bedtime. (ssct_sl5_3)	0	0	0	0	0	0	0
be more physically active. (ssct_sl5_4)	0	0	0	0	0	0	0
reduce my stress levels. (ssct_sl5_5)	0	0	0	0	0	0	0
keep my bedroom free of noise and nuisance. (ssct_sl5_6)	0	0	0	0	0	0	0
keep my sleep and wake times more consistent. (ssct_sl5_7)	0	0	0	0	0	0	0
take fewer daytime naps. (ssct_sl5_8)	0	0	0	0	0	0	0
avoid using technological devices, especially right before bedtime or in bed. (ssct_sl5_9)	0	0	0	0	0	0	0

Next, please rate to what extent each of the following behaviours is something you do automatically.

# Example: "[Avoiding caffeine] ... is something I do automatically."

	Strongly disagree (1)	Disagree (2)	Somewhat disagree (3)	Neither disagree nor agree (4)	Somewhat agree (5)	Agree (6)	Strongly agree (7)
Avoiding caffeine (ssct_sl6_1)	0	0	0	0	0	0	0
Avoiding nicotine (ssct_sl6_2)	0	0	0	0	0	0	0
Avoiding alcohol (ssct_sl6_3)	0	0	0	0	0	0	0
Regular exercise (ssct_sl6_4)	0	0	0	0	0	0	0
Reducing my stress levels (ssct_sl6_5)	0	0	0	0	0	0	0
Reducing the impact of noise and nuisance in my bedroom (ssct_sl6_6)	0	0	0	0	0	0	0
Keeping my sleep and wake times consistent (ssct_sl6_7)	0	0	0	0	0	0	0
Avoiding daytime naps (ssct_sl6_8)	0	0	0	0	0	0	0
Avoiding technological devices in my bedroom or in bed (ssct_sl6_9)	0	0	0	0	0	0	0

Next, we are going to ask you about your general planning related to sleep.

# I plan exactly where, when and how I will...

	No plans						Detailed plans
	1	2	3	4	5	6	7
avoid caffeine. (ssct_sl7_1)	0	0	0	0	0	0	0
avoid nicotine. (ssct_sl7_2)	0	0	0	0	0	0	0
avoid alcohol. (ssct_sl7_3)	0	0	0	0	0	0	0
exercise regularly. (ssct_sl7_4)	0	0	0	0	0	0	0
reduce my stress levels. (ssct_sl7_5)	0	0	0	0	0	0	0
minimise the impact of noise and nuisance in my bedroom. (ssct_sl7_6)	0	0	0	0	0	0	0
keep my sleep and wake times consistent. (ssct_sl7_7)	0	0	0	0	0	0	0
avoid daytime naps. (ssct_sl7_8)	0	0	0	0	0	0	0
avoid using technological devices right before bedtime or in bed. (ssct_sl7_9)	0	0	0	0	0	0	0

## SOCIOSTRUCTURAL FACTORS OF SLEEP Number of items: 4

Think about the order and safety in your neighbourhood; by this we mean the area ALL around your home that you could walk to in 10-15 minutes.

For each of the following statements, please rate your agreement by choosing the answer that corresponds to how you feel.

	Strongly disagree (1)	Disagree (2)	Neither disagree or agree (3)	Agree (4)	Strongly agree (5)
My neighbourhood is noisy. (spnd_1)	0	0	0	0	0
My neighbourhood is clean. (spnd_2)	0	0	0	0	0
There is a lot of crime in my neighbourhood. (spnd_3)	0	0	0	0	0
My neighbourhood is safe. (spnd_4)	0	0	0	0	0

## SLEEP HYGIENE INDEX Number of items: 15

For the following items, please indicate how frequently you do each of them.

	Never (1)	Rarely (2)	Sometimes (3)	Frequently (4)	Always (5)
I use alcohol, tobacco, or caffeine within 4 h of going to bed or after going to bed. (sshi1_6)	0	0	0	0	0
I do something that may wake me up before bedtime (for example: play video games, use the internet, or clean). (sshi1_7)	0	0	0	0	0
I go to bed feeling stressed, angry, upset, or nervous. (sshi1_8)	0	0	0	0	0
I use my bed for things other than sleeping or sex (for example: watch television, read, eat, or study). (sshi1_9)	0	0	0	0	0
I sleep on an uncomfortable bed (for example: poor mattress or pillow, too much or not enough blankets). (sshi1_10)	0	0	0	0	0
I sleep in an uncomfortable bedroom (for example: too bright, too stuffy, too hot, too cold, or too noisy). (sshi1_11)	0	0	0	0	0
I do important work before bedtime (for example: pay bills, schedule, or study). (sshi1_12)	0	0	0	0	0
I think, plan, or worry when I am bed. (sshi1_13)	0	0	0	0	0
I drink a lot of alcohol or coffee close to bedtime. (sshi1_14)	0	0	0	0	0
I smoke. (sshi1_15)	0	0	0	0	0

### schanges1

Thinking about the last seven days, have you made any changes to your sleep hygiene practices?

- Yes, major changes. (1)
- Yes, but minor. (2)
- No, I have made no changes. (3)

## schanges2

Thinking about the last seven days, have you experienced any major events or incidences (e.g., accident, injury, illness, tragic events in your network of friends and family) that would affect your stress levels, cause disruptions to your routines and your ability to sleep as normal?

- Yes, major events (1)
- Yes, but minor (2)
- Nothing out of the ordinary (3)

## Appendix N: Participant summary report test-retest study





1

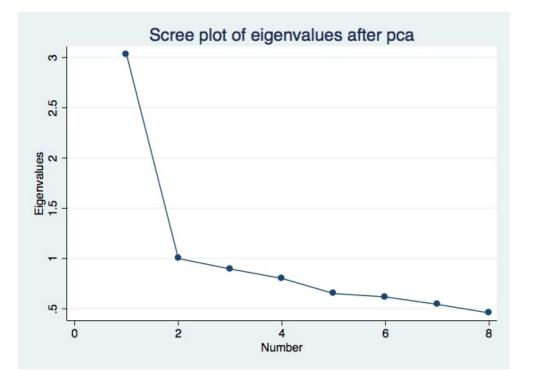
Associate Professor Mitch Duncan – CHIEF INVESTIGATOR Beatrice Murawski – PHD CANDIDATE/STUDENT RESEARCHER Priority Research Centre for Physical Activity and Nutrition School of Medicine and Public Health University of Newcastle, Callaghan, NSW, Australia, 2308 Phone: (02) 4921 2067 Email: synergystudy@newcastle.edu.au

#### Participant Summary Report for the Research Project:

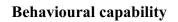
"Test-retest reliability of a scale assessing social cognitive mechanisms relating to sleep hygiene behaviours." University of Newcastle Human Research Ethics Committee, Approval No. H-2018-0012

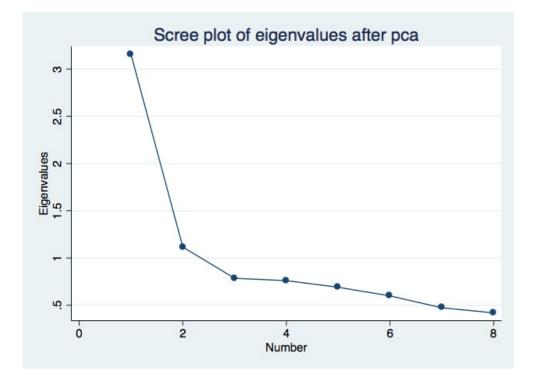
WHAT WE NEEDED TO KNOW?	*	The aim of this study was to learn more about how people think and feel in relation to practicing good sleep hygiene – a set of behaviours (e.g., regular exercise, limit alcohol intake before bed time) that promote good sleep. Because no previous instrument existed that helps us assess the thoughts and perceptions that determine sleep hygiene practice, we developed a new instrument for this and the study you took part in was undertaken specifically to test the reliability of the instrument. This tells us if people's answers are consistent when they answer our survey on multiple occasions.
WHAT WE DID?	*	Participants in this study were asked to answer our short online survey on two occasions (1 week apart) to provide us with the data necessary to test our survey reliability. The questions asked in the survey were related to 7 different domains, including how confident you felt about doing specific things during the day to allow a good night's sleep to occur, how strong your intentions and plans were to practice these behaviours and how important you think this was in relation to getting good sleep.
WHO SIGNED UP?	* * *	20 participants (12 females, 8 males) completed the survey at both occasions. The average age was 32 years. Participants reported an average Body Mass Index (BMI) of 23.80, which is within the healthy weight range. 5 participants rated their sleep as 'very good', 7 participants rated their sleep as 'fairly good', 1 participant rated their sleep as 'very bad' and the remaining 7 participants stated having 'fairly bad' sleep. On average, participants reported sleeping 6 hours 43 minutes per night, which is below the recommended sleep duration of 7 to 9 hours per night for this age group.
WHAT DID WE FIND?	*	The level of reliability between scores from two measurement points can be classified as 'excellent', 'good' or 'poor'. Our analyses showed that 4 of the 'scales' we developed were classified as having excellent reliability and 3 were classified as good.
WHAT DOES THIS MEAN?	*	This finding gives us confidence in the questionnaire we have developed and will help us better understand the mechanisms involved when trying to change sleep hygiene behaviours in future studies.
THANK YOU!	*	On behalf of the research team, we'd like to thank you for your participation and support with this project. Please do not hesitate to contact us at <u>synergystudy@newcastle.edu.au</u> if you have any questions relating to this research.

# **Appendix O: Scree plots**

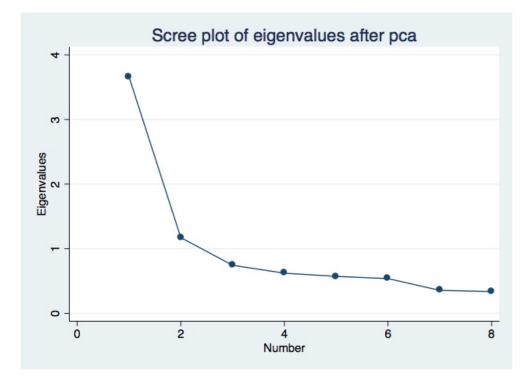


Self-efficacy

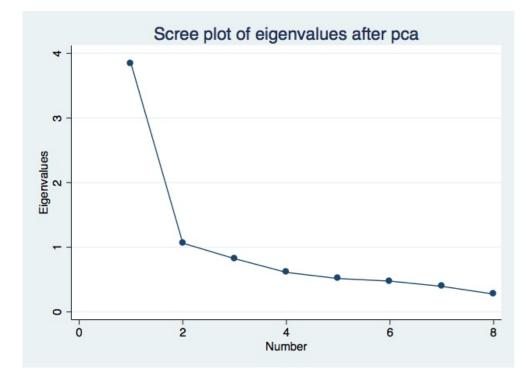




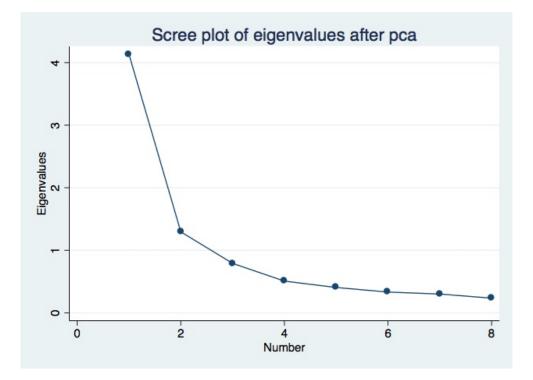
## **Outcome expectations**



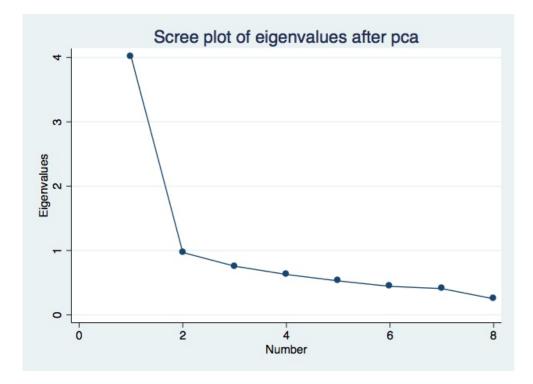
**Outcome expectancies** 

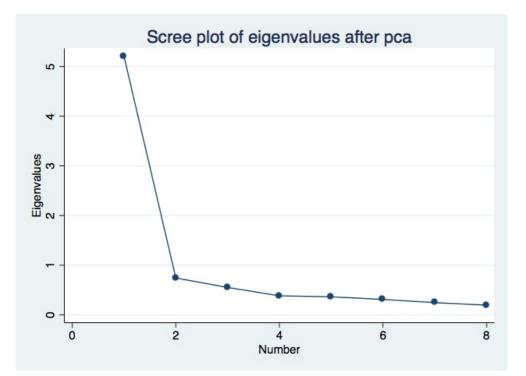


# Social support



Intention



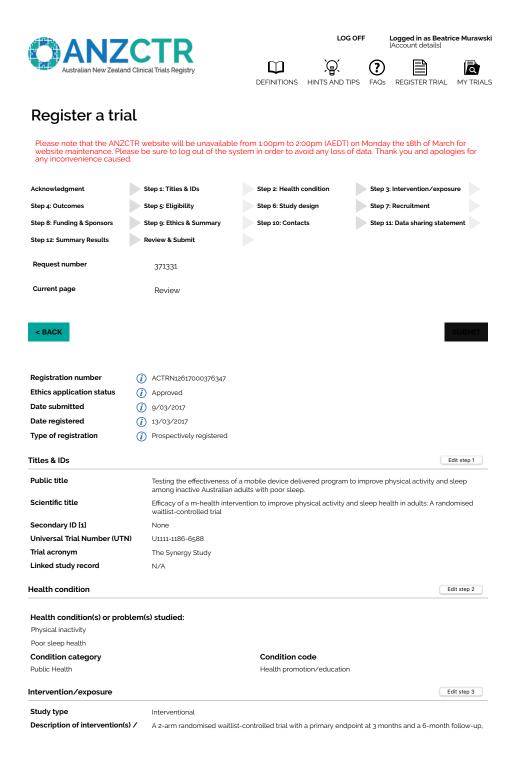


Planning

## **Appendix P: ANZCTR trial registration**

ANZCTR - Registration

https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?i...



