Lifestyle Risk Factors and Lifestyle Risk Management in People with Psychosis

Doreen Mucheru

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Statement of originality

I hereby certify that the work embodied in the thesis is my own work, conducted under normal supervision. The thesis contains no material which has been accepted, or is being examined, for the award of any other degree or diploma in any university or other tertiary institution and, to the best of my knowledge and belief, contains no material previously published or written by another person, except where due reference has been made. I give consent to the final version of my thesis being made available worldwide when deposited in the University's Digital Repository, subject to the provisions of the Copyright Act 1968 and any approved embargo.

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Thesis by publication

I hereby certify that this thesis is in the form of a series of papers. I have included as part of the thesis a written declaration from each co-author, endorsed in writing by the Faculty Assistant Dean (Research Training) attesting to my contribution to any jointly authored papers.

Doreen Mucheru

Supervisors

Primary Supervisor

Associate Professor Lesley MacDonald-Wicks

Priority Research Centre for Physical Activity and Nutrition

School of Health Sciences

Faculty of Health and Medicine

University of Newcastle, Australia

Co-Supervisors

Dr Mary-Claire Hanlon

Priority Research Centre for Brain and Mental Health & Hunter Cancer Research Alliance

School of Medicine and Public Health

Faculty of Health and Medicine

University of Newcastle, Australia

Associate Professor Mark McEvoy

Centre for Clinical Epidemiology and Biostatistics

School of Medicine and Public Health

Faculty of Health and Medicine

University of Newcastle, Australia

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Personal and Research Skills Developed During the PhD Candidature

The journey of my PhD candidature has been fulfilling, equipping me with skills that have increased my employability and led to my own personal growth.

My skills as a researcher have developed immensely through:

- Using varied research approaches including systematic review of literature, conducting research interviews, and qualitative and quantitative analysis of data.
- Learning to use variable research software during my candidature such as SPSS, STATA and Nvivo.
- Collating and presenting research findings in different forums that comprised national and international conference presentations, and internationally peer-reviewed journals.

My ability to problem solve has been consistently challenged during the course of my candidature, which has allowed me to think creatively. I demonstrated this by:

- Adopting new research methodology like the network meta-analysis, when seeking solutions for the various research questions.
- Finding and adopting solutions to concerns raised by research ethics committees and research reviewers.
- Forming professional relationships with people at the site where I conducted my research, to educate myself about the best ways to conduct various research processes during data collection.

My written communication has also seen extensive improvement, especially with regard to the use of objective language and synthesis of research findings. This was evidenced by:

- Authoring 6 peer-reviewed publications in the course of my PhD. Five of these have been accepted for publication.
- Participating in the ethics application process and obtaining approval for research.

My oral communication has also been developed though engaging in:

- Two oral presentations and two poster presentations at national and international discipline-related research conferences.
- Presentation of my research to university peers and mentors, to members of a local community managed organisation, and to staff at a local hospital.

My PhD journey has also provided opportunities to work with others who include my supervisors, study participants and co-authors. The effectiveness of this team-work and collaboration was proven by:

- Learning and successfully implementing two new research techniques by working remotely with mentors from Thailand and South Australia, leading to the co-production of peer-reviewed publications.
- Successful completion of data collection at the knowledge translation case study site. This required me to work together with participants and staff, with whom I maintained good relationships by ensuring I was reliable and looked out for the best interests of all who were involved.
- Producing peer-reviewed research publications that met the expectations of all the team members, based on feedback that was provided.

Receiving feedback on my work has also opened me up to new ways of thinking and has made me realise the value of seeking the views of those more experienced than myself, especially when working on projects. Incorporating feedback from others has definitely improved the overall quality of my thesis.

My initiative and leadership have expanded during my PhD. Successful completion has required me to take charge of all aspects of the research. This was demonstrated by:

- Approaching collaborators with specific expertise, for the purpose of working together on certain manuscripts.
- Advocating the importance of my research at the site where I collected my data.
- Following up co-authors and research participants with regard to completion of projects and participation in projects.
- Proposing timelines and direction for research projects, and maintaining accountability for this by reporting to my supervisors and other collaborators.

I have also had to maintain adequate planning and organisation during the course of my research. These skills were displayed by:

- Concurrently conducting multiple research projects, to ensure that the research work load was completed in a timely manner (3.5 years).
- Outlining short-term and long-term goals during the course of my research, and conveying this to the University's auditing systems so that accountability was maintained.

- Budgeting for research expenses, covered by Research Training Program government funding allocations, provided to each research higher degree candidate at the discretion of their Faculty and School.

Finally, I have had to adopt a teachable attitude, as many of the opportunities afforded to me during my PhD were new and required me to step away from fear of failure and learn new skills in the process.

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List of Tables and Figures

Common Acronyms and Abbreviations in the Thesis

ADGs	Australian Dietary Guidelines
BMI	Body Mass Index
CVD	Cardiovascular Disease
cm	Centimetres
CMO	Community Managed Organisation
CI	Confidence Interval
CONSORT	Consolidated Standards of Reporting Trials
CHD	Coronary Heart Disease
ES	Effect Size
GP	General Practitioner(s)
g	Gram
HR	Hazard Ratio
HDL	High-Density Lipoprotein
h	Hour
HIV/AIDS	Human Immunodeficiency Virus Infection and Acquired Immune Deficiency Syndrome
IDF	International Diabetes Federation
i-PARIHS	Integrated Promoting Action on Research Implementation in Health Systems
ICD	International Classification of Diseases
kg	Kilogram
kg/m^2	Kilogram per square metre
kJ	Kilojoules
Km^2	Square Kilometre
LPPDS	Low Prevalence (Psychotic) Disorders Study
LDL	Low-density Lipoprotein
MET	Metabolic Equivalent
MetS	Metabolic Syndrome
uIU/mL	Micro-international Unit per Millilitre
mg/dL	Milligrams per Decilitre
mmHg	Millimetres of Mercury
mmol/L	Millimoles per Litre
min	Minute
MI	Myocardial Infarction
NDIA	National Disability Insurance Agency
NDIS	National Disability Insurance Scheme
NHMRC	National Health and Medical Research Council
NSW	New South Wales
OR	Odds Ratio
PAD	Peripheral Arterial Disease
RCTs	Randomised Controlled Trials
RR	Relative Risk
n	Sample
SD	Standard Deviation
SMR	Standardised Mortality Ratio
SHIP	Survey of High Impact Psychosis
WMD	Weighted Mean difference

YLDs	Years of Life Lived with Disability

Common Symbols used in the Thesis

<	Less than
>	Greater than
≤	Less than or equal to
≥	Greater than or equal to
=	Equal to
%	Percent

Abstract and Scope of the Thesis

The research presented in this thesis primarily focused on people with psychosis, however, reference has been made to people with other mental illnesses with similar socioeconomic, cognitive, clinical and functioning profiles (1). Lifestyle risk and lifestyle risk management in people with psychosis were investigated, with a primary emphasis on nutrition and physical activity behaviour, however smoking was also explored in one study. These three risk factors are collectively known as lifestyle risk factors and are the primary downstream factors that contribute to modifiable cardiovascular disease (CVD) risk.

The first component of the research focused on the relationship between these lifestyle risk factors with modifiable CVD risk factors (dyslipidaemia, hypertension and hyperglycaemia) and potential confounders, to reveal the contributing factors of excess CVD risk in people with psychosis. The patterns of lifestyle risk factor co-occurrence or clustering were also assessed to enable the tailored design of interventions for this population.

Interventions with a focus on lifestyle risk management for people with psychosis were examined as part of the research; this included programs available in the community setting and existing research trials. Review of literature highlighted a knowledge gap on the utilisation and effects of attending Australian community nutrition and physical activity programs for people with psychosis. Moreover, strategies that contributed to the efficacy of lifestyle intervention research trials had not been clearly identified and these trials did not show evidence for translation into the Australian community setting following research completion; therefore, the issues that affected intervention translation into Australian practice settings were unknown.

International data from people experiencing psychosis and other mental illness was cited in the consideration of these topics. Epidemiological data from the Australian context was primarily from the Second Australian National Survey of Psychosis, known as Survey of High Impact Psychosis (SHIP), which was conducted in 2010, with 1,825 participants (2). Data from SHIP were analysed for two of the four studies included in this thesis.

The first study from SHIP aimed to:

- Describe the relationship between lifestyle risk factors for CVD (nutrition, physical activity, and smoking) and dyslipidaemia, hypertension and hyperglycaemia, while controlling for potential confounders.
- Identify clustering patterns of lifestyle risk factors in study participants and describe demographic characteristics associated with different clusters of lifestyle risk factors.

Results of the analyses between lifestyle risk factors with dyslipidaemia, hypertension and hyperglycaemia, were generally not reflective of patterns found in the general population, even after adjusting for clozapine use, sex and age. Although trained investigators applied valid and reliable research tools, SHIP was not a longitudinal study, which is a more appropriate design to elucidate the relationships that were investigated. Moreover, tools used to assess nutrition, physical activity and smoking relied on self-report and did not obtain broad research data, which could have impacted findings. Prospective longitudinal studies could add to current work by improving upon the issues that affected the research, along with pinpointing additional confounding variables that contribute to excess CVD.

This study also found that clustered occurrence of the three lifestyle risk factors was associated with certain demographic variables. Persons with the greatest co-occurrence of all three lifestyle risk factors were younger; males; those lacking tertiary qualifications; and people relying on pensions for income ($p<0.05$). Additionally, samples with a mixed demographic profile across age, gender, education attainment, and financial situation primarily showed risk of poor nutrition (inadequate fruit and vegetable intake) and inadequate physical activity ($p<0.05$). Finally, those most likely to present with nutrition that was consistent with guidelines (fruit and vegetable), the highest physical activity and non-smoking behaviour ($p<0.05$), were women; people with tertiary qualifications; persons less likely to rely on government pensions; and those who were older ($p<0.05$). Consideration of how lifestyle risk factors cluster in the design of lifestyle interventions for people with psychosis will enhance program quality, because the risk factors targeted and advice provided will be adapted to meet participant needs.

The second study from SHIP aimed to:

- Describe the self-reported attendance of community nutrition and physical activity programs in the government and non-government sector, and identify demographics associated with overall self-reported program attendance.
- Assess whether improved nutrition and physical activity outcomes were associated with program attendance.

Program participation was only 5.3% in the government sector and 8.7% in the non-government sector. The overall attendance of programs had a significant relationship with participant diagnosis, and was positively associated with education qualifications ($p<0.05$). The low utilisation of programs could be increased by following the relevant Royal Australian and New Zealand College of Psychiatrists (RANZCP) guidelines for physical health management, and advocacy efforts by front-line health professionals like general practitioners and case managers. Additionally, personal challenges that

inhibit service access (like low education attainment or capacity) should be addressed to mitigate some of the vulnerability that is experienced by this group. Inadequate evidence on distinct nutrition and physical activity benefits associated with program utilisation, creates a case for further evaluation of these services, to ensure that optimal outcomes are achieved.

The research component focusing on lifestyle intervention research trials, comprised of 2 main papers.

The first paper was a systematic review and network meta-analysis which aimed to:

- Pool and rank the efficacy of lifestyle intervention strategies that target weight, body mass index (BMI), waist-circumference and waist-to-hip ratio in people with psychosis, by comparing the effect size on these weight outcomes.
- Stratify lifestyle interventions according to their inclusion of dietary information that adheres to Australian Dietary Guidelines (ADGs).

The application of education, tailored advice or goal setting, and progress review, in both dietary and physical activity components of lifestyle interventions, produced the greatest decreases in weight (ES = -4.12, 95% CI=-7.772 to -2.760, p<0.000) and BMI (ES = -2.94, 95% CI=-1.78 to -0.357, p=0.003). Other essential intervention components that contributed to positive results were food and physical activity records, and supervised exercise. Inadequate reporting of waist circumference and waist-to-hip ratio outcomes limited generation of conclusions for these outcomes. Quality of the systematic review findings based on GRADE (Grading of Recommendations Assessment, Development and Evaluation) criteria ranged from low to very low. This was due to limitations in primary research studies that increased the risk of biased findings. The appraisal of dietary advice in lifestyle interventions using the ADGs generally showed compliance of studies, however, appraisals were (in some cases) hindered by vague and insufficient reporting in original research trials. Appropriate dietary approaches or advice for people with psychosis was therefore not identified in the study.

In light of poor reporting in lifestyle intervention trials, the second paper from the systematic review aimed to:

- Critically appraise lifestyle intervention studies that target weight outcomes for people with psychosis, against the methods component of the Consolidated Standards of Reporting Trials (CONSORT) statement for randomised trials of nonpharmacologic treatments.

Low utility of reporting guidelines in lifestyle interventions for people with psychosis was highlighted. This was evidenced by less than 50% of studies fulfilling reporting criteria for trial design, participants, interventions, outcomes, sample size, randomisation, blinding and statistical methods. Findings underline the vital importance of employing the CONSORT statement or similar guidelines to ensure

that research reporting meets the quality standards that safeguard consistency and comprehensiveness. This will increase the usability of information from existing clinical trials, which will enhance the likelihood of people with psychosis benefiting from the research.

The final component of the research was a qualitative study, conducted using semi-structured interviews in the context of a local Australian Community Managed Organisation (CMO) that delivers programs to people with mental illness. The study aimed to:

- Identify the factors that affect program access from the perspectives of both consumers and staff.
- Describe the elements that impact on program delivery from the perspective of staff.

This study was designed to pinpoint issues that are likely to affect translation of lifestyle interventions into CMOs. Study aims and interview questions were based on implementation concepts highlighted in the "Integrated Promoting Action on Research Implementation in Health Systems" (i-PARIHS) knowledge translation framework. Themes on factors that affected program access (based on consumer and staff perspective) were (1) consumer financial status, domestic responsibilities, and health; (2) the design and delivery of programs; (3) structure and practices of the organisation; (4) attitude, skills and effort of staff involved in program delivery; and (5) social connections and stigma experienced by consumers during program access. Program delivery was influenced by consumer attendance and interest in prospective programs, availability and restrictions to the use of funding, as well as the organisational structure and practices. Further examination of the concerns which shaped program access and delivery revealed that most barriers could be managed through efforts from the CMO; therefore, alleviating the effect of these factors during prospective translation of lifestyle interventions into this setting may promote efficiency and decrease resistance to the process.

The body of work presented in this thesis provides insight on the occurrence of lifestyle risk factors, specifically nutrition and physical activity behaviour, and the different interventions that are available for people with psychosis. The application of validated tools and processes for the synthesis of evidence enhances the quality and usability of findings by other parties. In addition, consideration of issues pertinent to prospective knowledge translation aims to inspire implementation of best-practice evidence, and maximise impact of research efforts in this field.

Chapter 1: Background

1.1: Psychosis

The International Classification of Diseases (ICD) defines psychosis as a state characterised by the experience of hallucinations, delusions, psychomotor retardation, and catatonic behaviour (3). A psychotic disorder is distinguished by the experience of these symptoms in addition to distress, causing interference with personal functioning (3).

Psychosis is experienced in a wide range of clinical mental health diagnoses but can also present in the absence of a mental health diagnosis (3). The manifestation of psychosis is predominant in schizophrenia spectrum disorders, and in some cases, occurs in mood or affective disorders (3).

Psychotic disorders are classified as a form of severe mental illness (4). Severe mental illness and serious mental illness are terms used to describe mental disorders that require frequent medical management (4). Despite inconsistency in the definition of these terms in Australia, it is apparent that determinants of serious or severe mental illness status may include the specific mental health diagnosis, duration and intensity of symptoms, and extent of disability caused (4).

Schizophrenia and schizoaffective disorder account for many presentations of psychotic illness, and are characterised by negative and positive symptoms (2). Negative symptoms are depicted by blunted affect (apparent unresponsiveness), alogia (poverty of speech), anhedonia (inability to show or feel pleasure), asociality (a seeming lack of desire for the company of others) and avolition (absence of spontaneity and initiative) (5). Positive symptoms are distinct traits that are a deviation from the usual behaviour or experience (6). They comprise hallucinations (sensory experiences that are not perceived by others); delusions (beliefs not based on reality); confused or disordered thinking; muddled speech or content that is difficult to understand; and behavioural disturbances like agitation and distress (6).

Positive symptoms are effectively treated using antipsychotic medications, while negative symptoms remain treatment-resistant (5, 6). Persistence in negative symptoms is usually the reason many with psychosis experience difficulties studying, working, establishing personal relationships, managing social situations and living independently (5, 6).

1.2: Psychosis in Australia

The most recent Australian data showed that the 1-month treated prevalence of psychosis was 3.1 people per 1,000 in 2010, giving an overall prevalence estimate of 5.3 people per 1,000 (2). Schizophrenia or schizoaffective disorder were the most prevalent forms of psychosis, as 63% of Australians with psychosis presented with these disorders (2). Prevalence estimates were based on

data of those in contact with public and private treatment services, translating to about 75,000 people experiencing the condition in any 1-month period, and thus requiring treatment and support (2). The estimated global median prevalence of psychosis was 4.6 per 1,000 people between 1990 and 2015 (7). Psychotic disorders affect a small proportion of the population and are thus classified as low prevalence disorders (7). The characteristics of those experiencing psychosis in Australia have been captured by two major cross-sectional studies, the Low Prevalence (Psychotic) Disorders Study (LPPDS) conducted in 1997-98 and the Survey of High Impact Psychosis (SHIP) which was completed in 2010 (2, 8). Briefly, these studies aimed to: estimate the 1-month treated prevalence of psychosis in adults in contact with public mental health services, describe the life profile of these people, determine service utilisation and assess the impact of psychotic illness (2, 8). SHIP built on information from the LPPDS by estimating the treated point prevalence of psychosis in adults not only in contact with public specialised mental health services but also in contact with non-government organisations (now known as community managed organisations [CMOs]) receiving funds to support those with mental illness (2, 8). SHIP also identified factors which could be associated with better outcomes in those with psychotic disorders (2, 8). The LPPDS and SHIP comprise the most comprehensive epidemiological research on Australians with psychosis (2, 8). Reference is made to these two studies as appropriate in the subsequent sections, however, our primary focus is on SHIP (2, 8).