1 of 7

#### https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?i...

exposure	testing the efficacy of a mobile device delivered (smartphone or tablet) program to improve physical activity and sleep. The 12-week intervention will be delivered using a combination of a mobile app and a message-based support service.
	The mobile app will operationalise goal-setting, self-monitoring and feedback strategies in relation to physical activity and sleep health. The message-based support service (Email and text messaging) will provide feedback on progress towards goals, prompts to practice the two behaviours and review/adjust goals, daily reminders (optional) and tool sheets on goal-setting, action planning and stress management.
	Participants will be asked to self-monitor their daily physical activity and sleep behaviours and set personal goals for both behaviours within the app. We will advise participants to log both behaviours on a daily basis, whereas goals can be reset at any time (if need be) or otherwise will remain unchanged. A summary report, which is sent to participants once weekly will assist with the process of goal review. Goal achievement is considered successful, if participants are within 20% of their goal. For example, if a participant aimed for 30 min of activity, their feedback dashboard (traffic light) will display a green light am their goal is reached, if the participant logged at least 24 min of activity or more for that day. Reference values for an orange light are 20-35% of goal and >35% of goal for a red light. Multiple entries per day are possible.
	In detail, the physical activity section of the app allows entries for moderate-to-vigorous intensity physical activity, a step count and resistance training sessions. The sleep section allows entries for bed and wake times, a sleep quality rating and a set of sleep hygiene behaviours (e.g. reducing the impact of noise and light in the bedroom, avoiding caffeine before bedtime, etc.). Based on the data entered by the participant, the app will generate instant feedback in the form of a traffic light, which changes colours by comparing individual goals against the data participants entered. In addition, progress charts will illustrate progress over time (daily, 1-week and 3-month charts) for both behaviours.
	A pedometer will be shipped to participants to facilitate the logging of a daily step count. Participants will be asked to set relevant and achievable goals (guidance provided); however, we will encourage individual to gradually work towards the recommended minimum of physical activity (PA) and sleep as per national guidelines, which is 150 min/wk (plus 2 days of resistance training) for PA and 7-9 hours of sleep per night
	The entirely remotely delivered trial will be advertised nationwide using social media and the baseline. 3-month and 6-month assessments will collect self-report measures of physical activity and sleep as well as secondary outcomes (mental health, health-related quality of life, sleep hygiene) and potential mediators (social cognitive correlates of physical activity and sleep) via online surveys. Fidelity and adherence will be assessed and reported as part of a process evaluation.
	The app and all other components are informed by social cognitive theories and follow behaviour change taxonomies to ensure consistency with implementation standards and reporting. Participants will be giver continuous access to the app.
Intervention code [1]	Behaviour
Intervention code [2]	Lifestyle
Intervention code [3]	Treatment: Devices
Comparator / control treatment	Participants in the waitlist-control arm will not receive an intervention and be asked to not change their usual physical activity and sleep behaviours between baseline and the 6-month time point. They will however, receive full access to an identical program following completion of their 6-month assessment.
Control group	Active
Dutcomes	Edit step 4
Primary outcome [1]	Minutes of moderate-to-vigorous intensity physical activity (weekly) measured using the Active Australia Questionnaire
Timepoint [1]	Assessed at baseline, 3 months and 6 months
Primary outcome [2]	Sleep quality (past 30 days) as per Pittsburgh Sleep Quality Index (PSQI) NB. All PSQI component scores will be assessed and reported.
Timepoint [2]	Assessed at baseline, 3 months and 6 months
Secondary outcome [1]	Health-related quality of life measured with the SF-12 as well as 3 additional items from the RAND-36 forming the energy/fatigue sub-scale.
Timepoint [1]	Assessed at baseline, 3 months and 6 months
Secondary outcome [2]	Mental Health measured with the DASS-21
Timepoint [2]	Assessed at baseline, 3 months and 6 months
Secondary outcome [3]	Sitting Behaviour measured with the Workforce Sitting Questionnaire
Timepoint [3]	Assessed at baseline, 3 months and 6 months
Secondary outcome [4]	Daytime sleepiness measured with the Epworth Sleepiness Scale
Timepoint [4]	Assessed at baseline, 3 months and 6 months
Secondary outcome [5]	Sleep hygiene measured with the Sleep Hygiene Index
Timepoint [5]	Assessed at baseline, 3 months and 6 months
	Assessed at baseline, 3 months and 6 months

2 of 7

#### https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?i...

	Constructs assessed include self-efficacy, outcome expectations/expectancies, sociostructural factors, goals, action planning and habit strength. Items for each construct are based on previously validated item
Timepoint [6]	Assessed at baseline, 3 months and 6 months
Secondary outcome [7]	Social cognitive factors relating to sleep hygiene (based on Social Cognitive Theory) Constructs assessed include self-efficacy, outcome expectations/expectancies, sociostructural factors, goals, action planning and habit strength. Items for each construct are based on previously validated item
Timepoint [7]	Assessed at baseline, 3 months and 6 months
Secondary outcome [8]	Participants' confidence in using the mobile app measured with the Internet Self-Efficacy Scale
Timepoint [8]	Assessed at the 3-month time point
Secondary outcome [9]	Perceived user satisfaction measured with the CAMPUS Scale
Timepoint [9]	Assessed at the 3-month time point
Secondary outcome [10]	Usability of the app measured with the System Usability Scale
Timepoint [10]	Assessed at the 3-month time point
Secondary outcome [11]	Overall interaction with the app throughout the intervention period measured through the app database (administrative management system), e.g., number of self-monitoring entries made and the duration of self-monitoring throughout the intervention
Timepoint [11]	continuous
Secondary outcome [12]	The number of days on which resistance training sessions occurred and the duration of resistance training per session will be assessed using 2 items.
	The outcome for resistance training (RT) will be the frequency (number of days per week) of participation in resistance training. The duration per session (in hours and minutes) will be reported as descriptive information for those participants engaging in resistance training.
	The two items are adapted from previously used items to assess resistance training. They were adapted specifically for the current study to assess RT participation over the last week.
Timepoint [12]	Assessed at baseline, 3 months and 6 months
Eligibility	Edit step 5
Key inclusion criteria	Participants will be eligible, if they self-report: 1. being aged 18 to 55 years: 2. living in Australia; 3. having a body weight and height consistent with a Body Mass Index (BMI) of 18.5 to 35: 4. accumulating less than 150 minutes of moderate to vigorous physical activity per week; 5. rating their sleep-quality (over the past month) as fairly bad or very bad; 6. being free of any condition that would make it unsafe to increase activity levels (frequency, intensity, duration) and being free of any condition that would make it unsafe to change sleep behaviours
Minimum age	18 Years
Maximum age	55 Years
Gender	Both males and females
Can healthy volunteers	Yes
participate?	
Key exclusion criteria	Individuals will be excluded from this study, if they 1 self-report having a diagnosed sleep disorder (chronic insomnia, sleep apnoea, sleepwalking, narcolepsy, restless legs syndrome, etc.): 2 are currently employed in night shift work; 4 are currently suffering from jet lag or planning to travel to a destination with a shift in time zone by more than three hours during the 3-month intervention period: 5 are currently pregnant or have given birth in the past 12 months; 6 are currently using a self-monitoring system or device to track or log physical activity and/or sleep (the includes non-device assisted applications); and 7 do not confirm that they have read and understood the information statement and consented to the terms & conditions that apply to the use of the intervention components (app).
Study design	Edit step 6
Purpose of the study	Treatment
Allocation to intervention	Randomised controlled trial
Procedure for enrolling a subject and allocating the treatment (allocation concealment procedures)	The allocation sequence will be held by an independent allocation officer with no direct involvement in the study. Following completion of baseline assessment, a member of the research team will contact the allocation officer to reveal the participant allocation to one of the 2 study arms.
Methods used to generate the sequence in which subjects will be randomised (sequence	Participants will be randomised into two groups (intervention or control) by a researcher not associated with the study using permuted block randomisation.

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#### https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?i...

Masking / blind	ding	Open (masking not used)				
Who is / are ma	asked / blinded?					
Intervention as	signment	Parallel				
Other design fe	atures					
Phase		Not Applicable				
Type of endpoi	nt(s)	Efficacy				
Statistical meth	nods / analysis	Power: Based on estimated char pilot study that targeted similar approaches and assuming an al moderate effect size (d = 0.45 for of 0.6, a total of 60 participants Therefore, the larger sample size account for this. In summary, the	outcomes in a sa pha of 0.025 (due r physical activity per group is requ e is used. A drop	Imple with similar character to measuring two main o r; d = 0.65 for sleep) and a e ired for physical activity ar -out rate of 25% is assume	eristics, using sir utcomes), powe correlation betw nd 35 per group d and the sampl	nilar intervention r of 0.80, a een measures for sleep quality. le is inflated to
		Analyses: All analyses will follow blinded to group allocation and differences in sleep quality and 3-month time point. Between-gr estimated using Generalized Lin including all available data in the physical activity and sleep. Grou same linear mixed modelling ap intervention group effects (seco interaction terms, or stratification	overseen by an i physical activity roup differences lear Mixed Mode e analysis. Two se proach, setting a ndary aims) will b	ndependent statistician. The between the control group in physical activity and sle Is (GLMM) adjusting for ba eparate GLMM will be use secondary outcome meas in alpha of 0.05 for each o	he primary aim i o and interventio ep quality (PSQI seline sleep qua d to examine ch ures will be estir utcome. Potentia	s to examine on group at the ) will be ality (ANCOVA), anges in mated using the al moderators of
Recruitment						Edit step 7
Recruitment sta	atus	Active, not recruiting				
Update		Completed				
Reason		The study has concluded and a	all data have bee	n collected.		
•	articipant enrolmo 1/06/2017	ent	Actual	2/06/2017		
Anticipated	1/00/201/		Actual	3/06/2017		
Date of last pa	rticipant enrolme	ent				
Anticipated			Actual	10/08/2017		
Date of last da	ta collection					
Anticipated	10/05/2018		Actual			
·			Update	30/03/2018		
			Reason	The last participant	interviews were	e conducted end
				of March 2018.		
Sample size						
Target	160	Accrual to date		Final	160	
Recruitment in						
Recruitment sta	ate(s)	ACT,NSW,NT,QLD,SA,TAS,WA,VI	C			
Funding & Spor	nsors					Edit step 8
Funding source	category [1]	Charities/Societies/Foundation	s			
Name [1]		National Heart Foundation of Au				
Address [1]		Unit 1, Level 1, 17-23 Townshend Phillip, ACT 2606				
Country [1]		Australia				
Primary sponso	or type	Individual				
Name		A/Prof Mitch J Duncan				
Address		ATC Building Level 2, The Unive	rsity of Newcastl	e, University Drive, Callagi	nan NSW 2308	
Country		Australia		5		
Secondary spo	nsor category [1]	Individual				
Name [1]		Prof Ron C Plotnikoff				

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#### https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?i...

Address [1]	ATC Building Level 2, The University of Newcastle, University Drive, Callaghan NSW 2308
Country [1]	Australia
Secondary sponsor category [2]	Individual
Name [2]	Beatrice Murawski
Address [2]	ATC Building Level 3, The University of Newcastle, University Drive, Callaghan NSW 2308
Country [2]	Australia
thics approval	Edit step 9
Ethics application status	Approved
Ethics committee name [1]	Human Research Ethics Committee
Ethics committee address [1]	Research Services Research Integrity Unit NIER, Block C The University of Newcastle Callaghan NSW 2308
Ethics committee country [1]	Australia
Date submitted for ethics approval [1]	30/05/2016
Approval date [1]	26/09/2016
Ethics approval number [1]	H-2016-0181
Summary	
Brief summary	A 2-arm randomised waitlist-controlled trial to test the efficacy of a m-health intervention to promote physical activity and sleep health in adults. The two main outcomes (MVPA and sleep quality) will be assessed after 3 months (primary endpoint) and followed up at the 6-month time point. The study will deliver a combined program including an app and message-based support to facilitate goal-setting, self- monitoring and feedback on progress towards goal for both behaviours.
	Physical inactivity is highly prevalent among adults and a large proportion of the population reports poor sleep health (characterised by inadequate sleep duration, low quality of sleep and inappropriate sleep timing, leaving people feeling insufficiently refreshed and unsatisfied with their sleep).
	Both behaviours independently influence risks for chronic disease and mortality and may have a bidirectional relationship, as such synergistic effects on health may be achieved. No studies to date have targeted the two behaviours simultaneously in a mobile device-delivered behaviour change intervention. In addition to testing the efficacy of such an intervention, we seek to identify potential moderators of intervention efficacy (e.g., age, gender, education) and test mediators of behaviour change (social cognitive factors, sleep hygiene).
Trial website	
Trial related presentations / publications	
Update	Murawski, B.,?Plotnikoff, R.C., Rayward, A.T., et al. Randomised controlled trial using a theory-based m-health intervention to improve physical activity and sleep health in adults: the Synergy Study protocol. BMJ Open 2018;8:e018997. doi:10.1136/ bmjopen-2017-018997
Reason	A full study protocol was published and the main outcomes paper is currently under review
Public notes	
Private notes	
Contacts	Edit step 10
Principal investigator	
Title	A/Prof
Name	Mitch Duncan
	Priority Research Centre for Physical Activity and Nutrition University of Newcastle
Address	ATC Building, Level 2 University Drive
	ATC Building, Level 2
Country	ATC Building, Level 2 University Drive Callaghan, 2308 NSW Australia
Address Country Phone Fax	ATC Building, Level 2 University Drive Callaghan, 2308 NSW