Survey of High Impact Psychosis covered seven main geographical regions in the sites where the survey was conducted (2). These included West Moreton in Queensland; Hunter New England and Orange services in New South Wales; North West Area Mental Health Service and St Vincent's Mental Health Service in Victoria; Northern Mental Health in South Australia; and Fremantle, Peel and Rockingham—Kwinana in Western Australia (Please see figure 1 on the next page for SHIP catchment sites) (2). These sites covered about 61.5km^2 with an estimated resident population of about 1,464,923 people aged 18–64 years, equivalent to 10% of Australians in the same age range (2). Although SHIP included people with psychosis who accessed treatment through the public or private health systems, those not accessing treatment and those exclusively treated in the private sector were not covered (9). This may have led to an underestimation of the true prevalence of psychotic illness in Australia (9). Nonetheless, SHIP captured those who experienced the most severe and persistent forms of psychosis; the final sample comprised of 1,825 adults, 60% of whom were men and the average participant age was 38 years (2, 9, 10). General population data for the same time period highlighted a median age of 37 years, and a sex ratio of 99.2 men per 100 women (11).

Figure 1: Australian Catchment Sites for the Survey of High Impact Psychosis (12)

1.3: Psychosis Onset

The risk of presenting with psychosis is considerably increased in those with a family history (6). People at risk of psychosis are also likely to have other comorbid mental health conditions, especially anxiety and depression, which occur in 15% and 41% (respectively) of people at high-risk for psychosis (6, 13). The onset of psychosis commences with the presentation of negative symptoms, as described earlier (6). Personal functions that also decline during onset of psychosis include memory and attention, social behaviour, personal hygiene, and interest in day-to-day activities (6). The period distinguished by the initial appearance of negative symptoms and deterioration in personal functioning is known as the prodrome (6). The prodrome is usually identified retrospectively and cannot be recognised distinctly until there is an established psychotic illness (6). If an intervention is not applied during the prodromal period, psychosis will inevitably follow (6). The development of psychosis is evident when positive symptoms appear which generally induce the urgency to seek treatment (5, 6).

1.4: Impact and Burden of Psychosis

Psychosis can result in long-term impairments in the personal, social and occupational lives of those affected (6). Magnitude of impairment intensifies with continued psychotic symptoms, increased negative symptoms, treatment side effects, duration of untreated psychosis, social adversity,

isolation, poverty and homelessness (6). Schizophrenia—the most common psychotic disorder—is among the top fifteen medical conditions that cause impairment and disability in different countries around the world (6, 14). In 2016, schizophrenia resulted in 13.4 (95% confidence Interval [CI] 9.9–16.7) million years of life lived with disability (YLDs) globally, equivalent to 1.7% of total YLDs in that year (15).

Hence, despite being classified as low prevalence disorders, the resultant annual economic costs of psychoses are disproportional to illness prevalence rates; the economic cost of schizophrenia alone averages between 0.02% and 5.46% of gross domestic product expenditure in different countries around the world (16). This cost is estimated from mortality, morbidity, hospital admissions, medical consultations, disease related-costs and other health indicators (16). The financial cost of schizophrenia thus translates to an annual expenditure between US$94 million and US$102 billion in these countries (16). In Australia, the cost of psychotic illness has been calculated as $4.91 billion per year, based on direct health sector costs and morbidity-related productivity losses (17). The health sector costs for people with psychosis is more than 3.9 times that of the average Australian (17).

Decline in quality of life, pain and suffering are the intangible costs of psychosis (16). These are difficult to quantify, and are thus omitted from economic evaluations (16). Intangible costs, nevertheless, have far-reaching consequences in the lives of persons living with psychotic illness (16).

People with psychosis are at increased risk for all-cause mortality compared to the general population (18). A meta-analysis on mortality in mental disorders, comprising all studies conducted until 2014, found the relative risk (RR) of death in those with psychosis was 2.5 (95% CI 2.35–2.75) times that of the general population (19). In Australia, estimates from SHIP in 2010 showed an all-cause mortality which was 5-fold (standardised mortality ratio [SMR]; 5.47 95% CI 4.29–6.98) that of the general population (20). Research on the causes of premature death in people with psychosis shows that suicide and accidents account for about 25–40% of the deaths, while 60–75% are a result of illness or ageing (21, 22).

The experience of psychosis can be debilitating, affecting multiple facets of one's life including life expectancy; physical and mental health; social participation and functioning; economic productivity and potential; and family relationships (2).

1.5: Treatment Pathway for People with Psychosis

Although the Australian mental health system lacks an overarching design due to service fragmentation, general practitioners (GP) are usually the first point of contact for many seeking help for mental illness in the Australian context (23). Where this is not the case, public and private hospital

emergency departments provide an alternative point of care when treatment needs are urgent or when after-hours care is required (24). Upon hospital discharge, a discharge summary is forwarded to the GP who provides further care and arranges any additional services (25). GPs make referrals to specialist services including psychiatry and psychology (26). Psychiatrist referrals are made if the patient's mental illness cannot be managed effectively through general practice (27). The referral might involve transfer of mental health care, shared care or inquiry for a treatment opinion (27). The role of a GP is especially crucial for people who are managing mental illness in the community without a case manager (26). In these situations, the person is either self-managed, or case management is provided by GPs, family members and carers who are responsible for ensuring necessary support services are in place (26).

A case manager is employed by a community mental health service to support clients of the public mental health system who have recurring or chronic mental illness (28). This is one of the major types of community aftercare provided for mental illness and typically involves a single case manager and 'consumer' (29). The case manager is responsible for assessing, monitoring, planning and advocating on behalf of the 'consumer', and linking them to appropriate rehabilitation and support services (29). Most participants from SHIP (69.2%) had a case manager, indicating that many had recurring forms of psychosis and required supports of various kinds (2, 28).

In summary, the core health support team for persons with mental illness in the Australian community setting comprise the GP, case manager and psychiatrist (26). Australians with mental illness can also access various services that provide mental health care and different professionals who provide this care in a range of settings (24). All services accessed by people with mental illness can loosely be categorised into specialised mental health services and other support services which sometimes provide mental health-related services (24). Those seeking care may find this fragmented structure difficult to navigate, which may negatively impact health outcomes (30). Table 1 (on the next page) provides a summary of the different facets of mental health care accessible for people with mental illness in Australia (24).

Table 1: A Summary of Mental Health Care Accessed by People with Mental Illness in Australia [23]

<table>
<tr><th colspan="3">General Practitioners (GPs)</th></tr>
<tr><td colspan="3">GPs are often the first point of contact for persons seeking care for mental illness, making referrals to other health professionals including psychologists, psychiatrists, social workers, occupational therapists, mental health workers and Aboriginal and Torres Strait Islander health workers (23).</td></tr>
<tr><th colspan="3">Specialised Mental Health Care Services</th></tr>
<tr><td>Psychiatric hospitals/ psychiatric wards in the public and private sector provide treatment for acute, urgent or after hours care and make referrals to health professionals in the community upon discharge for continuity of care (23, 24).</td><td>Community mental health care referrals can be made via self-referral, GPs, general hospitals and psychiatrists. Services include case management, hospital outpatient clinics, non-hospital community mental health services, consultation/liaison services, outreach services and day programs (23, 31).</td><td>Government and non-government residential mental health care services provide care in a domestic-like environment and may include rehabilitation, treatment or extended care e.g. group homes and supported accommodation (23).</td></tr>
<tr><th colspan="3">Other Support services</th></tr>
<tr><td>Disability support services e.g. National Disability Insurance Scheme (NDIS) which provides participants experiencing disabilities with funding to purchase necessary and reasonable supports. See</td><td>Homelessness support services which include accommodation services, advice or information, advocacy on behalf of clients or material aid (24).</td><td>Mental health programs e.g. Better Access to Psychiatrists, Psychologists and GPs through the Medicare Benefits Schedule (Better Access) initiative– provides Medicare rebates</td></tr>
</table>

section 1.5.1 (that follows) for further information (32-34).		for certain mental health services (35).

1.5.1: The National Disability Insurance Scheme

The National Disability Insurance Scheme is an Australian Federal Government funding initiative for disability support services, including psychiatric services (32). Australians under 65 years with permanent disabilities are eligible; NDIS values the choice and control of consumers, and acknowledges their right to self-determination and thus refers to those accessing the scheme as 'participants' (32). The NDIS is administered through the National Disability Insurance Agency (NDIA) which provides individualised plans based on a person's goals, and allocates corresponding budgeted funds for the purchase of necessary supports (32). The NDIS presents a shift in the allocation of government funding; block funding allotted to service providers has diminished, so that participants directly receive funds to purchase necessary services directly from providers (36). Funding for mental health programs is now included in the NDIS funding pool (32). Roll out of the NDIS commenced in 2013 with full implementation anticipated by 2020 (32). Concerns raised regarding applicability of the NDIS to participants experiencing mental illness were (32):

- Underestimation of the persons eligible.
- The requirement for a 'permanent' disability to access the NDIS, as many experiencing mental illness do not view their condition as permanent.
- The flexibility of NDIS in accommodating the changing needs of people with episodic mental illness.
- Availability or lack of adequate early intervention support services.
- Potential changes in mental health service delivery due to changes in how funding is allocated.
- Solutions for those deemed not eligible or who choose not to access the NDIS.
- Definite demarcations between services accessible via the NDIS and those available through the rest of the health system.

Given that the NDIS is still quite new, solutions for these issues are still being identified (32). Evidence from the United Kingdom shows that the NDIS model of self-directed support has the potential to facilitate recovery in people with mental illness (32). Effectiveness can be achieved through tailoring NDIS delivery to the different groups of participants, such as young people or those with episodic mental illness (32). Moreover, access to the NDIS can be enhanced through engaging clinicians, as they are a major service access pathway for people with mental illness (32). Finally, feedback from clinicians, participants, and carers in the NDIS trial sites is pivotal for the success of the scheme (32).

1.6: Physical Health in People with Psychosis

People living with psychosis experience extremely poor physical health (1, 37-40). Physical health conditions that raise concern in this group are cardiovascular disease (CVD), cancer, metabolic syndrome, diabetes, chronic obstructive pulmonary disease, obesity, asthma, arthritis, kidney disease, liver disease, tuberculosis, vision problems, hearing difficulties, 'Human Immunodeficiency Virus Infection and Acquired Immune Deficiency Syndrome' (HIV/AIDS), chronic pain, migraines, and epilepsy (2, 40, 41). Incidence of most of these physical health conditions is higher in people experiencing psychosis than in the general population (2, 40, 41). Underlying reasons for this require further investigation, but researchers hypothesise that poor lifestyle choices, disparities in health care, genetics, and various inflammatory and immunological mechanisms contribute to the link between psychosis and physical illness (1, 40).

Physical health problems contribute quite considerably to decreased life expectancy seen in people with psychosis; on average, life expectancy is 10 to 25 years shorter than that of the general population (18, 20, 21, 42). The widened mortality gap is largely a result of physical illness, with CVD contributing most significantly to (physical illness) mortality in those with psychosis (43). Cardio metabolic problems escalate significantly with the commencement of antipsychotic treatment, which induces weight gain, hyperglycaemia and dyslipidaemia (44-46).

1.7: Cardiovascular Disease in People with Psychosis

Cardiovascular disease is an umbrella term for disorders that affect the heart and blood vessels; these disorders include coronary heart disease (CHD), cerebrovascular disease, peripheral arterial disease (PAD), rheumatic heart disease, congenital heart disease, deep vein thrombosis and pulmonary embolism (47). The various forms of CVD can lead to strokes and heart attacks/myocardial infarction (MI)—acute outcomes of obstructed blood vessels (47). CVD is the global leading cause of death and claimed 17.9 million lives in 2016, which represented 31% of deaths that year (47).

A large-scale global meta-analysis on CVD prevalence, incidence and mortality in 3,211,768 people with psychosis and other severe mental illness found that they had a 53% (odds ratio [OR] 1.53; 95% CI 1.27–1.83) higher risk of having the condition compared to a regionally matched sample from the general population: they also had a 78% (hazard ratio [HR] 1.78; 95% CI 1.60–1.98) increased risk of developing CVD and an 85% (HR 1.85; 95% CI 1.53–2.24) elevated risk of dying from the condition (43). Specific reasons for elevated CVD in those with psychosis and other severe mental illness is not fully understood (10, 43, 48, 49). However, it could be attributed to the comorbid relationship or shared pathophysiology between CVD and psychosis, elevation in risk factors and treatment with antipsychotic medications (10, 43, 48, 49).

Cardiovascular disease risk factors are typically categorised as non-modifiable and modifiable (50). Non-modifiable risk factors are generalisable across different populations and confer an inherent risk to the condition (50, 51). They comprise age, gender, family history and ethnicity (50, 51). Age predisposes one to developing CVD due to physical deterioration of organs (52, 53). Gender differences in the general population reveal that men develop CVD 7 to 10 years earlier than women, and thus risk losing more years of life (50, 53). Hereditary susceptibility to CVD is positively or negatively influenced by family history and ethnicity (52, 54, 55).

In contrast, modifiable risk factors are reversible and constitute dyslipidaemia, hypertension, diabetes mellitus, low physical activity, poor nutrition/diet, smoking, overweight and obesity (body mass index [BMI] of ≥25 and ≥30 respectively) (50, 51). Occurrence of poor nutrition/diet, inadequate physical activity and smoking directly leads to the development of the other modifiable risk factors, and are collectively known as lifestyle risk factors (1, 41, 51). Alcohol consumption also contributes to the modifiable risk of CVD, however, the debate on whether effects are positive or negative is ongoing (56, 57). This is discussed in detail in section 1.7.1.7.

The use of atypical or second generation antipsychotics also increases the modifiable risk of CVD in people with psychosis (58-60). Atypical antipsychotics are the preferred pharmacologic treatment for psychotic symptoms due to their effectiveness on a broad spectrum of symptoms, and decreased neurological side effects, compared to first generation antipsychotics (58-60). Atypical antipsychotics are, however, associated with undesirable side effects—including weight gain, hyperglycaemia and dyslipidaemia (medications discussed comprehensively in section 1.7.3.2) (58-60).

1.7.1: Modifiable Risk factors for Cardiovascular Disease in People with Psychosis

Research indicates that people with psychosis and other severe mental illness are more susceptible to modifiable risk factors for CVD than the general population (43). The different risk factors are discussed in detail in subsequent sections.

1.7.1.1: Metabolic Syndrome

The International Diabetes Federation (IDF) defines metabolic Syndrome (MetS) as a cluster of clinical and metabolic abnormalities, diagnosed with the simultaneous presentation of raised blood pressure /hypertension, central adiposity, dyslipidaemia and elevated fasting blood glucose/hyperglycaemia; or with the co-occurrence of three of these syndromes (61). Raised blood pressure/hypertension based on IDF criteria refers to blood pressure that is above reference ranges (≥130/85mmHg), while central adiposity describes waist circumference measures greater than established cut-off values of >80cm in women and >94cm in men (61). Dyslipidaemia constitutes raised triglycerides (1.7mmol/L)

or low high density lipoprotein (HDL) cholesterol (≤1mmol/L in males and ≤1.3mmol/L in females) while elevated fasting blood glucose/hyperglycaemia is ≥100 mg/dL (≥5.5mmol/L) (61).

Established cut-off values for hypertension, central adiposity, dyslipidaemia and insulin resistance can differ based on country of residence, thus the diagnostic criteria for Mets vary (61, 62). The cause of symptom clustering in MetS is unclear but it is apparent that central adiposity and insulin resistance are integral to the condition developing (62-64).

Worldwide estimates reveal that the prevalence of MetS is about 50% in those with established psychosis (1, 64). Estimates in Australia correspond to this, as 55% of those who took part in SHIP had a diagnosis of MetS (2). Although conclusive research is unavailable, it is hypothesised that antipsychotic use could contribute to the high rates of MetS in people with psychosis due to medication induced weight gain, plasma lipid and glucose changes (64). MetS is a strong predictor of diabetes, CVD and CVD mortality (65, 66). Evidence from the general population shows that MetS quadruples the risk of developing type 2 diabetes, while the likelihood of mortality from CHD triples (1). MetS does not however indicate absolute risk associated with CVD because age, sex and smoking status are not considered when diagnosing the syndrome (61).

1.7.1.2: Type 2 Diabetes/Diabetes Mellitus

Diabetes mellitus is characterised by glycaemic levels ≥ 7.0mmol/L after fasting, or ≥11.1mmol/L at least two hours after meal intake, according to World Health Organisation diagnostic criteria (67). Type 2 diabetes is also marked by insulin resistance and insulin deficiency (68). The global prevalence of diabetes was 8.8% (95% CI 8.4–9.5) in 2015, and led to 3.1 million deaths in the same year (69). Absolute costs associated with the condition were US$1.32 trillion (95% CI 1.28–1.37) and this is projected to increase to more than $2.1 trillion (2.06–2.20) by 2030 (69).

Overweight and obesity, coupled with lifestyle risk, have been shown to contribute most significantly to the development of diabetes in the general population; general population research shows that the relative risk of diabetes, in populations who are obese, can be up to 17.5 (95% CI 12.9–23.9) times that of people who are not obese (70, 71).

Diabetes increases the risk of blindness, renal failure, amputation, and CVD, due to glucose and lipid metabolites that promote mechanisms of vascular injury and inhibit vascular protection (72-77). A systematic review which covered 220,689 people from the general population, indicated that the relative risk of all-cause mortality was 1.85 (95% CI 1.79–1.92) in those with type 2 diabetes (78). CVD is one of the more severe consequences of diabetes (72-76). Alarmingly, the risk of type 2 diabetes in people with schizophrenia is double (OR 1.99; CI 1.55–2.54) that of the general population (79). In a meta-analysis with 82,754 people, young adults (<24 years) with diabetes were 8.9 times (95% CI 7.0–

11.3) more likely to be taking antipsychotics than age-matched controls, highlighting extreme vulnerability to diabetes at younger ages due to antipsychotic use (80). Average diabetes onset in people living with psychosis is 10 to 20 years earlier than the general population (2). Research in this field also reveals that 70% of diabetes in this population remains undiagnosed, in contrast to about 30% in the general population (81, 82).