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	ies	
Title	A/Prof	
Name	Mitch Duncan	
Address	Priority Research Centre for Physical Activity and Nutrition University of Newcastle ATC Building, Level 2 University Drive Callaghan, 2308 NSW	
Country	Australia	
Phone	+61 2 4921 2084	
Fax		
Email	mitch.duncan@newcastle.edu.au	
Contact person for scientific qu	Jeries	
Title	A/Prof	
Name	Mitch Duncan	
Address	Priority Research Centre for Physical Activity and Nutrition University of Newcastle ATC Building, Level 2 University Drive Callaghan, 2308 NSW	
Country	Australia	
Phone	+61 2 4921 2084	
Fax		
Email	mitch.duncan@newcastle.edu.au	
Data sharing statement		dit step 11
Will individual participant data (IPD) for this trial be available (including data dictionaries)?	Undecided	
No/undecided IPD sharing reason/comment	Data may be made available upon request following ethical approval.	
What supporting documents are/will be available?	Study protocol	
Attachments/websites		
Type [1]	Study protocol	
URL/details/comments [1]	Murawski, B., Plotnikoff, R.C., Rayward, A.T., et al. Randomised controlled trial using a theory-bas m-health intervention to improve physical activity and sleep health in adults: the Synergy Study BMJ Open 2018;8:e018997. doi:10.1136/ bmjopen-2017-018997	
Attachment [1]	http://www.anzctr.org.au/Steps11and12/371331-(Uploaded-19-11-2018-19-59-52)-Study-related document.pdf	
Summary results	E	dit step 12
Have study results been published in a peer-reviewed journal?	No	
Other publications		
	Yes	
Have study results been made publicly available in another format?	Tes	
publicly available in another format?		
publicly available in another format?	Conference abstract	
publicly available in another format? Other publication details		

Results – basic reporting Results – plain English summary

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## Appendix Q: Eligibility survey Synergy Study

## **Survey Flow**

Intro (1 Question) Age (1 Question) Gender (2 Questions) BMI (2 Questions) Work (1 Question) Travel (1 Question) Physical Activity (1 Question) Sleep (1 Question) Sleep Disorder (1 Question) Sleep Meds (1 Question) Behaviour Change Safe (1 Question) Access (2 Questions) App User (2 Questions) Contact (4 Questions) **Start of Block: Intro** 

intro\_elig The following questions will **help us determine if you are eligible** to participate in the Synergy Study. Please provide your honest responses.

**End of Block: Intro** 

Start of Block: Age

qdem2 What is your current age? (Enter years)

End of Block: Age

Start of Block: Gender

### qdem1a Are you:

- Male (1)
- Female (2)

Display This Question: If Are you: = Female

qdem1b Are you currently **pregnant** or have you **given birth in the past 12 months**?

- Yes (1)
- o No (2)

**End of Block: Gender** 

Start of Block: Height/Weight

qdem4a What is your **height** in centimetres? (Example: 175)

IMPORTANT:

Please enter your height in **metric units (centimetres)** instead of imperial units (foot/inches), for example: 5'7" = 170cm; 5'8" = 173cm; 5'9" = 175cm; 6'0" = 183cm; 6'1" = 185cm

qdem4b What is your current **body weight** in kilograms? (Example: 65 kg)

End of Block: Height/Weight

Start of Block: BMI

info\_dem4c Based on the height and weight you have entered, we calculated a **body mass index (BMI)** of:

\${e://Field/output}

(Info: A healthy BMI is between 18.5 and 25)

End of Block: BMI

**Start of Block: Work** 

qemp4a How would you describe your usual working hours?

- Only during the day (1)
- Only during the afternoon/evening (2)
- Only during the night/early morning hours (3)
- Rotating shifts (if your usual work requires you to rotate between days and nights) (4)
- Not working (5)

End of Block: Work

Start of Block: Travel

qemp4b Will you frequently **travel** (once a month or more often) to a destination with a shift in time zones by **3 or more hours** (during the intervention period)?

- Yes (1)
- No (2)

End of Block: Travel

**Start of Block: PA** 

qupa1 As a rule, do you do at least half an hour per day (30 min/day) of moderate or vigorous exercise (such as walking or a sport) on 3 or more days a week?

- Yes (1)
- No (2)
- Not sure (3)

End of Block: PA

**Start of Block: Sleep** 

qusleep1 During the past month, how would you rate your **sleep quality** overall?

- Very good (1)
- Fairly good (2)
- Fairly bad (3)
- Very bad (4)

**End of Block: Sleep** 

**Start of Block: Sleep Disorder** 

qusleep2 Have you ever been told by a **doctor** that you have any of the following **chronic sleep problems**? (multiple responses possible)

### Important:

If you have suffered from any of the listed conditions in the past (e.g., during your childhood), but you no longer experience any symptoms or chronic problems, please select '*none*'.

If you experience some symptoms, but you are not sure about the cause and you have not been told by a doctor that you have any of the listed chronic sleep problems, also select '*none*'.

If you are unsure about your answer and you wish to discuss this with our

research team, please select '*other*' and we will contact you for further clarification.

- Obstructive Sleep Apnoea (1)
- Restless Legs Syndrome (2)
- o Insomnia (3)
- None (5)
- Other (please specify) (4) \_\_\_\_\_\_

End of Block: Sleep Disorder



### qusleep3 Are you currently taking any medication to help you sleep?

If you are taking prescription medicines or any over-the-counter pharmaceuticals specifically formulated to induce sleep, please select 'yes'.

If you are taking any herbal remedies, such as lavender or valerian, please select '*no*'.

If you are not sure how to classify any medication you are taking, please select '*not sure*' and a member of the research team will contact you for further clarification.

- Yes (1)
- No (2)
- Not sure (please explain) (3)

End of Block: Sleep Meds

Start of Block: Behaviour Change Safe

qsafe1 Do you have any **physical or mental condition** that would make it **unsafe for you to change your physical activity or sleep behaviours**?

- Yes (1)
- No (2)

End of Block: Behaviour Change Safe

**Start of Block: Access** 

qowner Do you own an Apple or Android **phone or tablet** that you can access the **Internet** from?

- Yes (1)
- o No (2)

Display This Question:

If Do you own an Apple or Android phone or tablet that you can access the Internet from? = Yes

qcompat To be **compatible** with our mobile app, your mobile phone or tablet is required to have the following **software versions** installed:

**iOS 8.0 or higher** (on Apple devices) or **API14/Android Version 4.0 or higher** (on Android devices).

Open the document in the link below to find out what version you are currently running on your mobile device:

How to locate your software version

If your device is currently incompatible, but is capable of running on newer versions, **please update to the latest software version** and select 'Yes, it is compatible.'

We are happy to assist you with any updates. If you require help, select 'Not sure, please call me'.

### Is your device compatible?

- Yes, it is compatible (1)
- No, it is incompatible (2)
- Not sure, please call me (3)

**End of Block: Access** 

**Start of Block: App User** 

qappuser2 Do you currently use an **app or activity tracker** (wristband, watch, clip, etc.) to monitor your daily activity or sleep behaviours?

If you have used smartphone apps or tracking devices in the past, but you are no longer using them, please select '*no*'.

- Yes (1)
- No (2)
- Not sure, please call me (3)

\_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_

qcontact2 Do you currently reside in Australia?

- Yes (1)
- No (2)

End of Block: App User

### **Start of Block: Contact**

intro\_contact On the following page, we will ask you to provide your contact details, so that we can inform you about your eligibility and send you some important instructions related to your participation.

qcontact1a Please enter your **first name only** (at this stage, we do not require a surname).

qcontact3a Please enter your **email** address.

qcontact3b Please enter your **phone** number (numbers only).

**End of Block: Contact** 

## **Appendix R: Tool sheets**

# **Goal-Setting Tool for Physical Activity**

Physical activity includes a broad spectrum of movement from casual strolling to hiking, gardening, aerobics, weight training, dancing, swimming and sports. Most importantly, being physically active is good for our physical and mental health and well-being.

Being active has so many benefits, but it takes time and often people will put it aside because of other priorities and, as you lose fitness, the idea of exercise doesn't always seem attractive.

Dedicating time to prioritise your health - including physical activity - is not a selfish choice, it ensures that you can be your healthiest self - be it in your role as a parent, a colleague or a friend. It should be part of your daily life in the way that brushing your teeth is.

Having well-defined goals generally makes it easier to cope during stressful periods and helps us keep on track with our priorities. With clear goals in mind, we know what we need to invest and what outcomes we get in return. This concept should also apply to exercise, but many people do not have a clear idea about the type and quantity of exercise they wish to achieve each day.

To set your first goals, start with something easy and try to find something you enjoy. Don't start out trying to be an elite athlete! Gain some confidence doing something simple, then build up. And remember, be okay with what you can manage TODAY.

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In order to set your goals, you will need to take into consideration:

- 1. Your current level of fitness and activity
- 2. Your current number of steps (wear your pedometer for a few days to get an idea)
- 3. Your current number of sessions of muscle strengthening activity (e.g., push-ups, stair climbing, squats). This might be none at all
- 4. How much time you can make available for activity each day? What can you eliminate? How can you integrate activity in to things you already spend time on (e.g. active transport)? What can you cut down that stops you from spending more time being active?
- 5. The *when*, *where*, *what*, *who with* and *how* of being active that will fit in with your daily routine.

Use your app to set personally meaningful goals (go to Dashboard > Activity).

- Work out how much time you can dedicate to being active each day and make that your Activity Goal.
- Avoid picking a day, which already is your busiest day of the week - it is easy to drop activity, when there is a lot going on and you feel quite fatigued already. Give yourself the best chance of sticking on track towards your goals.
- Decide how many steps you want to do each day (start out by adding around 500-1000 steps above your usual step count) and make that your Step Goal.

Decide how many sessions (about 20 min/session) of muscle strengthening activities you would like to do per week. Make that your Muscle Strengthening Goal.

## Keep your goals

SMART (Specific, Manageable, Attainable, Relevant, Timely)

By having a personal preference (list) of physical activities, your goal is **SPECIFIC** 

By using the app to log your activity each day, your goal is MEASURABLE

By starting out easy and adding one thing at a time, your goal is **ATTAINABLE** 

By knowing what you get out of investing into being active, your goal is **RELEVANT** 

By knowing when and where to be active, your goal is TIMELY

We advise you to work towards the recommended 150 minutes of moderate intensity physical activity (huff and puff) adults need for optimal health and wellbeing as well as 10,000 steps/day and two muscle strengthening sessions/week.

- Build up gradually (over several weeks), as opposed to making drastic changes.
- Prepare for setbacks.

Remember, setting goals and achieving them can be two different things. Sometimes unexpected things crop up in life and derail our schedules and plans - some days life will get in the way, but just set that aside and get back on track the next day. Find out what works best for you.

To *put your goals into action,* please refer to the action planning tool and the in-app resources section.

Please contact us, if you have any questions about this tool.

# Happy goal-setting!

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# Action Planning Tool for Physical Activity

## How?

Knowing about the importance of physical activity is a fundamental first step. Understanding how to make changes to it enables you to make the change actually happen.

We have put together a few ideas to help you structure a plan to build up your physical activity routines. Feel free to re-visit this plan whenever you need to, if it's time to get back on track, or to update your plan. You can either use the examples we provide below or prepare your own action plan by working through the following concepts and amending any sections to suit your own needs and ambitions.

# Why?

To give yourself a good reason and committing to making changes and getting active, consider the benefits (short & long-term) you will gain from increasing your current physical activity level. Take some time to reflect on what is important to you. For example:

...being active will improve my health & fitness and I will be able to keep up with my kids and provide a good role model for them...

...increasing my physical activity is important to me, because I have a family history of heart disease and I know that keeping active will lower my risk of...

...once I get fitter, I will finally be able to ...

## When?

Finding time to be active is important. Think about what time is best for you to allocate activity time. It might be first thing in the morning before you have a shower, or it might be during your lunch break. Life may already seem too full to fit in a time for activity, but perhaps you could cut down on time spent watching TV or incorporate it into other daily tasks such as parking further away from work and walking the rest of the way. You can always make time if you try.

<u>Tip:</u> Many people find it works best to put their activity time in their calendar so they can schedule other activities around it and prioritise their activity.

## Where?

Being active can be done almost anywhere! You don't have to have a gym membership (although if that suits you then go for it).

- Take a look at your neighbourhood and think about the sorts of activities you would be happy to do there. If there is a safe place to cycle you could ride your bike.
- Perhaps there is a park nearby where you could walk or jog or throw balls for your dog. If you like swimming, find out where your local pool is located.
- Look around your house and yard. You can always do squats, situps and star-jumps at home and if you have stairs and a bench, you have enough to do some muscle strengthening activities.

## Who with?

Exercising with a friend has plenty of benefits. It can make the whole undertaking more enjoyable and knowing someone is waiting for you is a great way to make yourself be more likely to turn up and do it.

Socialising is also important for your health and people who exercise in company are more likely to improve their physical activity levels. So, enlist your partner or a friend (or a group of friends) or your kids or even the dog, to be active with you or join an exercise class/group or a sporting team.

## What?

Physical activity comes in many forms and you should try to choose activities which you find enjoyable.

- We recommend that you work towards doing at least 150 minutes of activity, which makes you "huff and puff" (aerobic-based exercise) on most days of the week (try to aim for 5), combined with muscle strengthening sessions on 2 days each week. Also set a goal for how many steps you take each day.
- "Huff and puff" exercises include anything which increases your heart rate and makes you sweat. How hard you push yourself depends on how fit you are and how much effort you decide to make. Examples include brisk walking, jogging, cycling, swimming, dancing or a fitness class as well as many more.
- Muscle strengthening exercises include any activities which make your muscles work harder than usual. This can include lifting weights or using elastic resistance bands, but it can also include yoga, climbing the stairs, and using your own body weight to do push-ups, sit-ups, squats, etc. It is a good idea to use different muscle groups (e.g. legs, arms, chest, shoulders, back, abdomen) and do a number of repetitions (e.g. 8-15 each) then rest before doing another 1-2 sets of repetitions.