Despite the high rates of undiagnosed disease, prevalence of diabetes is considerably higher in people with psychosis than the general population (79, 83). A worldwide meta-analysis of 161,886 people with psychosis found that 9% had diabetes despite an average participant age of 38 years (79). Results from SHIP revealed that one fifth (20.5%) of the sample had diabetes and the average reported age was 38 years (2, 84). Increased and premature incidence of type 2 diabetes in this group is a consequence of heightened occurrence of lifestyle risk factors, antipsychotic treatment and genetic predisposition (39, 45, 79, 83).

1.7.1.3: Overweight and Obesity

Overweight and obesity are physical states characterised by excessive regional or global fat accumulation that pose risk to health (85). Overweight and obesity are assessed in different ways, however, the most widely used and recognised measures are BMI and waist circumference (85). BMI is calculated from body weight and height (kg/m^2); a BMI of ≥25 kg/m^2 corresponds to overweight status and a BMI of ≥30 kg/m^2 is indicative of obesity (85). Waist circumference, a measure of central adiposity, is a more valid and reliable predictor of chronic disease risk than BMI (86, 87). Waist circumference measures of >80cm in women and >94cm in men are associated with greater likelihood of chronic disease (88). Comorbidities of overweight and obesity present at various thresholds of measurement, and can differ based on the population in question (85). Research from the general population indicates that obesity reduces life expectancy and heightens risk of dyslipidaemia, hypertension, respiratory difficulties, certain cancers, type 2 diabetes and CVD (89-91).

Evidence shows that people with psychotic disorders could be at a greater risk for overweight and obesity than those in the general population (79). Worldwide overweight and obesity estimates average at about 50% in different countries (92). Overweight and obesity in populations experiencing psychosis is as high as 79% in America and Australia (2, 10, 93-95). Elevated overweight and obesity in people with psychotic disorders is primarily a result of lifestyle risk factors; however, antipsychotic medications are also recognised for their influence in the development of these physical states (96).

1.7.1.4: Poor Nutrition/Diet

Food consumption that is consistent with meeting an individual's nutritional requirements is known as good nutrition (97). Nutrition or nutritional status is dependent on individual dietary patterns or

the usual foods consumed; a healthy diet is generally high in fruits, vegetables, legumes, nuts and whole grains but low in added salt and sugar, and saturated fats (98, 99). Mortality and chronic disease risk can be modified through diet (100). Poor diet is a lifestyle risk factor for CVD and is usually an underlying cause of other modifiable risk factors associated with the condition such as hypertension, overweight and obesity; addressing dietary risk thus minimises the related modifiable risk (51). Dietary change can be achieved through individualised dietetic care, where a personalised plan is implemented with the support of a dietitian (101).

Implementation of dietary strategies can directly decrease likelihood of developing CVD or alter any associated risk through controlling subsequent markers of risk (51, 100, 102, 103). Wang et al. 2014 (100) in their meta-analysis of 833,234 participants from various populations around the world found CVD mortality is reduced by 4% for each additional serve of fruits and vegetables per day (HR 0.96; 95% CI 0.92–0.99) (100). The maximum threshold of benefit is experienced when consuming 5 serves of fruits and vegetables a day (100). Conversely, analyses of over 149,000 people from different countries demonstrate that frequent consumption of wholegrains (2.5 servings/day) reduces the risk of CVD by 21% (OR 0.79; 95% CI 0.73–0.85) (102, 104). A summary with 367,000 individuals shows that legumes are associated with a 10% risk reduction in CVD (RR 0·90; 95% CI 0·84–0·97) (105). Moreover, results based on a 22-study meta-analysis from the general population show that dietary fibre (which is a constituent of wholegrain foods) has an inverse relationship with CVD (RR 0.91; 95% CI 0.88–0.94) for each intake of 7g/day (106). Declines in coronary death (of 36%) are seen with the consumption of 1–2 servings of fish in a week (95% CI 20%–50%) (107, 108). Over 60 trials from the general population confirm that the replacement of dietary saturated fats with unsaturated fats improves total and HDL cholesterol (103, 109, 110). Finally, nuts, alcohol and dairy products are other foods appreciated for their cardio-protective properties (107, 111-113).

Diet studies among people with psychosis reflect poor dietary patterns, characterised by high consumption of fat and sugar, and low intake of fibre, fruits and vegetables. Please see Table 2 (on the following page) for an outline of the dietary behaviours prevalent in this population. These are likely contributors to the elevated risk of CVD (1, 114).

Table 2: The Evidence-base on Dietary Intake in People with Psychosis

Author	Study type and population	Dietary Findings
Mccreadie 2003 (115)	Cross-sectional study of 102 people in Scotland with schizophrenia	• 10% consumed cooked green vegetables ≥5 times a week • 1% ate cooked root vegetables ≥5 times a week • 25% reported consuming raw vegetables ≥2 times a week • 43% had oily fish >1 per month
Kilbourne et al. 2007 (116)	Cross-sectional study of 6,710 people from America. Persons with schizophrenia and bipolar disorder made up 55% of sample	• >90% of people with schizophrenia and bipolar disorder ate < 3 servings of fruit/day • >85% of those with schizophrenia and bipolar disorder reported <3 servings of vegetables/day • About 30% of those with schizophrenia and bipolar disorder had difficulty obtaining or cooking food and ate <1 meal/day
Brown et al. 1999 (117)	Cross-sectional study of 102 people with schizophrenia from the United Kingdom	• 0% of the sample ate five portions of fruit or vegetables per day • 51% had low intake of daily fibre (≤20 g) • 34% reported high (>122 g) total daily fat intake
Ryan et al. 2003 (118)	Cross-sectional study of 26 drug-naïve inpatients with schizophrenia	• Mean intake of saturated fat was 54.7 units per week which differed significantly ($p<0.002$) from a healthy comparison group (38.5 units)
Elmslie et al. 2001 (119)	Cross-sectional study of 89 persons with bipolar disorder	• Total daily sucrose intake was 73g for women and 89g for men which was significantly higher than a sex and age matched reference group
Kilian et al. 2006 (120)	Cross-sectional study of 625 inpatients from Germany with various psychiatric diagnoses	• When compared to the general population, the sample were more likely to report unhealthy dietary behaviours including—eating ready-to-serve meals several times per week, never eating fruits or vegetables, daily consumption of sweets and salty snacks, and fast food consumption several times per week
Morgan et al. 2012 (2)	Cross-sectional study of 1,825 people living with psychosis in Australia (SHIP)	• 71.1% did not eat fruit or ate ≤ 1 serve per day • 48.6% did not eat vegetables or ate ≤ 1 serve per day

1.7.1.4.1: Dietary Guidelines

Dietary guidelines are established for the purpose of making recommendations on the types and amounts of food necessary to promote health (121). The Australian Dietary Guidelines (ADGs) are based on current scientific evidence on promotion of health and well-being through diet, and aim to decrease risk of diet-related conditions such as obesity, elevated blood pressure and lipids; and to minimise risk of chronic health conditions including type 2 diabetes, CVD and cancer (121). The ADGs can be used by health professionals, policy makers, food manufactures, educators, food retailers and researchers in the support of healthy dietary patterns for Australians (121). These guidelines are applicable to all Australians, even those with common health conditions like obesity; however, should not be used for dietary management of specific medical conditions (e.g. diet-controlled diabetes) (121). It is imperative that dietary advice targeting chronic disease risk reduction in people with psychosis adheres to AGDs or other similar guidelines, because an evidence-based and clinically acceptable approach is proposed (121). The ADGs make recommendations on:

- Healthy weight maintenance through physical activity and selection of food portions that meet energy needs of the person(s).
- Variety in the diet through consumption of fruits, vegetables, grains or cereals, lean meats and meat alternatives and reduced-fat dairy.
- Limiting intake of foods that contain saturated fats, alcohol and added salt and sugars.
- Adequate food preparation and storage to prevent contamination.

1.7.1.5: Physical Activity

Physical activity is the movement of skeletal muscles which results in energy expenditure and generally includes all actions performed during routine activities of daily living, occupation and leisure (122). Exercise is a subdomain of physical activity categorised under the domain of leisure, and involves planned, structured and repetitive activity (123). The intensity, duration and frequency of all physical activity undertaken gives the total estimate (122). Sedentary behaviour is distinct from physical activity, and describes activities which entail little or no energy expenditure (124). Sedentary behaviour negatively impacts physical activity levels through detracting from physical activity time and is emerging as an important independent contributor to CVD risk (124).

Australia's Physical Activity and Sedentary Behaviour Guidelines recommend a minimum of 150 min of moderate-intensity or 75 min of vigorous-intensity physical activity per week to minimise the risk of CVD and other physical health conditions (122, 125, 126). These guidelines are applicable to all adults who are between 18 and 64 years, regardless of their gender, physical activity ability and cultural background (126). Intensity of physical activity referenced in the guidelines is determined using metabolic equivalent (MET) intensity levels, the ratio of metabolic rate during a selected activity

relative to standard resting metabolic rate of 1.0 (4.184 kJ) $\cdot kg^{-1} \cdot h^{-1}$ (127). Moderate-intensity activities expend 3–6 METs (e.g. recreational swimming or brisk walking) while those requiring >6 METs are classified as vigorous (e.g. aerobics or jogging) (125, 127). Activities that utilise <3 METs are categorised as light intensity (e.g. housekeeping or bowling) (127, 128). Conversely, sedentary behaviour guidelines recommend that prolonged sitting should be minimised and long periods of sitting should be broken up as frequently as possible (125). Specific details on the interval ratios for breaking up sedentary behaviour are however not provided (125).