**Remember:** With any type of activity, you should start easily to prevent injury and undue soreness and gradually build up the effort and time. It is also a good idea to warm up and cool down and follow exercise with some gentle stretching.

Please contact us, if you have any questions about this tool.

# Happy planning!

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# **Examples of Strength Training Exercises**

Here are some examples of muscles strengthening exercises and some brief descriptions of to how to perform them. When you do a muscle strengthening session, try to choose a mixture of exercises for several large muscle groups. That way you rest some muscles while you use a different group of muscles between sets.

Tip: You can use cans of food or milk bottles filled with water as weights.

For example: a session of muscle strengthening might include

- > a set (8 reps) of lunges followed by
- > a set (8 reps) of push-ups and
- a set (8 reps) of abdominal crunches before repeating each set once or twice.
- As you get fitter, you can increase the number of repetitions and/or the number of sets per session and/or add different exercises (e.g., planks, burpees)
- Always remember to warm up (for 5-10 min) before you begin a workout and stretch out your muscles (for 5-10 min) at the end of every workout

Exercise	Instructions
Lunges	<ol> <li>Start with your feet shoulder width apart and put your hands on your hips</li> <li>Take a generous step forward and bend the front knee to form a right angle between the floor and</li> </ol>

	<ul> <li>your lower leg whilst allowing the back leg to bend and the back heel to come off the floor</li> <li>3. Keep a wide stance (left leg in line with left shoulder, right leg in line with right shoulder)</li> <li>4. Hold for a second, then push back to a standing position</li> <li>5. Repeat using the other leg</li> <li>&gt; This is one <i>repetition (rep)</i>. Do 8 to 12 <i>reps</i> to make</li> </ul>
	a <i>set.</i> Do 2-3 sets in a <i>session.</i>
Calf Raises	<ol> <li>Place the front of one foot on the edge of a step near a railing/wall you can hang on to for balance</li> <li>Lift the other foot off the ground slightly</li> <li>Slowly raise the heel of the foot you are standing on as high as is comfortable and lower to the level position</li> <li>Drop the same heel until you feel a slight stretch in the calf muscle and raise back to the level position</li> <li>Repeat using the other foot</li> <li>This is a good example of an exercise you can do while brushing your teeth or while the kettle is boiling</li> <li>To also improve your balance, take your hands off the rail/wall and hold your arms out to the side</li> </ol>
	This is one <i>repetition (rep)</i> . Do 8 to 12 <i>reps</i> to make
	a <i>set.</i> Do 2-3 sets in a <i>session</i> .
Squats	<ol> <li>Start with your feet shoulder width apart and put your hands on your hips</li> <li>Engage your core muscles to protect your lower back by drawing in your belly button (continue to breathe normally)</li> </ol>

<ul> <li>3. Slowly lower yourself, bending at the hips and knees, until your thighs are parallel to the floor (or as far as feels comfortable for you)</li> <li>4. Slowly return to standing by firmly pushing both your heels against the floor</li> <li>5. As a variation, you can turn your feet outward slightly or take a wider stance</li> <li>&gt; This is one <i>repetition (rep)</i>. Do 8 to 12 <i>reps</i> to make</li> </ul>
a <i>set.</i> Do 2-3 sets in a <i>session.</i>
<ol> <li>Stand with your feet shoulder width apart, knees slightly bent. Hold a small weight in each hand with palms facing out, arms by your side but not fully straight</li> <li>Bend one elbow (keeping it near your waist) and raise your hand and weight to your shoulder. Keep the rest of your body still and do not rotate your torso by pulling this shoulder forward and towards the weight</li> <li>Slowly lower your hand back to the starting position.</li> <li>Repeat using the other arm</li> </ol>
This is one <i>repetition (rep)</i> . Do 8 to 12 <i>reps</i> to make
a <i>set.</i> Do 2-3 sets in a <i>session.</i>
<ol> <li>Find a stable chair/bench</li> <li>Face away from the chair/bench. Place hands on the edge of the chair/bench with your fingers pointing down and stretch your legs in front of you with your knees bent.</li> <li>Lower your body towards the ground keeping your back close to the chair/bench and elbows pointing backwards</li> <li>Raise your body back to the starting position</li> </ol>

	This is one <i>repetition (rep)</i> . Do 8 to 12 <i>reps</i> to make
	a <i>set.</i> Do 2-3 sets in a <i>session.</i>
Push-ups	<ol> <li>Get into the push-up position by getting on all fours with your hands beneath your shoulders. Then extend your legs behind you putting the weight on the balls of your feet or on your knees if you need to reduce the effort</li> <li>Engage your core muscles to protect your lower back by drawing in belly button (don't forget to breathe)</li> <li>Lower your chest towards the ground keeping your body straight but do not touch the ground</li> <li>Push your body back to the starting position</li> </ol>
	This is one <i>repetition (rep)</i> . Do 8 to 12 <i>reps</i> to make
	a <i>set.</i> Do 2-3 sets in a <i>session.</i>
Wall Push-ups	<ol> <li>Face a wall with feet shoulder width apart. Place your palms on the wall at shoulder height with straight arms</li> <li>Step your feet back a couple of steps. (The further your feet are away from the wall, the more difficult the push-up)</li> <li>Bend your elbows and lean in towards the wall keeping your hips, knees and shoulders in line</li> <li>Slowly straighten your arms and push yourself back to the starting position</li> <li>This is one <i>repetition (rep)</i>. Do 8 to 12 <i>reps</i> to make a <i>set</i>. Do 2-3 sets in a <i>session</i>.</li> </ol>
Pull-ups	<ol> <li>Find a bar which is about waist height (e.g. a walking rail at a park). Position yourself with your chest beneath the bar, grasping the bar with your</li> </ol>

	<ul> <li>hands shoulder width apart. Straighten your arms and extend your legs</li> <li>2. Pull your chest towards the bar keeping your body straight</li> <li>3. Lower your body back to the starting position</li> <li>&gt; This is one <i>repetition (rep)</i>. Do 8 to 12 <i>reps</i> to make a <i>set.</i> Do 2-3 sets in a <i>session.</i></li> </ul>
Prone Bridge	<ol> <li>Position yourself on the ground on your elbows with your legs extended behind</li> <li>Hold this position for 60 seconds (choose 30 seconds if this is too hard) keeping your shoulders, hips and knees in line</li> <li>This is one <i>repetition (rep)</i>. Do 2-3 <i>reps</i> to make a <i>set</i>. Do 1 set in a <i>session</i>.</li> </ol>
Seated Abdominal Twists	<ol> <li>Sit on the edge of a chair with your feet flat on the floor shoulder width apart and your knees bent. Cross your forearms and raise them to shoulder height</li> <li>Lean back slightly, engage your abdominal muscles and twist as far as you can in one direction</li> <li>Hold briefly before twisting as far as you can in the other direction</li> <li>This is one <i>repetition (rep)</i>. Do 10-20 <i>reps</i> to make a <i>set</i>. Do 2-3 sets in a <i>session</i>.</li> </ol>
Wrist to Knee Abdominal Crunches	<ol> <li>Lie on your back with your knees bent and your feet flat on the floor, shoulder width apart and your hands on your thighs</li> <li>Press your lower back against the floor, curl in your tailbone</li> </ol>

	<ol> <li>Keeping your arms straight, slide your hands up your thigh towards your knees as you raise your body off the floor</li> <li>Lower your body slowly back to the floor as you slide your hands back down your thighs</li> </ol>
	This is one <i>repetition (rep)</i> . Do 10-20 <i>reps</i> to make a <i>set.</i> Do 2-3 sets in a <i>session.</i>
Back Extensions	<ol> <li>Lie face down on the floor. Bend your elbows and touch your ears lightly</li> <li>Tighten your leg muscles and raise your chest &amp; shoulders off the ground</li> <li>Hold briefly before lowering yourself slowly back to the ground</li> </ol>
	This is one <i>repetition (rep)</i> . Do 8 to 12 <i>reps</i> to make a <i>set</i> . Do 2-3 sets in a <i>session</i> .

# Example of a Physical Activity Action Plan

	Activity	Duration	Where	When	Who with
Monday	Brisk	30 min	From my house	Before	Му
	walking		to the park and	breakfast	neighbour
			back		
Tuesday	Strength	20 min	In the lounge	After	My
	session		room	work	partner
	3 sets of				
	push-ups,				
	squats				
	and				
	lunges				
Wednesday	Brisk	2 x 25	Park car 2km	Before	Му
	walking	min	away from work	and after	colleague
			and walk to and	work	
			from		
Thursday	Strength	20 min	In the park using	After	My
	session		the steps and the	work	partner
	3 sets of		park bench		
	sit-ups,				
	lunges				
	and				
	triceps				
	dips				
Friday	Swimming	20 min	Local pool	After	The kids
				work	
Saturday	Brisk	45 min	Parkrun	Before	My best
	walking			breakfast	friend
Sunday	Bike ride	30 min	Along local cycle	Mid-	Whole
			way	afternoon	family

Total Minutes of "huff and puff" activity	180 minutes
Total number of strength sessions	2 sessions

# Template: My Physical Activity Action Plan

	Activity	Duration	Where	When	Who with
Monday					
Tuesday					
Wednesday					
Thursday					
Friday					
Saturday					
Sunday					

Total Minutes of "huff and puff" activity	
Total number of strength sessions	

# **Goal Setting Tool for Sleep**

Sleep is the preparation you need for a busy day and it is the recovery you need after a busy day. Dedicating time to your health priorities - including sleep - is not a selfish choice, it ensures that you can be your healthiest self - be it in your role as a parent, a colleague or a friend.

Having well-defined goals generally makes it easier to cope during stressful periods and helps us keep up with priorities. With clear goals in mind, we are aware of what we have to invest and which outcomes we get in return. This concept should also apply to sleep health, but most people do not have a clear definition of the quality or the quantity of sleep they wish to secure each night.

To set your first goals, start with something easy. Don't start out trying to break all your worst habits at once. Gain some confidence doing one thing, then add to it. And remember, sleep and sleep hygiene are not about perfectionism. Always allow for a certain degree of flexibility, because worrying and pondering aka the '*could have, should have...*' do not facilitate good sleep health. Be okay with what you can manage TODAY.

Before you determine *"how much sleep"* you want, which requires you to first set goals for your bed and wake times, think about your sleep hygiene behaviours (for further info see: action planning tool and the inapp resources section), as they contribute to the quality of your sleep. We refer to sleep hygiene as a set of behaviours which allow good quality sleep to occur

**Use the Balanced app** (go to Dashboard > Sleep) to scroll through all the different sleep hygiene behaviours (e.g., avoid caffeine, reduce noise, manage stress, etc.) and make a list of what you already do right. Aim to expand this initial list by adding another one or two behaviours. Make them your sleep hygiene goals.

## Keep your goals **SMART**

By having a personal selection (list) of sleep hygiene behaviours, your goal is **SPECIFIC** 

By using the app to indicate what behaviours you practiced, your goal is **MEASURABLE** 

By starting out easy and adding one thing at a time, your goal is **ATTAINABLE** 

By knowing what you get out of investing into better sleep, your goal is
RELEVANT

By knowing when and where to practice good sleep hygiene, your goal is TIMELY

Choose just a few goals to begin with, so there is always something you can reach. You may even reduce your goals over the weekend to give yourself a break as your routines may differ compared to the work week.

If you consciously plan your habits around sleep hygiene, any changes in your sleep quality and the amount of recovery you secure each night will be Significant, Meaningful, Adequate, Rewarding and Tangible.

**Remember**: Consistent bed and wake times are key elements of good sleep hygiene and help you be in control of the amount of sleep you are getting. Pick a bed and wake time that is achievable and also aligns with the total sleep duration you would like to get. While it feels more manageable to set an alarm at the same time every day, it might not be as simple to avoid some of the distractions or commitments that are due at bedtime.

### Ask yourself:

What can you eliminate? What can you cut down? What can you get out of the way at other times of the day? What can someone else do for you?

We advise you to work towards the recommended 7-9 hours of sleep adults need for optimal health and wellbeing. Work with 15-minute increments and make gradual (over several weeks), as opposed to drastic changes. Prepare for setbacks - some nights will be shorter than others, which is okay as long as you know how to avoid making short sleep a habit.

We understand that it can be difficult to switch off sometimes, even if you did all the right things and you had the best intentions. You cannot force yourself to fall asleep, you can only allow it to happen. Avoid feelings of frustration, leave the bed if you cannot fall asleep at all and return later. Practice some relaxation techniques to help you calm your mind. Our third tool on stress management provides an overview of the most common techniques. Find out what works best for you.

Our recommendation for time management relating to sleep: To help you keep regular bedtimes, we advise you to set up a daily alarm on your phone, which reminds you that it is time to wind down and get ready for bed. Set this reminder to occur approximately 30-60 minutes prior to your goal bedtime on weekdays (Monday-Friday) and on weekends, if you wish to maintain a very strict sleep pattern. For example, if your goal bedtime is 10pm, set your alarm to go off between 9pm and 9.30pm. Utilise this reminder to stop yourself from spending too much time on unnecessary tasks in the evening and use the time between the reminder and your actual bedtime to de-stress

and unwind. Dim your lights, change into comfortable clothing, eliminate sources of light and noise.

Please contact us, if you have any questions about this tool.

# Happy sleeping!

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# **Action Planning Tool for Sleep**

# How?

This is a very important question when it comes to changing any of your health behaviours.

We have put a list of queries together that help you commit to your goals by building a plan around your sleep habits. Feel free to come back to this tool at a later point or whenever you feel like things have fallen out of place and you need to convince yourself that you do have the ability to make changes. You can either print this document or prepare your own plan of priorities by completing some of the statements below:

# Why?

To give yourself a meaningful reason for making an effort, consider any benefits (short-term & long-term) you expect from improving your sleep health, for example:

...I have decided to look after my sleep health, because... ...by sleeping better, I will be able to... ...and it is important to me to sleep well, because...

# When?

To take care of our sleep, we need to focus on the things we can consciously control - so while we are awake - and this concerns everything we do upon waking, throughout the day and at bedtime. Good sleep hygiene is about making good choices as part of health awareness.

Go to the in-app resources for a list of sleep hygiene recommendations and use the goal-setting tool to define some goals that you feel are challenging, but easy enough to be implemented on at least 3-4 days a week.

<u>Tip:</u> Focus on consistency first, then add to the quantity of goals and ask yourself what you can do to allow good sleep to happen on a regular basis.

# Where?

Many things can influence the quality of our sleep, but having a good sleep environment can make a big difference. It requires some active management to create an environment that promotes good sleep.

Ask yourself these questions and brainstorm some solutions, if the answer is "no"

- ... is the temperature in my bedroom right and does the air feel fresh? ... is my bedroom dark and noise-free?
- ... do I have the right bedding, sheets and PJs (suited to time of year)? ... are all technological devices switched off at night, so they won't disturb me?
- ... [if you regularly travel for work and you sleep in hotel rooms] do you consider managing unfamiliar environments or situations to suit your needs, for example by wearing an eye mask or ear plugs?

# Who with?

Be communicative about your sleep needs. If your partner is restless or snores, find ways to manage these issues together and make it a priority to secure some good slumber time.

Sleep is associated with quality of life and you will soon notice how your rest & recovery periods affect your daytime functioning, productivity, emotional wellbeing and much more. If you have young children, who tend to wake you halfway through the night, have a plan in place that helps all of you settle back down easily. For example, always use dim lighting if you do get up. Keep your feet warm until you get back into bed (e.g., wear slippers or socks) and know what helps you worry less. The same applies to pets (dogs, cats) and their midnight needs. If you do have a pet that sleeps in your bedroom, consider ways that help your pet interrupt your sleep as little as possible.

If you are a caretaker, establish the best possible routine to keep any night-time duties managed in an efficient way: be prepared, keep those things handy that might need using and have a system in place that allows you to rest worry-free in between your duties (e.g., alarm bell, timers, care aids, etc.).

# What?

Consistency with your sleep habits depends on a solid **routine**. Develop your own bedtime ritual, which begins 30-60 minutes prior to your goal bedtime.

- > Set strict limits for any work you might be doing in the late evening.
- Dim the lights, listen to some relaxing music or take a bath, read a book.
- Switch off any devices that omit blue light or set them to night shift mode (on the iPhone: go to settings > display & brightness > night shift). Android devices require you to download an app to filter the lights in your device at night-time. Go to the Google Play Store and search for 'Night Shift: Blue Light Filter' or 'Twilight' to download this feature.

Practice some relaxation techniques and bring calmness your breathing. Our stress management tool provides further info on how to de-stress before it is bedtime.

Slowing down mentally and physically will help you ease into good quality sleep.

Please contact us, if you have any questions about this tool.

# Happy sleeping!

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# **Stress Management Techniques**

Stress affects us in many ways and many people experience high levels of stress. Stress is our response to an event or situation that causes us to worry, which affects how we are thinking and feeling.

Although stress hormones help us function when external demands become overwhelming and daunting, they provide an intense, but very short-lived boost of energy that drains us in the long run.

When stress begins to affect how you are thinking and feeling it is important to manage your stress using calming techniques, some of the most popular ones of which we have summarised in this sheet.

Practising these techniques regularly will help you recover from stressful situations and also give you a greater sense of control when you are dealing with the cause of stress.

# **Relaxed breathing**

- Practise deep breathing at a regular time and in a quiet place where you won't be disturbed.
- Loosen or remove any tight clothes you have on, such as shoes or jackets.
- > Make yourself feel completely comfortable.
- Sit in a comfy chair which supports your head or lie on the floor or bed.
- Place your arms on the chair arms, or flat on the floor or bed, a little bit away from the side of your body with the palms up.

If you're lying down, stretch out your legs, keeping them hip-width apart or slightly wider. If you're sitting in a chair, don't cross your legs.

Relaxation techniques usually start with focusing on your breathing. The way to do it is to breathe in and out slowly and in a regular rhythm as this will help you to calm down.

- Fill up the whole of your lungs with air, without forcing. Imagine you're filling up a bottle, so that your lungs fill from the bottom.
- > Breathe in through your nose and out through your mouth.
- Breathe in slowly and regularly counting from one to five (don't worry if you can't reach five at first).
- > Then let the breath escape slowly, counting from one to five.
- Keep doing this until you feel calm. Breathe without pausing or holding your breath.

Practise this relaxed breathing for three to five minutes, two to three times a day (or whenever you feel stressed).

# **Deep muscle relaxation**

This technique takes around 20 minutes.

It stretches different muscles in turn and then relaxes them, to release tension from the body and relax your mind.

> Find a warm, quiet place with no distractions.

- > Get completely comfortable, either sitting or lying down.
- Close your eyes and begin by focusing on your breathing, breathing slowly and deeply, as described above.

If you have pain in certain muscles, or if there are muscles that you find it difficult to focus on, spend more time on relaxing other parts.

You may want to play some soothing music to help relaxation. As with all relaxation techniques, deep muscle relaxation will require a bit of practice before you start feeling its benefits.

For each exercise, hold the stretch for a few seconds, then relax. Repeat it a couple of times. It's useful to keep to the same order as you work through the muscle groups:

- Face push the eyebrows together, as though frowning, then release.
- Neck gently tilt the head forwards, pushing chin down towards chest, then slowly lift again.
- Shoulders pull them up towards the ears (shrug), then relax them down towards the feet.
- Chest breathe slowly and deeply into the diaphragm (below your bottom rib) so that you're using the whole of the lungs. Then breathe slowly out, allowing the belly to deflate as all the air is exhaled.
- > Arms stretch the arms away from the body, reach, then relax.
- Legs push the toes away from the body, then pull them towards the body, then relax.

Wrists and hands - stretch the wrist by pulling the hand up towards you, and stretch out the fingers and thumbs, then relax.

Spend some time lying quietly after your relaxation with your eyes closed. When you feel ready, stretch and get up slowly.

# **Mindfulness**

Mindfulness is about being aware of what is happening in the present on a moment by moment basis, while not making judgements about whether we like or don't like what we find.

We all have the capacity to be mindful. It simply involves enhancing our ability to pay attention in the present moment and allows us to disengage from mental "clutter" and to have a clear mind. It makes it possible for us to respond rather than react to situations, which improves our decision-making and potential for physical and mental relaxation.

Below are some brief instructions to help you practice mindfulness from the above resource:

## **One-minute Exercise**

Sit in front of a clock or watch that you can use to time the passing of one minute. Your task is to focus your entire attention on your breathing, and nothing else, for the minute. Have a go - do it now.

## **De-stressing Exercise**

Bring yourself into the present by deliberately adopting an erect and dignified posture.

- > Then ask yourself: "What is going on with me at the moment?"
- You simply allow yourself to observe whatever happens. Label any thoughts that you have and then leave them alone.... just be prepared to let them float away.
- Attend to your breathing or simply take in your surroundings instead.
- Besides thoughts, there may be sounds you hear, bodily sensations that you are aware of. If you find yourself constantly elaborating on thoughts, rather than labelling them and returning to the neutral, remember to observe your breathing.
- When emotions or memories of painful events occur, don't allow yourself to become caught up by them.
- Give them short labels such as "that's a sad feeling", "that's an angry feeling" and then just allow them to drift or float away. These memories and feelings will gradually decrease in intensity and frequency.
- More importantly, you will begin to identify yourself as an objective observer or witness rather than a person who is disturbed by these thoughts and feelings. This requires practise but can then be used whenever you are stressed.

# Mindful Eating

This involves sitting down at a table and eating a meal without engaging in any other activities - no newspaper, book, TV, radio, music, or talking.

- Now eat your meal paying full attention to which piece of food you select to eat, how it looks, how it smells, how you cut the food, the muscles you use to raise it to your mouth, the texture and taste of the food as you chew it slowly.
- You may be amazed at how different food tastes when eaten in this way and how filling a meal can be. It is also very good for the digestion.

## Mindful Walking

- Here the same principle, while walking you concentrate on the feel of the ground under your feet, your breathing while walking.
- Just observe what is around you as you walk, staying IN THE PRESENT.
- Let your other thoughts go, just look at the sky, the view, the other walkers; feel the wind, the temperature on your skin; enjoy the moment.

## Associated Breathing Exercises

- Stay with any distressing thoughts for a few moments, then as you let them float away, you gently redirect your full attention to your breathing.
- Pay attention to each breath in & out as they follow rhythmically one after the other.
- This will ground you in the present and help you to move into a state of awareness and stillness.

Please contact us, if you have any questions about this tool.

# Happy de-stressing!

# **BEATRICE MURAWSKI - PROJECT LEADER**

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# **Appendix S: Participant handbook**



# Participant Handbook



# Contents

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#### Summary.

We appreciate your participation in the "Synergy Study" and hope that our programme will contribute to your health through improved lifestyle behaviours.

This handbook is intended to help you make a start and familiarise yourself with our mobile app, called *"Balanced"*. You will also find several tool sheets at the back of this handbook, all of which provide some step-by-step assistance with goal-setting, action planning and stress management.

The "Synergy Study" is designed to make it easy for you to achieve improvements in both, physical activity and sleep by giving you the control over the process, while helping you utilise those strategies that enable you to make changes in the long run. It is important to note that our study is targeting physical activity and sleep at the same time, to make use of the boosting effects that these two behaviours have on each other.

During the first 12 weeks, you will use the mobile app in combination with a support service provided to you through SMS & Email (you can use the app as much or as little as you like). We understand not all the information we offer is equally important or relevant to every one of our participants, so please be patient with any aspects that may not apply to you. You may continue using the app after your 12-week assessment or for as long as you like.

Once again, we would like to thank you for taking part in the

#### "Synergy Study"

#### Beatrice Murawski - Project Leader

BSc (Sport Performance & Coaching) | MSc (Sport & Exercise Psychology) | PhD Candidate (Behavioural Sciences) at the Priority Research Centre for Physical Activity & Nutrition School of Medicine & Public Health, Faculty of Health and Medicine The University of Newcastle, University Drive, Callaghan NSW 2308

> T: +61 (0) 2 4921 2067 E: <u>synergystudy@newcastle.edu.au</u>

## Your Schedule.

Below is an overview of important time points, including your **3 online assessments**. Don't worry, we will send you a reminder when they are coming up. In the meantime, install the app, read through the resources, track your behaviour and please get in touch, if you have any questions.

 $\star$  you are eligible to participate and we enrol you in the study  $\checkmark$ 

- ✤ you complete your baseline assessment ✓
- $\star$  we randomly allocate you to one of two groups  $\checkmark$
- $\star$  you receive your pedometer and this handbook  $\checkmark$
- \* you install the app and start making improvements to your physical

activity and sleep behaviours and we support you for 12 weeks

- \* you complete your 12-week assessment
- \* you may continue to use the app, but message-based support ends
- \* we follow up with you after another 12 weeks (24-week assessment)

	Your	assessment	dates are:
8 9 10 17 18 19 20 15 19 17 18 19 20 22 23 24 28 28 27 29 29 30 31			(baseline)
			(12-week assessment)
AGLET			(24-week assessment)

## Research Team & Contact Details.

#### Who are we?

We are a team of health researchers from the Priority Research Centre for Physical Activity & Nutrition at the University of Newcastle, NSW. The *"Synergy Study"* is conducted as part of a study series for Miss Beatrice Murawski to fulfil her PhD Thesis requirements and the project is supervised by Associate Professor Mitch Duncan and Professor Ron Plotnikoff.

#### Who and when to contact?

Please contact the study team for any questions regarding your participation in the programme including trouble-shooting for any functional or technical issues related to using the app. Our support hotline and Emails are generally answered during usual office hours: **Monday-Friday 9am-5pm**, so please leave a message, if you are calling outside of these hours and we will get in touch as soon we can.

→ Email synergystudy@newcastle.edu.au or call +61 (0) 2 4921 2067

This includes the reporting of any new medical events or concerns, which you have sought treatment for, as well as any changes to your circumstances, if these limit your ability to make changes to your physical activity and sleep behaviours (e.g., starting night shift work or falling pregnant).

If you require urgent attention in the case of an emergency, **call 000** or your local *GP Access After Hours* to seek help.

If you have an **ethical concern, complaints or feedback** regarding this research project, please contact chief investigator Associate Prof Mitch Duncan (<u>mitch.duncan@newcastle.edu.au</u> or by phone +61 (0) 2 4921 7805) or the Human Research Ethics Committee of the University of Newcastle (<u>Human-Ethics@newcastle.edu.au</u> or + 61 (0) 2 4921 7894), quoting our Approval No. H-2016-0181.

### System Requirements.

We would like to remind you that as a minimum, your device requires the following system specifications for our mobile app to be user-friendly and to run smoothly throughout the duration of your participation:

	Apple	Android
Software	iOS 8.0 or higher	API14/Version 4.0 or higher

We generally recommend you have the most recent update installed on your device. Please contact us, if you require assistance with any updates.

#### Some general information.

- If there appears to be a bug in the system or the app stops working, try turning your phone off and back on; if we have sent you an Email to ask you to update the Balanced app on your device, please do so; if any problems persist, please contact us
- If there is a bug in the system, do not panic, your data is not lost if ever it should disappear from the app, as we back it up. Although you might have to re-set your goals, your progress history is backed up and will re-appear on your progress screen
- If a major software update is released while the study is running and if this causes temporary outages or interferes with the functionality of the app, we will contact you with further information/instructions. Our developers work very hard to keep up to speed with the latest software.
- Please note, our text message & Email support system is separate to the app and generated individually by the research team. If at any time, you feel like the content or timing of these messages is either inappropriate or incorrect, please contact the research team and we will do our very best to resolve the problem

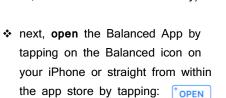
## Getting Started.