Physical activity decreases the risk of CVD mortality by 35% (95% CI 30%–40%) and improves HDL cholesterol, LDL cholesterol, triglycerides, blood pressure, blood glucose levels, and overweight and obesity (122, 129-132). Increased physical activity intensity is associated with decreased mortality; the relative risk for all-cause mortality per hour increment of physical activity/week is 0.91 (95% CI 0.87–0.94) for vigorous activity and 0.96 (95% CI 0.93–0.98) for moderate activity (122).

A review on activity levels in people with psychosis highlights low participation in physical activity (133). This review by Stubbs et al. 2016 (133) with 3,453 people with schizophrenia revealed that participation in physical activity was 80.44 min for light activity (95% CI 68.32–92.52, n = 2658), 47.1 min for moderate activity (95% CI 31.5–62.8, n=559) and 1.05 min for vigorous activity (95% CI 0.48–1.62, n=2533), each per day (133). This cohort was less likely to meet targets for moderate and vigorous physical activity than the general population, and primarily engaged in physical activity through light walking (133). About a third of Australians living with psychosis are sedentary and more than 95% show low physical activity levels based on duration and intensity of activity (2, 10, 134). This is likely to contribute to the high prevalence of CVD and associated modifiable risk factors (133).

1.7.1.6: Smoking

Smoking is the primary means of tobacco consumption throughout the world and leads to nicotine addiction (135). Apart from advancing age, smoking is the most notable contributor to the development of CVD (136). Cardiovascular risk is largely influenced by the number of cigarettes smoked per day (136). Chemical substances produced during smoking induce cardio toxic effects, doubling the risk of experiencing sudden cardiac death among smokers (136). Research in the general population among people who were 60 years and older shows that the risk of CVD mortality doubles (HR 2.07; 95% CI 1.82–2.36) in current smokers and also shows elevation (HR 1.37; 95%1.25–1.49) in former smokers, when compared to those who had never smoked (137). Blood lipids show significant changes within 8 weeks of smoking abstinence with HDLs increasing (from 1.16 ± 0.06 mmol/L to 1.32 ± 0.06, $p<0.001$) and LDLs decreasing (from 3.78 ± 0.16 mmol/L to 3.52 ± 0.17, $p = 0.015$) (136, 138). Moreover, smoking cessation almost entirely eliminates the risk of smoking-related CVD, and is one of the most effective CVD prevention measures (136). Evidence on smoking cessation in the general

population highlights that the most effective approaches are nicotine replacement therapy, prescription medications (Bupropion and Varenicline), and clinical counselling and consultation (139). When compared to control conditions (after 1 year of treatment), those on nicotine replacement therapy show 1.71 odds of quitting (95% CI 1.55–1.88), while those on Bupropion show odds of 1.56 (95% CI, 1.10–2.21), and participants taking Varenicline have odds of 2.96 (95% CI 2.12–4.12) (140).

Worldwide research shows that people with schizophrenia are 5.3 times (95% CI 4.9–5.7) more likely to smoke than the general population (114, 135). Prevalence of smoking is around 60% among people with schizophrenia in different countries (114, 135). In Australia, smoking rates in those experiencing psychotic disorders is about two thirds (66%) of the population, compared to 19% in the general population (141). This prevalence has remained unchanged over a 10-year duration, indicating that people with psychosis are not benefiting from public health smoking cessation efforts that prove successful in the general population (141). The implementation of targeted strategies may be required among people with psychosis, because they are more likely to display heavy smoking and nicotine dependence, and experience more difficulties when attempting to quit (114, 135). Research studies in this population show that smoking cessation is most efficacious when Bupropion and Varenicline are utilised, resulting in at least 2 times (95% CI 1.61–5.34) the quit rates of placebo comparisons (142).

1.7.1.7: Alcohol

Alcohol is considered a controversial topic with regard to its effect on CVD (56, 57). This is because moderate intake is linked to some protective effects whereas the risks of some types of CVD increase with heavy consumption (56, 57). A meta-analysis of 84 studies assessing the association between alcohol and cardiovascular outcomes shows that cardio-protective effects of alcohol are seen with intakes between 2.5g and 60g a day, but are not detected above 60 g/day (56). Although consensus on safe levels of alcohol has not been reached, the National Health and Medical Research Council (NHMRC) recommends an intake of no more than 2 standard drinks (20g of alcohol) per day to minimise risk of alcohol-related harm over a lifetime (143).

A meta-analysis with over 2 million participants highlights the cardio-protective effects of alcohol consumption: the risk of CVD mortality is reduced in those who consume alcohol, compared with those who do not (RR 0.75, 95% CI 0.70–0.80) (144). CHD incidence and mortality also display reductions (RR 0.71, 95% CI 0.66–0.77 and RR 0.75, 95% CI 0.68–0.81 respectively) (144).

Conversely, effects of heavy alcohol use on CVD are also evident (56, 57). An 84-study meta-analysis by Ronksley et al. 2011 (144) found a 1.6 risk (95% 1.32–1.98) of incident stroke in those who consumed 60g of alcohol per day compared to abstainers; moreover, data from 1,425,513 individuals

assessing alcohol intake and stroke shows that >3 drinks/day is associated with increased risk of all stroke outcomes (56). Further, according to a case-control study of 12,461 individuals with myocardial Infarction (MI) and 14,637 controls, consumption of ≥6 drinks increases the risk of MI by odds of 1.4 (95% 1.1–1.9) in the 24 hours following intake (56). MI-induced heart failure is reported to triple with ≥5 alcoholic drinks/day in older populations (mean age 68 years) (56). Finally, cross-sectional research in 14,618 Chinese men shows that ≥60 g/day of alcohol is linked to peripheral arterial disease, while research in Mediterranean populations shows that hypertension is linked to the consumption of ≥1 drink/day on ≥5 days of the week (RR 1.45 95% CI 1.06–2) (56, 145).

Although the research on alcohol consumption and CVD is not specific to populations with psychosis, results help us recognise that heavy alcohol use can contribute to the risk of CVD (56, 57). Half (50.5%) of SHIP participants reported a lifestyle history of alcohol abuse or dependence, which may contribute to CVD and the associated modifiable risk (2). Lack of conclusive evidence in the field limits the use of alcohol intake recommendations for the prevention of CVD (56, 57).

This thesis primarily focuses on nutrition and physical activity risk factors, however, smoking is discussed in one paper.

1.7.2: Co-occurrence or Clustering of Cardiovascular Disease Lifestyle Risk Factors

Cardiovascular disease risk factors cluster or co-occur in those presenting with these behaviours in the general population (146). Clustering is observed when certain lifestyle risk factors are more likely to present simultaneously than separately (146). Clustering is calculated by comparing the incidence of multiple lifestyle risk factors in individuals, against the likelihood of lifestyle risk factor occurrence (based on actual prevalence of individual lifestyle risk factors) (146).

Clustering is common in lifestyle risk factors or the down-stream risk factors directly related to developing CVD (146). Clustering generally involves two or more CVD lifestyle risk factors (146). Clustering of lifestyle risk factors in the general population shows that individuals are more likely to present with all the health risk behaviours or the alternate healthy behaviours rather than single behaviours in isolation (146). Despite this, many health interventions have focused on single health behaviours rather than holistic treatments (146). Knowledge on corresponding clustering patterns should help inform the development of appropriate interventions (146).

Lifestyle behaviour clusters often correlate to specific participant sociodemographic characteristics, which are likely to differ based on the study setting and sample (146). In the general population, the clustering of all lifestyle risk factors is most prevalent among younger men, with low education and socioeconomic status (146). This information provides a definite target group for health behaviour

interventions (146). Research of this nature is valuable for the CVD intervention process in the general population, however, similar research is lacking for those with psychosis (146).

1.7.3: Other Factors Contributing to Cardiovascular Disease Risk in People with Psychosis

The effect of other intrinsic and environmental factors needs to be accounted for when assessing CVD susceptibility in people with psychosis, because these elements confound the relationship between risk factors and CVD (10, 43, 147). Information from the general population on risk factors for CVD is frequently generalised to people with psychosis, consequently, the effect of other risk modifiers and confounders largely remains unaccounted for (10, 43, 147). These factors are explored in greater detail below.

1.7.3.1: Antipsychotic Medications

All antipsychotic medications have the propensity to induce weight gain; first generation medications are, however, less obesogenic than atypical medications—the cornerstone of current psychosis treatment (21, 148, 149). First generation antipsychotics (developed in the 1950s) are classified according to their chemical structure, whilst atypical (or second-generation) antipsychotic medications (emerging in the 1980s) are categorised based on their pharmacological properties (60, 150, 151). The pharmacological properties of atypical antipsychotics are linked to minimal or no extrapyramidal symptoms (akathisia or inner restlessness and inability to stay still; parkinsonism or symptoms similar to those of Parkinson's; tardive dyskinesia or uncontrollable facial movements; and involuntary contraction and contortion of muscles known as dystonia) (60, 150, 151).