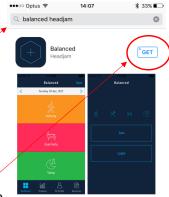
Installing the Balanced App on your device requires you to access the **App Store** (if you have an Apple device) or the **Google Play Store** (Android devices) using your personal account/user name. Our app is free of charge.



#### App Store Download.

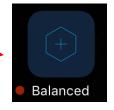
- ✤ Go to the app store
- Search for 'Balanced Headjam' and look for the Balanced icon (we recommend you connect to Wifi)
- tap 'GET' to start downloading the app (this may prompt you to enter the password associated with your apple ID, make sure to have it handy)



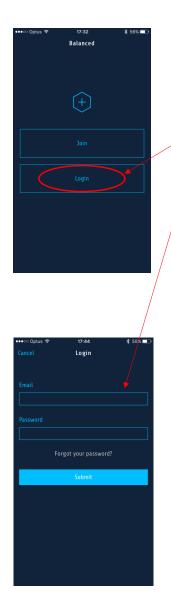








✤ you will see a navy-blue screen with an option to 'Login'



## INSTRUCTIONS.

It is **very important** that you use the **Login** tile to enter the credentials we have provided for you

You can find **your user details** on the cover page of this handbook. If you have lost your name label or it was missing when you received your materials, please contact the research team to get your login details - we are happy to help

Please **do not** join up by creating your own account, as this will not provide you with the programme specifically designed for our study



# Google Play Store Download (Example device: Samsung Galaxy S6)

- tap the Apps icon in the bottom right of your home screen
- swipe left or right until you find the play store icon





Using the search bar at the top of the screen, type "Balanced Headjam" followed by the magnifying glass symbol or enter





 $\boldsymbol{\diamondsuit}$  tap this icon every time you wish to use the app

\* tap 'LOGIN' to access your user account



## IMPORTANT

Please ensure you tap Login and enter the user details we have provided on the front of your handbook, otherwise you will not be receiving the additional support we offer as part of the study

DO NOT select Join

### App Interface.

#### Dashboard.

Welcome to your dashboard. This screen allows you to access your daily logs and goal-setting options for physical activity and sleep. Its main function is to provide you with instant feedback on progress towards your goals.

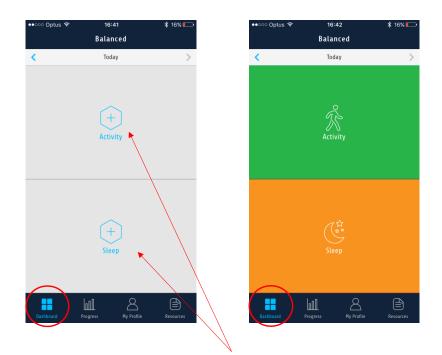
The two dashboard tiles resemble a traffic light that changes between green, orange and red, as soon as you have entered both, goals and your stats. Your traffic light for activity relates to your **activity time** and your traffic light for sleep is based on your **total sleep duration** (calculated from the bed and wake times you have entered).



Red means you are >35% away from your goal Orange means you are within 20-35% of your goal Green means you are within 20% of your goal or you have exceeded your goal

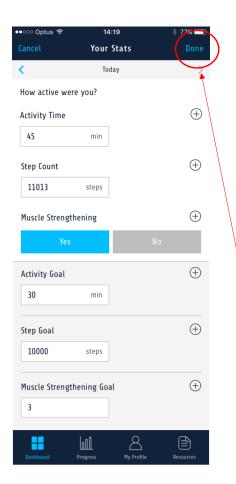
The more activity the better, which is why the activity light will be green, if you are within 20% of goal, exactly hitting your goal, or way over it. However, for sleep duration, this colour scale will be applied on either side of your goal times, for example, if your sleep duration is 25% over your sleep duration goal (which we calculate from the goal bed and wake times you enter) you will get an orange light, just like you would when you are 25% under the calculated goal sleep duration.

Set your goals based on what you think is **achievable** on a daily basis. As a rule of thumb, we think your goals should be set at a level that makes it challenging, yet easy enough to get a green light on at least 3 days per week. Our tool sheets include further detailed information on how to set goals.



- Tap any one of the tiles to log a behaviour or to set goals. See page 16 for further details on logging and setting goals
- Tip: You may want to log your sleep first thing in the morning when it is easy to recall your bed and wake times. Most people enter their Stats for active time, steps & muscle strengthening activities at the end of the day, but you can log those at a time that is convenient for you
- Your Stats (see screenshot on page 13) for activity refer to any activity you have accumulated on this day, whereas the sleep log refers to the time you went to bed the previous night and the time you woke up this morning. Any data you enter will be displayed in the progress section, where you can view your personal summaries of activity and sleep. You can re-enter and update your log as many times as you like each day

### Your Stats.



## INSTRUCTIONS.

- tap each box to enter your data
- tap the plus icon to receive more information about what to enter
- indicate whether you have done any muscle strengthening exercise today by tapping 'Yes' or 'No' (selection = blue)
- ✤ enter a new goal or keep your previous goal
- ALWAYS tap 'Done' in the top right hand corner once you have finished or your data will not be saved
- tap the sleep tile to log your stats and set goals for sleep

#### Progress.

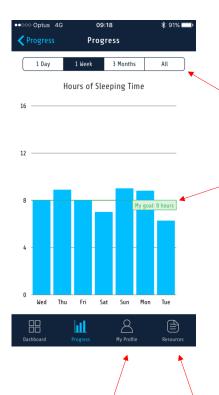
The progress section is divided into sub-categories for activity & sleep and contains bar charts for your daily, 1-week, 3-months progress and a chart showing all progress since you have started using the app (page 15).

The graphs you can view for each behaviour are based on the stats you have entered and allow you to compare your progress against your goals.

Use each graph as guidance to review and adjust your goals on a regular basis and give you the insights you need to reflect on progress and areas for improvements. Our tool sheets provide more details on how to build a realistic plan for yourself.

Tap any one of the 7 categories on the progress overview to check your progress (scroll down to get to the sleep hygiene category)

			$\sim$		
●●○○○ Optus ᅙ	12:59	∦ 84% 💷 •	••○○○ Optus 夺	12:59	* 849
	Progress			Progress	
x Activit	ty	>	💏 Step Co	ount	
📌 Step C	ount	>	💏 Resista	ince Sessions	
💏 Resist	ance Sessions	>	seep D	Duration	L
ssep	Duration	>	sleep C	Juality	
☆ Sleep	Quality	>	Sleep L	.og	
Sleep	Log	>	Sleep H	łygiene	
Dashboard	Progress My Profile	Resources	Dashboard	Progress My Profile	Resour



#### My Profile.

This section provides a summary of your user account and you may use the logout button to sign out of the app. We recommend staying logged in, as this makes it quicker and easier to enter data and view progress.

### INSTRUCTIONS.

- use the horizontal bar at the top
   of the screen to change from a daily to a 1-week or 3-month
   view of your progress
- the green line shows your goal for each behaviour (remember: your muscle strengthening goal is a weekly goal; all other goals are daily goals
- the more you log, the more complete you will find any information this section
- averages on the 1-week and 3months graphs will be dragged down if you forget to log your stats, as this is treated as an

#### Resources.

The resources section is intended to provide some information on why it is important to be physically active and sleep well and how you can take some simple steps in the right direction. You may find it helpful to return to this section from time to time to remind yourself of the value of these health behaviours and to find additional guidance, whenever you need it.

### Logging.

**Why?** Studies have shown that people who self-monitor and review their daily achievements or progress towards health goals are more successful at changing a behaviour.

"Self-monitoring" or keeping track of your behaviour also helps you understand which decisions you make and how you keep on progressing in the face of barriers (e.g., time restrictions, fatigue, other commitments, etc.). Selfmonitoring does not have to be complex and we have designed this app to allow you to track and review your progress whenever and wherever you like.

#### What can be logged?

- > daily *minutes of activity*
- > a daily *step count* (we provide the pedometer to measure this)
- > whether you did any *muscle strengthening activities* (today)
- > the time you went to bed (yesterday)
- the time you woke up (today)
- > the *quality of your sleep* and
- which sleep hygiene behaviours you practiced (yesterday). "Sleep hygiene" is about doing all the right things to allow good sleep to occur

#### Setting Goals.

Why? Having a goal for something is like knowing your destination when you are travelling. It is easier to stay motivated and self-assured, if we know where we are going and what it takes to get there.

"Goal-setting" also helps us break down a challenge into more manageable portions and your focus should be on keeping things "moderate but regular" rather than "extreme but infrequent". Break it down into small, achievable but challenging steps and remember, setbacks are okay, just take some time to evaluate what threw you off track and how to overcome any barriers. One of the tools we provided focusses on all the important aspects of setting SMART

goals, making the journey towards your goal Specific, Measurable, Attainable, Relevant and Timely.

What can you set goals for? You can set goals for the same items you also log your stats for. We will provide personalised feedback in an Email at the end of each week and prompt you to review your goals, if need be. You do not need to enter your goals on a daily basis. You only update them when you need to change your goals (e.g., when they have become too easy or too difficult to accomplish). Check out the in-app resources section or the goal-setting tool sheets in this handbook to find out how much physical activity and sleep is recommended in the national guidelines for Australian adults.

#### Messaging Support.

Why? Health behaviour change programmes with additional support have been shown to produce better results. We know how hard it can be to break a habit or to add something new to an already busy life. Our programme will use a series of messages to help give you the support you need to see your progress and keep you on track.

Our messaging system is external to the app and we will use either SMS (text message) or Email to deliver information or instructions to you. We generate these messages individually for you to make your participation a personal experience and help keep you motivated.

What will you receive and when? We aim to keep our messaging support as personal, relevant and timely as possible.

Messages consist of *reminders*, *prompts*, personalised *feedback* or *facts* including valuable knowledge around health, physical activity and sleep.

Below is an overview of the different types of messages you will receive throughout the period of your **12-week intervention**:

Туре	Purpose	Delivery	Timing
REMINDERS (optional)	You may wish to use the alarm function on your device to set yourself a bedtime reminder to prompt you when it is time to wind down. This can help you keep consistent bedtimes. We recommend you set this reminder to occur between 30- 60 min prior to your goal bedtime.	Own device	Daily (in the evening)
PROMPTS	(a) To remind you that your assessment is due or overdue	SMS and Email	as needed
	(b) To ask you to re-engage with the app, in case you did not log any data on 4 (or more) out of 7 days*	SMS (first 3 weeks) and Email (if we have no stats for three consecutive weeks)	Weekly if needed
FACTS (12 in total)	Valuable thoughts and advice on health, physical activity and sleep.	SMS	Weekly
SUMMARY REPORT (12 in total)	To provide a comprehensive summary of your progress in the previous week, which can help you set new goals and manage time.	Email	Weekly

\* The *Balanced* app comes with an integrated feature, which generates an **on-screen message (push notification),** if you have not logged any data in the last 24 hours. Please contact us to receive instructions on **how to disable this feature**, if you do not wish to receive these on-screen prompts.

### Pedometer Instructions.

We have sent you a "Yamax Digi-Walker" pedometer for you to be able to log your daily step count. This is a great method of continuous self-monitoring throughout the day and allows you to measure light, moderate and vigorous intensity physical activity. Pedometers have been shown to be accurate in particular for walking and running activities.

You will not be asked to return the pedometer at the end of the study, so feel free to continue to use it.

Please follow these instructions to use the pedometer:



- 1. open the top flap/lid to view the step count display
- 2. **push the yellow button to reset** the pedometer once you have received it as it will have accumulated some steps on its way to you
- 3. to get the correct reading each day, please **start at zero** by resetting your pedometer (pressing the yellow reset button once)
- if an unusual or half digit is displayed, press and hold the reset button for 5 seconds until 88888 is displayed. The display will shortly change to zero. You are now ready to get stepping
- 5. your pedometer will only count to 99,999 steps, after which it will reset itself to zero. This is most likely to happen if you forget resetting your pedometer on a new day and you reach 100,000 steps. Avoid losing steps by always starting a new day at zero. This way, even if you went all the ways from 0 to 110,000 in one day, you can just add 100,000 to your final daily reading (which in this case would be 10,000).
- place your pedometer on your waistband or belt, in line with your right knee. If you are wearing clothing without a waistband/belt (e.g., a

dress), please wear the pedometer under your clothing, attached to your underwear

- 7. **use the strap** we provided when clipping the pedometer to your belt/waistband to keep it safe, in case it falls off
- you should wear your pedometer during waking hours, except when you are showering, bathing or swimming. The pedometer is **not waterproof**, so please keep it dry.
- 9. pedometers do not accurately capture your activity during a bicycle ride, so please enter any cycling activities as minutes of moderate or intensity physical activity in the app. Alternatively, 10 minutes of moderate intensity activity are the equivalent of 1000 steps and 10 minutes of activity at vigorous intensity are the equivalent of 2000 steps
- 10.keep your pedometer next to your bed at night so it is ready to put on as soon as you get out of bed the next morning
- 11.let us know, if your pedometer is broken or faulty and we will send you a replacement

### Troubleshooting.

Always remember, if you are unable to resolve any issues related to your participation in the *"Synergy Study"*, please contact us and we will do our best to assist you.

Phone: +61 (0) 2 4921 2067 Email: <u>synergystudy@newcastle.edu.au</u>



## Tool Sheets.

The remaining pages of this handbook contain your tool sheets for behaviour change relating to physical activity and sleep.

You can use these sheets whenever it suits you best and work through them one at a time or all at once. However, to spread things out, we will send you an Email at weeks 3, 6 and 9 to explain a little more about the value and purpose of each tool, so don't worry if you do not get a chance to use the sheets straight away.

We will be focussing on one sheet per month in the following sequence (Note: we will send you an Email, as soon as you are due to review these sheets).

Tool Sheet Focus	Week
1. Goal Setting	3
2. Action Planning	6
3. Stress Management	9

21

# Appendix T: Weekly summary report

weekly report	SLEEP DURATION 8h19m average		SLEEP HYGIENE 6/10 average items	SLEEP QUALITY 3 average rating
<b>Beatrice</b> 30 April – 6 May 2018	ACTIVE TIME	STEP COUNT	BED TIMES	WAKE TIMES
What's next?		COONT	TIVIES	TIVIES
	25	62879	23:40	07:28
If you found it easy to	total	total	average	average
reach your goal on 4 or				
more days last week, consider setting more	4	8983		
challenging goals.	- average	average	varied by	varied by
			87	37
If you found it too difficult	A	A CONTRACTOR	minutes	minutes
to reach your goals on at			minutes	minutes
least 3 days last week,	GOAL	GOAL	Over the last 7	Over the last 7
consider setting more attainable goals.	reached on	reached on	days, your bed	days, your bed
attaillable goals.		5/7	times varied by	times varied by
Review our tips &	2/7	-	more than 60	less than 60
recommendations for goal-	days	days	minutes	minutes
setting and make use of	close on	close on		
the dashboard & progress	0/7	1/7	_	_
sections of the app for	days	days		
instant feedback.				
Blank fields, question marks or zeros indicate we've had insufficient data to generate a report this week. Help us help you by logging your data.	MUSCLE STRENGTHENING 2 sessions		Consistency is key. Set yourself a bedtime reminder to	Well done, you are on track. Keep up any routines that help you
Any questions? synergystudy@newcastle.edu.au +61 (0) 2 4921 2067	Goal reached?		keep a more consistent routine next week.	manage your inner clock.

# **Appendix U: Weekly fact SMS**

# Purple = PA & Sleep; Blue = PA; Green = Sleep

#### Week 1

From Synergy Study: Did you know, activity & sleep boost each other? Regular activity leads to better sleep and better sleep increases activity levels. Building good routines for better health & wellbeing requires making good choices throughout your day. To stay motivated, remind yourself of your very own reasons for keeping healthy & be clear about the benefits you wish to see in the long run. View the goal-setting & action planning tool sheets for more info.

### Week 2

From Synergy Study: Did you know, the national guidelines for physical activity recommend 75-100 minutes of vigorous-intensity physical activity or 150-300 minutes of moderate intensity physical activity per week, combined with strength training on at least 2 days per week for optimal health and reduced disease risk? We encourage you to gradually work towards this amount and remember, any step is better than no step. Visit the Resources section of the app for more info.

### Week 3

From Synergy Study: Did you know, keeping a 'healthy' bedroom environment contributes to your ability of keeping your sleep healthy, too. A healthy bedroom environment includes having fresh air, removing distractions such as light or noise & avoiding the use of technology. Visit the Resources section of the app for more info.

#### Week 4

From Synergy Study: Did you know, choosing a type of activity that you enjoy and sharing your active time with an exercise buddy helps you increase your activity levels and also makes it easier to stay active on a regular basis? If you prefer to be active by yourself and the going gets tough, focus on those aspects that you enjoy to shift your attention away from any negative feelings. Remember to choose exercises that are safe and take the time to learn how to do them properly to prevent injury. Visit the Resources section of the app for more info.

#### Week 5

From Synergy Study: Did you know, people with good sleep health have much lower risks of developing chronic diseases such as type-2-diabetes, heart disease and cancer. Good sleep health also helps prevent weight gain and boosts concentration & memory. Remember, good sleep includes the right amount duration, quality & timing of sleep that leaves you waking up feeling refreshed. For most people this requires 7-9 hours of sleep per night. Visit the Resources section of the app for more info.

#### Week 6

From Synergy Study: Did you know, it can be very difficult for us to distinguish cognitive or mental fatigue from physical fatigue? If you feel drained after a tough day of working your brains in the office, sit back and think about whether you have actually tired out any of your muscles? Try to separate the tired brain feeling from the tired muscles feeling. If you then engage in some physical work, you can experience some benefits on the cognitive and even the emotional level. It's a win win.

### Week 7

From Synergy Study: Did you know, through any healthy choices you are making, you can also influence your family, children and friends' decisions? People tend to behave in a similar way to those around them, so consider yourself a role model to your family, children, friends or colleagues and share some health behaviour awareness.

### Week 8

From Synergy Study: Did you know, the different phases of sleep each have a purpose? During deep sleep, your body focuses on decluttering and restoring the many systems that help you function throughout the day. In phases of light sleep, the brain condenses large amounts of information to support memory and emotional balance.

### Week 9

From Synergy Study: Did you know, around half the Australian population is not sufficiently active which means not meeting the recommended amount of huff and puff, often combined with high volumes of sitting? Not being active and sitting a lot increase the risk of chronic disease and early mortality. Get moving today to help reverse this national trend. For more info on how to build an action plan, find our email outlining the 'how to' of being more active.

### Week 10

From Synergy Study: Did you know, 4 in 10 Aussies do not get sufficient sleep! Being constantly tired negatively affects your decision-making, productivity as well as your metabolic health. Losing one night of good sleep is enough to upset our body. To reset your systems, make use of natural daylight (a morning walk is great for this) and avoid stimulants close to bedtime as this helps you sync your inner clock. Visit the Resources section of the app for more info on good sleep hygiene and stimulus control.

### Week 11

From Synergy Study: Did you know, maintaining behaviour change can be more difficult than initiating it? Build a system that works for you and one that you would describe as sustainable, yet flexible. For some people, this is about attending the same thing at the same time in the same place each week, for others, it is about mixing it up and trying out new things. To build a health habit that becomes "the easy option", rather than a source of pressure or stress, you should keep revising your goals and improvise in the face of new barriers. There is never going to be a perfect time and healthy living is a lifelong investment, so keep going.

### Week 12

From Synergy Study: Did you know, stress and a racing mind can disrupt sleep? If this is you, check the resources section for tips on different relaxation techniques and get yourself a bedtime routine so you can wind down before bed. Practice a relaxation technique that works well for you and define a bedtime ritual that helps you settle down. Slowing down your mind is not easy and requires patience and a good understanding of the sources of stress and how they affect our thoughts, emotions as well as actions. Be open to tips & advice and don't just be ok with being a bad sleeper. Reconsider what is within your control and seek support if you feel like you have exhausted all options to self-manage your sleep.

## **Appendix V: Telephone interview items**

# Introduction

Hi, this is Beatrice calling from the University of Newcastle. I am the project lead of the Synergy Study.

Thanks for agreeing to take part in our short interview, [NAME], how are you going today?

### OR

We have sent you an Email notification to let you know you were randomly selected for a short telephone interview about your experience in the study including what you liked, disliked, and what you expected the program to do. If you have the time to answer some of my questions, that would be really great. Is it a good time for you to talk?

Participant ID: \_\_\_\_\_

# **Interview Questions**

- 1. Where did you see the study advertised?
- 2. What did you expect from your participation in the study?
- 3. To what extent did we met this expectation, if you had to give a rating from 0-10?
- 4. What was your favourite component of the intervention (e.g., handbook, app, reports)? Why?
- 5. What was the most useful part of the intervention in terms of helping you change your activity and sleep habits? And why?
- 6. What components of the intervention were not useful?
- 7. If you could add a single component to the programme, what would it be?
- 8. Would you continue using Synergy in the future?

- 9. How did you find using the pedometer? Was it useful? How could we improve this part of the study?
- 10. Did you find the app easy to use?
- 11. How did you find keeping track of both PA and sleep? Was it difficult/easy to look after both at the same time? Was one easier than the other?
- 12. Were the graphs useful? Was the self-monitoring process useful? Easy data input?
- 13. If you decided to continue looking after any health and lifestyle habits in the future, what would it be? PA, sleep, both or something different?
- 14. Who do you think the Synergy Study is for? (e.g. older adults, younger people, those who have more time, men/women)?
- 15. Do you think we should add anything else to the Synergy Study, such as diet or alcohol consumption? Why/why not?
- 16. Any other comments, questions or feedback for the team?

# **Appendix W: Process evaluation items**

# **Survey Flow**

Participation (7 Questions)
PASR-12 (2 Questions)
Participant Satisfaction (1 Question)
Campus (8 Questions)
System Usability Scale (1 Question)
Internet Self-Efficacy (1 Question)

**Start of Block: Participation** 

spart\_intro In the following questions, we will ask you about your participation in the **Synergy Study**.

Your feedback is much appreciated and will help us evaluate the various aspects of our programme.

Please provide your honest responses.

spart1 What was **the main reason** that you signed up for the Synergy Study? (Please select one response)

- To increase my physical activity (1)
- To improve my sleep (2)
- To increase my physical activity AND improve my sleep (3)
- To lose weight (4)
- To be able to monitor my physical activity level using a pedometer (5)
- To be able to monitor my physical activity level using the app (6)
- To improve my health (7)
- Because I was curious about the program (8)
- Because it was recommended to me by a friend (9)
- Other (specify below) (10)

spart2 Why did you choose to use an **online programme** to improve your physical activity and sleep when compared to an institution-based program (e.g., research centre, health centre, etc.)

- Ease of use (1)
- Convenience (2)
- Anonymity (3)
- Record keeping (4)
- Because it is quicker (5)
- Because it allows graphical representations (6)
- Because it helps to set goals (7)
- Other (specify below) (8)

spart3 Which **aspect of the programme** did you like the best? (Please select one response)

- Using a pedometer (1)
- Using the app (2)
- Receiving reminders/prompts (3)
- That it allows logging activity and sleep, so I can track my progress over time
   (4)
- The resource sections for physical activity and sleep health (5)
- The autonomy of doing as much or as little as I can do/like to do (6)

spart4 Please indicate how useful you found each element of the programme.

	I did not use this part of the programme (1)	Not at all useful (2)	Not very useful (3)	Neutral (4)	Somewhat useful (5)	Very useful (6)
The pedometer (spart4_1)	0	0	0	0	0	0
The app (spart4_2)	0	0	0	0	0	0
The reminders/prompts (spart4_3)	0	0	0	0	0	0
Logging activity and sleep to track progress over time (spart4_4)	0	0	0	0	0	0
The resource section for physical activity (spart4_5)	0	0	0	0	0	0
The resource section for sleep (spart4_6)	0	0	0	0	0	0
The weekly facts (spart4_7)	0	0	0	0	0	0

spart5 When using the **pedometer**, have you **always logged your steps** within the app?

- Always (1)
- Most of the time (2)
- Sometimes (3)
- Never (4)
- At first, I only used the pedometer, but later I also started to log my steps in the app (5)
- At first, I logged my steps in the app, but now I only use my pedometer (6)

spart6 Following a **moderate or vigorous intensity step-based activity** (such as running), did you log both, the steps and the minutes of MVPA?

- Neither, as I did not know what to log (1)
- Steps only (2)
- Active minutes only (3)
- I logged both (4)

**End of Block: Participation** 

Start of Block: PASR-12

Please choose the one answer that applies to the **strategies you used** during the programme.

	Never used strategy				Used strategy very often
	1	2	3	4	5
l mentally kept track of my PA. (spasr1_1)	0	0	0	0	0
I mentally noted specific things that helped me be active. (spasr1_2)	0	0	0	0	0
I set short- term goals for how often I am active. (spasr1_3)	0	0	0	0	0
I set PA goals that focused on my health. (spasr1_4)	0	0	0	0	0
I asked someone for PA advice or demo. (spasr1_5)	0	0	0	0	0
I asked a PA expert or health professional for PA advice or demo. (spasr1_6)	0	0	0	0	Ο
After PA I focused on how good it felt. (spasr1_7)	0	0	0	0	0
l reminded myself of PA health benefits. (spasr1_8)	0	0	0	0	0

I mentally scheduled specific times for PA. (spasr1_9)	0	0	0	0	0
I rearranged my schedule to ensure I had time for PA. (spasr1_10)	0	0	0	0	0
l purposely planned ways to do PA when on trips away from home. (spasr1_11)	0	0	0	0	0

Please choose the one answer that applies to the **strategies you used** during the programme.

	Never used strategy				Used strategy very often
	1	2	3	4	5
I mentally kept track of my sleep. (spasr1_12)	0	0	0	0	0
I mentally noted specific things that helped me sleep. (spasr1_13)	Ο	0	0	0	0
I set short- term goals for how often I would practice good sleep hygiene. (spasr1_14)	0	0	0	0	0
I set sleep goals that focused on my health. (spasr1_15)	0	0	0	0	0
I asked someone for sleep hygiene advice or demo. (spasr1_16)	Ο	0	0	0	0
I asked a sleep expert or health professional for advice or demo. (spasr1_17)	Ο	0	0	0	0
After a restful night of sleep, I focused on how good it felt. (spasr1_18)	Ο	0	0	0	0

I reminded myself of PA health benefits. (spasr1_19)	0	0	0	0	0
I mentally scheduled specific times for sleep. (spasr1_20)	0	0	0	0	0
I rearranged my schedule to ensure I had time to keep my sleep/wake times consistent. (spasr1_21)	0	0	Ο	0	0
I purposely planned ways to get my sleep right when on trips away from home. (spasr1_22)	0	0	0	0	0

End of Block: PASR-12

Start of Block: Participant Satisfaction

The next few questions relate to **what you thought about the usefulness** of the Balanced app. Please be honest about your opinions.