Research on antipsychotic weight gain suggests that weight increase is the result of medication effects on serotonergic, histaminergic and dopaminergic neurotransmitter systems, leading to sedation, increased appetite and food intake (152, 153). Further, cognitive impairments experienced by people with psychosis may inhibit their ability to restrain food intake when they experience appetite increase, thus exacerbating weight gain (154).

Most antipsychotic medications induce a 20% weight gain in drug-naïve patients, and excessive weight gain is often treated using metformin—a drug that improves insulin sensitivity, and is also speculated to minimize appetite and inhibit fat storage in peripheral tissues (152, 155, 156). Commonly-used first generation antipsychotics include chlorpromazine, haloperidol, zuclopenthixol dihydrochloride, prochlorperazine maleate, trifluoperazine, flupenthixol, fluphenazine, pericyazine and clopenthixol (157). Conversely, popular atypical antipsychotics are amisulpride, aripiprazole, asenapine, paliperidone, sertindole, risperidone, quetiapine, ziprasidone, clozapine and olanzapine (157). In Australia, atypical antipsychotics are recommended as the first-line treatment for psychosis (158).

Clozapine is reserved for persons who do not respond to other available treatments whilst olanzapine is the most widely prescribed antipsychotic (158).

Olanzapine and clozapine produce the most rapid weight gain; increases of up to 17kg are possible within the first 12 months of treatment (148, 149). Other atypical antipsychotic drugs that cause substantial weight gain are risperidone, amisulpride and sertindole (159). Antipsychotic weight gain is most significant in the first 3 months of treatment and slows down after 12 months (157). Overweight and obesity are often the end result of this weight gain (1).

Atypical antipsychotic medications also lead to changes in blood lipids (159). Alteration in serum lipids is primarily an outcome of weight gain, however, researchers claim that another more direct relationship exists between antipsychotics and blood lipids (160). Olanzapine results in the largest serum lipid changes; aripiprazole, risperidone, quetiapine and ziprasidone also show similar changes but to a lesser degree (159). These changes can result in dyslipidaemia, contributing towards modifiable CVD risk (51, 161).

Another side effect of atypical antipsychotics is elevation in blood glucose levels (159). Olanzapine and clozapine are the most detrimental to blood glucose (159). It is unclear though whether raised glucose levels are chiefly the result of weight gain (1, 162, 163). Elevation in glucose levels in those using these medications can lead to type 2 diabetes and metabolic syndrome, contributing considerably to CVD risk (51, 159).

1.7.3.2: Inequalities in Health Care

A review by De Hert et al. 2011 (164) underlined the impact of disparities in access, utilisation and provision of health care services among people with psychosis, in contributing to the disproportionately higher prevalence of physical health problems. This has also led to a large number of undiagnosed and untreated medical conditions (164). These health care inequalities are a product of elements related to the population group, treatment providers and the health system (164).

People with psychosis are less likely to seek physical health care due to their mental health (164). Low education attainment, unemployment, poverty, poor social networks and social isolation may also diminish their capacity to seek health care (164). Cognitive impairment, a common manifestation in psychosis, may influence comprehension of health care advice, execution of medical management plans, compliance with treatment, and awareness and communication of medical needs (164). The stigma of mental illness is also a barrier to accessing appropriate health care (165, 166).

Treatment providers also play an integral role in ensuring adequate health care provision in those with psychotic illness (164). Research shows that inequalities in health care are experienced because

treatment has previously focused on mental health, with less emphasis on physical health (164). Additionally, quality of physical health care in this group, is in some cases, poorer than that offered to the general population; care is marked by lack of assessments, poor monitoring and disconnect in the continuum of care—reasons for this remain unknown (164). Diagnostic overshadowing further inhibits adequate physical health care provision among those with psychosis; this occurs when presenting symptoms are presumed to be psychiatric, thus the physical ill-health remains undiagnosed and untreated (164). Poor communication between health care workers, and complexity in coordinating physical and mental health care are other factors that contribute to diminished levels of care (164).

Health system factors also present as important barriers to optimal physical health care among people with psychosis (164). For example, lack of clarity in the persons responsible for ensuring adequate physical health care in those with psychosis, fragmentation of services, and poor accessibility of services, potentially contribute to the high prevalence of CVD and related risk factors in people with psychosis (164).

1.7.3.3: Genetics

People with schizophrenia may have an underlying genetic risk of CVD (167). Proponents of this theory argue that there is an overlap in genes associated with CVD and schizophrenia (167). These genetic factors could be responsible for high rates of hypertension, dyslipidaemia, obesity and insulin resistance seen in drug-naïve patients experiencing their first episode of psychosis (45). Abnormalities in glucose metabolism and insulin signalling pathways have also been noted in drug-naïve persons with schizophrenia, indicating genetic vulnerability to type 2 diabetes (168). Finally, other research shows that people with psychosis could be predisposed to elevated basal cortisol—a stress hormone which has the potential to increase CVD risk (169, 170).

1.8: Commonly used Interventions for Elevated Cardio Metabolic and Lifestyle Risk in People with Psychosis

1.8.1: Pharmacology

Pharmacology is the principal intervention used to treat increased hypertension, dyslipidaemia, insulin resistance, diabetes and CVD among people with psychosis (10). Research from the general population reveals that pharmacological treatment incompletely decreases the risk associated with these conditions because pharmacological treatments do not eliminate underlying lifestyle risk behaviours (51). Consequently, medically managed persons with unhealthy lifestyle habits remain at a higher risk for CVD than those who practice healthy lifestyle habits (51). Lifestyle modification is the most important strategy for the primary prevention of CVD because of the multifaceted physical health

benefits of making lifestyle changes (discussed in sections 1.7.1.4-1.7.1.7 of the thesis); nonetheless, pharmacotherapy remains crucial for the management of non-modifiable CVD risk (51).

1.8.2: Non-pharmacological Interventions

Non-pharmacological interventions that target cardio metabolic risk range from those that are designed for entire population groups to those that focus on local research settings (171-173). Interventions that are executed across entire or large populations are known as public health interventions (171). These interventions often focus their efforts at modifying nutrition, physical activity and smoking through mass media campaigns, government policy changes and environmental interventions (2, 171, 174, 175). Reach and effectiveness of these public health efforts in Australians with psychosis is largely unknown because the emphasis of follow-up assessments is usually on the general population as a whole (2, 171, 174, 175). Studies on smoking behaviour in those with psychosis imply limited effectiveness of these interventions (2, 8). Smoking rates among Australians with psychosis have shown stagnation in the past decade despite general population decreases (2, 8). Decreased efficacy of public health interventions in people with psychosis could be related to the many challenges they encounter—social isolation, poor health, high rates of unemployment, financial difficulties and homelessness (2, 8). Interventions that specifically target people with psychosis may be more appropriate to achieve changes in nutrition, physical activity and smoking behaviour (2).

Small scale interventions that target modifiable cardio metabolic risk take the form of community health programs which are run in the government and non-government sectors (173). Government-run community health programs are sometimes part of larger public health initiatives (173, 176). Non-government community health programs are usually localised to a specific geographical area and serve a smaller population group (173). Information on small-scale community health programs is not widely described on the internet hence it is difficult to assess the specific content of these programs (173). In many cases, it is unknown how these programs are developed and if they are evidence-based (173). Additionally, evaluation of program efficacy is often lacking (173, 176). Existing community health programs generally serve the needs of the general population and are executed within various community settings such as schools, health settings and organisations (173). Information on community health programs that target cardio metabolic risk in people living with psychosis is unavailable—the probable result of poor information dissemination rather than program unavailability (173).

Research trials that target cardio metabolic risk are usually initiated by investigators and are independently-funded studies executed primarily for scientific investigation (177-204). Many of these interventions cease after the funding period, and treatment benefits are seldom maintained after the

intervention period (177-204). Trials that recruit people with psychosis are often exclusive to this group because of their unique physical and health needs (172). These are discussed in detail in section 1.8.2.1 that follows.

1.8.2.1: Research Trials

Research on the management of cardio metabolic risk in people with psychosis generally targets lifestyle risk behaviours (172, 177-204). The term lifestyle intervention is often used in reference to these research trials due to the reliance on behaviour change strategies to modify health behaviour (172). Behaviour change strategies primarily target nutrition and physical activity aspects of lifestyle (172). Smoking is often excluded from lifestyle interventions because smoking cessation is most efficacious when pharmacotherapy is applied in interventions involving people with psychosis (205, 206). Consequently, a clear distinction is seen between trials that utilise pharmacotherapy and those which solely focus on behaviour change in the management of CVD risk among people with psychosis (205, 206).

Existing lifestyle interventions for people with psychosis are typically developed from theories (such as stages of change theory and social cognitive theory), or are adapted from existing trials in the general population (177-204). Lifestyle interventions are targeted at those who are overweight or those presenting with an at-risk status due antipsychotic medication use (177-204). Primary outcomes reported are weight and BMI; evidence summaries show average decreases in weight of 3.12kg (95% CI −4.03 to−2.21, p<0.0001) and 0.95 kg/m^2 BMI points (95% CI −1.45 to −0.43, p=0.0003) (207). The systematic review by Alvarez-Jimenez et al. 2008 (208) found that total weight change was about 2.5–4% in some participants.