	Strongly disagree (1)	Somewhat disagree (2)	Neither disagree nor agree (3)	Somewhat agree (4)	Strongly agree (5)
Overall, the app was useful in helping me keep track of my behaviours. (ssat1_1)	0	0	0	0	0
Overall, the app was useful in helping me to change my behaviours. (ssat1_2)	0	0	0	0	0
It didn't take much time each day to use the app to track my behaviours. (ssat1_3)	0	0	0	0	0
I would like to keep using the app in the future. (ssat1_4)	0	0	0	0	0
The frequency of feedback in the app was useful in helping me change my behaviour. (ssat1_5)	0	0	0	0	0
The detail of feedback in the app was useful in helping me change my behaviour. (ssat1_6)	0	0	0	Ο	0

Entering my daily data into the app was easy. (ssat1_7)	0	0	0	0	0
The information on my behaviours in the app was accurate. (ssat1_8)	0	0	0	0	0
The traffic light system was useful in helping me change my behaviours. (ssat1_9)	0	0	0	0	0
The graphs were useful in helping me change my behaviours. (ssat1_10)	0	0	0	0	0
The tips were useful in helping me change my behaviour. (ssat1_11)	0	0	0	0	0

End of Block: Participant Satisfaction

**Start of Block: Campus** 

scampus1 Please choose the one response that best reflects **your personal opinion** on how the **Balanced app is designed** (please complete each statement).

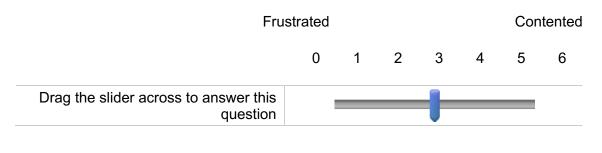
# I had the impression that the Balanced app is...

"clean".       0       0       0       0         "clear".       (scampus1_2)       0       0       0       0         "aesthetic".       (scampus1_3)       0       0       0       0       0         "aesthetic".       (scampus1_3)       0       0       0       0       0       0         "pleasant".       (scampus1_4)       0       0       0       0       0       0         "symmetrical".       (scampus1_5)       0       0       0       0       0       0         "symmetrical".       (scampus1_5)       0       0       0       0       0       0         "sophisticated".       (scampus1_6)       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0		Strongly disagree (1)	Disagree (2)	Somewhat disagree (3)	Neither disagree nor agree (4)	Somewhat agree (5)	Agree (6)	Strongly agree (7)
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"innovative". (scampus1_14) • • • • • • • • •		0	0	0	0	0	0	0

scampus2 Please indicate to what extent you **agree or disagree** with the following statements.

	Strongly disagree (1)	Disagree (2)	Somewhat disagree (3)	Neither disagree nor agree (4)	Somewhat agree (5)	Agree (6)	Strongly agree (7)
Learning how to use the Balanced app was easy. (scampus1_15)	0	0	0	0	0	0	0
Using the Balanced app was easy. (scampus1_16)	0	0	0	0	0	0	0
The Balanced app was user friendly. (scampus1_17)	0	0	0	0	0	0	0
Using the Balanced app was fast. (scampus1_18)	0	0	0	0	0	0	0
The Balanced app was easy to navigate. (scampus1_19)	0	0	0	0	0	0	0
I was able to complete all the Balanced tasks successfully. (scampus1_20)	0	0	0	0	0	0	0
Given the tasks, the sought after information was accurately obtained. (scampus1_21)	0	0	0	0	0	0	0

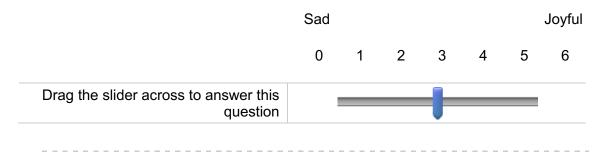
scampus3 Please indicate your **level of satisfaction** associated with your experience of the app. Thinking about **my experience with the efficiency of the Balanced app** for self-regulating my physical activity and sleep behaviours, I feel:



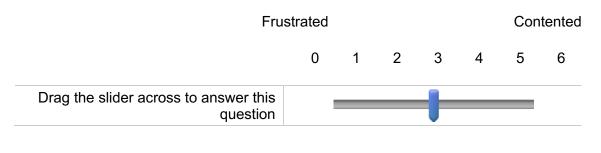
scampus4 Please indicate your **level of satisfaction** associated with your experience of the app. Thinking about **my experience with the efficiency of the Balanced app** for self-regulating my physical activity and sleep behaviours, I feel:

Unhappy							ratified
	0	1	2	3	4	5	6
Drag the slider across to answer this question							

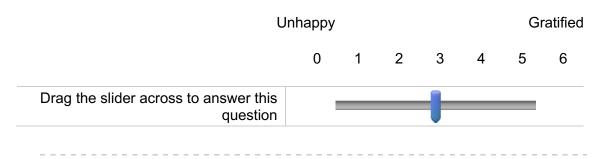
scampus5 Please indicate your **level of satisfaction** associated with your experience of the app. Thinking about **my experience with the efficiency of the Balanced app** for self-regulating my physical activity and sleep behaviours, I feel:



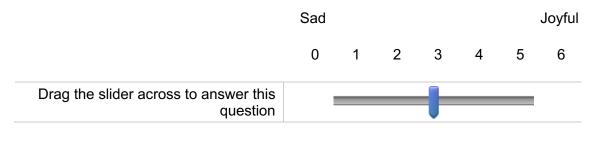
scampus6 Please indicate your **level of satisfaction** associated with your experience of the app. Thinking about **my experience with the effectiveness of the Balanced app** for self-regulating my physical activity and sleep behaviours, I feel:



scampus7 Please indicate your **level of satisfaction** associated with your experience of the app. Thinking about **my experience with the effectiveness of the Balanced app** for self-regulating my physical activity and sleep behaviours, I feel:



scampus8 Please indicate your **level of satisfaction** associated with your experience of the app. Thinking about **my experience with the effectiveness of the Balanced app** for self-regulating my physical activity and sleep behaviours, I feel:



End of Block: Campus

Start of Block: System Usability Scale

ssus1 Please choose the response that best matches **how you feel or think** about using our mobile app **Balanced** 

	Strongly disagree (1)	Somewhat disagree (2)	Neither disagree nor agree (3)	Somewhat agree (4)	Strongly agree (5)
I think that I would like to continue using Balanced frequently in the future. (ssus1_1)	0	0	0	0	0
I found the system unnecessarily complex. (ssus1_2)	0	0	0	0	0
I thought the system was easy to use. (ssus1_3)	0	0	0	0	0
I needed the support of a technical person to be able to use this system. (ssus1_4)	0	0	0	0	0
I found the various functions in this system were well integrated. (ssus1_5)	0	Ο	0	0	0
I thought there was too much inconsistency in this system. (ssus1_6)	0	0	0	0	0
I would imagine that most people would learn to use this system very quickly. (ssus1_7)	0	0	0	0	0

I found the system very cumbersome to use. (ssus1_8)	0	0	0	0	0
I felt very confident using the system. (ssus1_9)	0	0	0	0	0
I needed to learn a lot of things before I could get going with this system. (ssus1_10)	0	0	0	0	0

End of Block: System Usability Scale

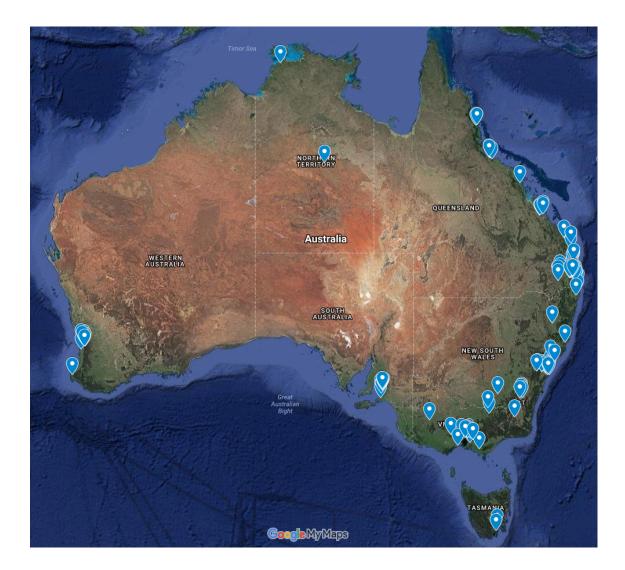
Start of Block: Internet Self-Efficacy

sises1 Please choose the one statement the best applies to you (please complete each statement). I feel confident...

	Strongly disagree (1)	Disagree (2)	Somewhat disagree (3)	Neither disagree nor agree (4)	Somewhat agree (5)	Agree (6)	Strongly agree (7)
understanding terms/words relating to smartphone/tablet hardware. (sises1_1)	0	0	0	0	0	0	0
understanding terms/words relating to smartphone/tablet software. (sises1_2)	0	0	0	0	0	0	0
describing functions of smartphone/tablet hardware. (sises1_3)	0	0	0	0	0	0	0
trouble shooting smartphone/tablet problems. (sises1_4)	0	0	0	0	0	0	0
explaining why a task will not run on the smartphone/tablet (sises1_5)	0	0	0	0	0	0	0
using the smartphone/tablet to gather data. (sises1_6)	0	0	0	0	0	0	0
learning advanced skills within a specific smartphone/tablet app. (sises1_7)	0	0	0	0	0	0	0
turning to an online discussion group when help is needed. (sises1_8)	0	0	0	0	0	0	0

End of Block: Internet Self-Efficacy

# Appendix X: Map of participants across Australia



# Appendix Y: Participant summary report Synergy Study



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#### Participant Summary Report for the Research Project:

"Efficacy of a theory-based mobile intervention to improve physical activity and sleep behaviour in adults: A randomised waitlist-controlled trial"

University of Newcastle Human Research Ethics Committee, Approval No. H-2016-0181

#### WHAT WE NEEDED TO KNOW

- No previous studies have combined physical activity and sleep health to target these behaviours together and because there is evidence that the combined effects on health may be greater than the effects gained when targeting these behaviours individually, we developed the Synergy Study.
- The aim of this study was to test if a mobile device-based ('app') intervention is effective at improving the physical activity and sleep behaviours of Australian adults.

#### WHAT WE DID

- Eligible participants were randomly allocated to either the intervention group or a control group. Participants completed 3 online surveys before the start of the intervention, and then 3 and 6 months later. The intervention group received access to the intervention after they completed the first survey, and the control group were given access after the 6-month survey. People in the control group were asked to maintain their current behaviours for us to evaluate how effective the intervention was.
- The intervention consisted of a mobile app that allowed participants to track their daily physical activity and behaviours. Participants also received a pedometer to count their steps and received weekly summary reports comparing their progress to their goals. Participants were also given simple information to help increase their activity, participation in resistance training, manage stress and improve their sleep. In addition, 10% of participants were randomly selected to be interviewed to help us understand what participants thought of the intervention.

#### WHO SIGNED UP

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160 participants (80% females, 20% males) from across the country enrolled in the study. A total of 125 participants completed the 3-month survey and 89 completed the 6-month survey.

- The average age was 41.5 years. Participants reported an average Body Mass Index (BMI) of 27.90, which is consistent with the national average. The majority of participants were married or in a relationship, highly educated, employed in a professional occupation and reported having one or more chronic diseases.
- At baseline, 95% of participants did not meet guidelines for at least 150 minutes of 'huff and puff' (moderate to vigorous intensity) exercise as well as muscle strengthening exercises on at least 2 days per week, which is what our national guidelines recommend for optimal health. In addition, 95.6% of participants were classed as having poor quality sleep.

#### WHAT WE FOUND

- During the 3-month study period, participants entered data into the app on an average of 38 days (out of 84 days), which is longer than what is commonly seen in mobile health interventions, but 90% of all participants stopped using the at some point during this time. On average, participants were satisfied with the ease of use of the app.
- Our analyses compared if the two groups (intervention vs. waitlist-control) differed in regards to their physical activity and sleep quality and a range of secondary outcomes at 3 and at 6 months.

#### At 3 months:

- Participants had doubled their weekly minutes of physical activity ('huff and puff' exercise), but there was no difference between groups, which means we could not show that this change was due to the intervention.
- Significantly more participants in the intervention group engaged in at least 2 days/week of muscle strengthening exercises, which is a very important finding given the many benefits these exercises have for health and wellbeing.
- The intervention group reported better overall and subjective sleep quality, taking less time to fall asleep, woke up at the same time of day more consistently (which can help improve sleep), better sleep hygiene practices (all the good things you do to ensure a good night's sleep), insomnia severity (the amount of symptoms of clinical severity), less daytime sleepiness and less stress than waitlist-controls.
- In addition, three times as many participants in the intervention group met guidelines for 'huff and puff' exercise and resistance training, compared to control group participants, who met these guidelines at 3 months.
- The same was found for sleep quality, with 30% more people in the intervention group reporting good quality sleep, compared to those in our control group.

#### WHAT IT MEANS

- The findings suggest that is it possible to improve physical activity and sleep in combination using our intervention. This is a promising result considering the benefits these behaviours have for health and wellbeing.
- Our findings are important for the additional reason that a large number of adults report low activity levels and poor sleep, and given that our intervention which was delivered using a mobile app, it has the potential to reach a large proportion of our population, including those in very remote areas of the country, who may have limited access to health care.

#### THANK YOU.

- On behalf of the research team, we'd like to thank you for your participation and commitment for this project. This project has contributed some valuable knowledge to the evidence base and further enabled Beatrice to fulfil some of her proposed research aims as a requirement for her PhD Thesis.
- Please do not hesitate to contact us at <u>synergystudy@newcastle.edu.au</u> if you have any questions relating to this research or you wish to receive any additional information.

#### At 6 months:

- The improvements we saw in the intervention group at 3 months were maintained for sleep hygiene practices, insomnia severity, daytime sleepiness and stress symptoms.
- Additional differences that we did not find at 3 months, but found at 6 months were bedtime variability (meaning day-to-day bedtimes have become more consistent), reduced daytime dysfunction (the amount of limitations experienced due to excessive sleepiness) as lower anxiety levels, all of which were lower in the intervention group.

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