Existing trials in this field were carried out in highly controlled environments and under ideal circumstances, even where studies were in real-world settings, thus only tested efficacy (172, 209, 210). Effectiveness research generally follows less restrictive methodological standards and is more oriented towards routine conditions (172, 209, 210). These trials nonetheless show that substantial weight reduction is attainable, comparable to that realised when metformin is used in this population (211).

Direct effects of lifestyle interventions on intermediate CVD risk factors such as blood lipids, blood pressure and blood glucose are rarely reported (172, 207, 212). The few studies that report on intermediate CVD risk factors show that significant changes are attainable for total cholesterol (weighted mean difference [WMD]=−20.98 mg/dL, 95% CI −33.78 to −8.19, p=0.001); triglycerides (WMD=−61.68 mg/dL, CI −92.77 to −30.59, p=0.0001); fasting blood glucose (WMD=−5.79 mg/dL, CI−9.73 to −1.86, p=0.004); waist circumference (WMD=−3.58 cm, 95% CI −5.51 to −1.66, p=0.03); and

insulin levels (WMD=−4.93 uIU/mL, CI −7.64 to −2.23, p=0.0004) (172, 207, 212). Short follow-up periods, however, limit broader assessment of these risk factors (172, 207, 212)

The behaviour change strategies that promote lifestyle intervention efficacy have not been clearly distinguished; pairwise comparisons from meta-analyses show that interventions delivered using an individual or one-on-one approach produce greater weight loss (ES=-0.67, 95% CI -1.04 to -0.30, p =0.0004) than those delivered in a group setting (ES=-0.36, 95% CI -0.60 to -0.13, p=0.002) (172). Moreover, interventions which utilise both individual and group delivery are the best for weight loss (ES=-0.99, 95% CI -1.61 to -0.37, p =0.002) (172). Lack of additional information on these intervention features and other characteristics associated with trial success, is a major evidence gap (172, 207, 209, 212-214). This hinders further testing of these intervention components and the generation of conclusions on appropriate practice in the field (172, 207, 209, 212-214).

The use of behaviour change strategies in lifestyle interventions results in inherent design complexities, associated with standardising and administering treatments, and reporting and reproducing the processes followed in the interventions (215, 216). Adherence to guidelines designed for implementing and reporting studies which utilise behavioural or nonpharmacologic techniques is important for generation of comprehensive evidence on lifestyle interventions for people with psychosis (215, 216). The Consolidated Standards of Reporting Trials (CONSORT) statement for randomised controlled trials (RCTs) of nonpharmacologic interventions, are evidence-based guidelines that address the challenges associated with lifestyle interventions, to ensure transparent and coherent implementation and reporting of research (212, 213). The CONSORT statement for nonpharmacologic interventions are an extension of the original guidelines which were developed for all clinical trials, however, these are specifically tailored for behavioural treatments (212, 213). The CONSORT statement for nonpharmacologic interventions can therefore serve as tool for appraising reported evidence on lifestyle interventions for people with psychosis, because they are designed to uphold the quality of these type of interventions (215, 216).

Finally, clinical robustness of nutrition and physical activity content in lifestyle interventions for people with psychosis has not been assessed or reported (99, 126, 172, 207, 209, 212-214). Clinically robust nutrition and physical activity advice should undergo necessary testing to ensure that safety, health and well-being are promoted, and not only weight loss (99, 126). Guidelines such as the ADGs and Australia's Physical Activity and Sedentary Behaviour Guidelines are based on the best scientific evidence and expert opinion, and are useful tools for assessing the quality of existing lifestyle interventions (99, 121, 126, 172, 207, 209, 212-214).

1.9: The Current Situation on Management of Cardio Metabolic and Lifestyle Risk for Australians with Psychosis

Epidemiological research among Australians with psychosis shows that 36.5% access different programs in the community—some of which target lifestyle risk behaviour (2, 9). These community health programs are specifically tailored for those with mental illness to provide education, supports of various kinds, and individual recovery plans for the purpose of facilitating independent functioning, minimising disability and promoting recovery (9). Community health programs are usually delivered through the government and non-government sectors (2, 9, 217). Avenues of program delivery in the government sector are the public mental health services, while the non-government sector offers these services through community managed organisations (CMOs) (9).

Community managed organisations provide community-based support services that aim to keep participants well; these include psychosocial supports which are geared towards the community participation of consumers, and different programs which support the health and well-being of consumers (218). The support services available in CMOs are complimentary to clinical services which provide medical treatment options (30). New South Wales alone has nearly 250 CMOs for mental health service consumers, and more than 300 different programs are delivered through these organisations (30). The scale of the CMO mental health work-force is currently not well understood, however, the most recent national mental health report from 2013 reported an increase in CMO expenditure (4, 30). CMO funding is experiencing a shift from Commonwealth and State funding, to competitive tendering arrangements and the individualised packaging and brokering system available through the NDIS (30). The current customer driven funding environment may lead to changes in how CMO programs and services are delivered to consumers (30).

It is apparent that people with psychosis are more likely to utilise programs in the non-government or CMO sector (22.4%) than those in the government sector (14.5%), but reasons for this are presently unclear (9). Information on utilisation and efficacy of community programs targeting nutrition and physical activity in people with psychosis remains unknown for both the government and non-government sectors (9). This information would improve understanding on the role of these services among Australians with psychosis, so that resources are appropriately managed, delivered and evaluated (219, 220). This is an existing research gap which warrants further investigation.

Results from existing lifestyle intervention trials show that Australians with psychosis generally experience decreases in weight and BMI following participation, despite the previously highlighted study limitations—lack of clarity regarding study adherence to nutrition and physical activity

guidelines and uncertainty in characteristics associated with efficacy (190, 194, 221). Although important, lifestyle intervention trials do not provide a permanent health solution for those in this cohort and should be translated to different service delivery settings (190, 194, 221). Adoption of lifestyle interventions is not evident after these trials are completed in Australian settings (190, 194, 214, 221). Consequently, processes and considerations involved during translation of evidence-based lifestyle interventions for people with psychosis in the Australian community context remain unknown (214, 222-224).

1.10: Translating Knowledge from Research Trials

Knowledge translation is a process that involves the synthesis, and application of knowledge to improve health, provide more effective products and services, and strengthen the health care system (225). Synthesis of knowledge involves development of summaries of evidence (such as systematic reviews) and practice recommendations (226). The quality of evidence and strength of recommendations should then be rated using structured and transparent criteria (226). The GRADE (Grading of Recommendations Assessment, Development, and Evaluation) approach is a tool that can be used for this purpose as it provides a valid process for developing and presenting evidence summaries and rating recommendations (226). Factors that influence strength of recommendations include risk of bias, magnitude of treatment effect, dose response, presence of confounders, consistency of results, indirectness of evidence, overall study limitations, balance of desirable/undesirable outcomes, and values and preferences of study participants (226). Practice recommendations for a particular field may however require more than one summary of evidence, to cater to all relevant outcomes (226).

The application of knowledge (in the translation process) aims to enhance the usefulness of research by progressing evidence beyond simple dissemination into implementation (225). Implementation of research from lifestyle interventions should be guided by knowledge translation frameworks because they aid in identifying the most appropriate approaches and considerations (227). The “Integrated Promoting Action on Research Implementation in Health Systems” (i-PARIHS) is an example of a knowledge translation framework that is suitable for this purpose (227, 228). A review on knowledge translation highlighted that tools and frameworks designed for this purpose are likely to show greater success if they align with research goals and context, show broad adaptability to a wide variety of intervention activities, align with the field of application, and demonstrate efficacy (229). I-PARIHS aligns with these criteria as the framework was primarily developed for health services, is adaptable to a wide range of contexts and interventions, and has been successfully trialled in various settings (230). Moreover, the framework is a practical tool that can be used by researchers and practitioners

because it clearly outlines the multifaceted techniques and elements involved in knowledge translation (227, 228). I-PARIHS presents these factors as four constructs—innovation, recipients, context and facilitation (227).

Innovation includes evidence from research and local practice, and any adaptations of the evidence that would need to occur prior to implementation being conducted; these adaptations are based on existing practice in prospective implementation contexts (227). All persons who influence or are affected by the implementation process are the recipients (227). Recipient feelings, attitudes, motivation, goals, knowledge, skills and resources as they relate to the planned intervention require due consideration (227). The context comprises of a bi-layer made of local and external factors which need to be accounted for (227). Local level factors include organisational considerations like the culture, leadership and mechanisms for embedding and evaluating change, whilst external factors comprise wider health system factors that would affect implementation (227). Facilitation consolidates the framework and refers to all efforts directed towards evidence implementation, guided by a facilitator and facilitation process (227). Facilitation entails responding to the characteristics of the other i-PARIHS constructs to enable successful implementation—please see Figure 1 (on the following page) for a summary of i-PARIHS (227). Investigation of these elements as they pertain to translation of evidence-based lifestyle interventions into an Australian CMO would typically generate information that is contextually specific, however, some of the details especially as they relate to the considerations of recipients (people with psychosis and their service providers) are generalisable (222, 223, 227). Research of this nature would highlight issues that could influence external validity and implementation of lifestyle interventions into CMOs; the information obtained would pertain to various barriers, enablers and processes for knowledge translation in CMOs (214, 227). This information could then be used to facilitate prospective uptake of lifestyle interventions, and hence requires generation (222, 223, 227).

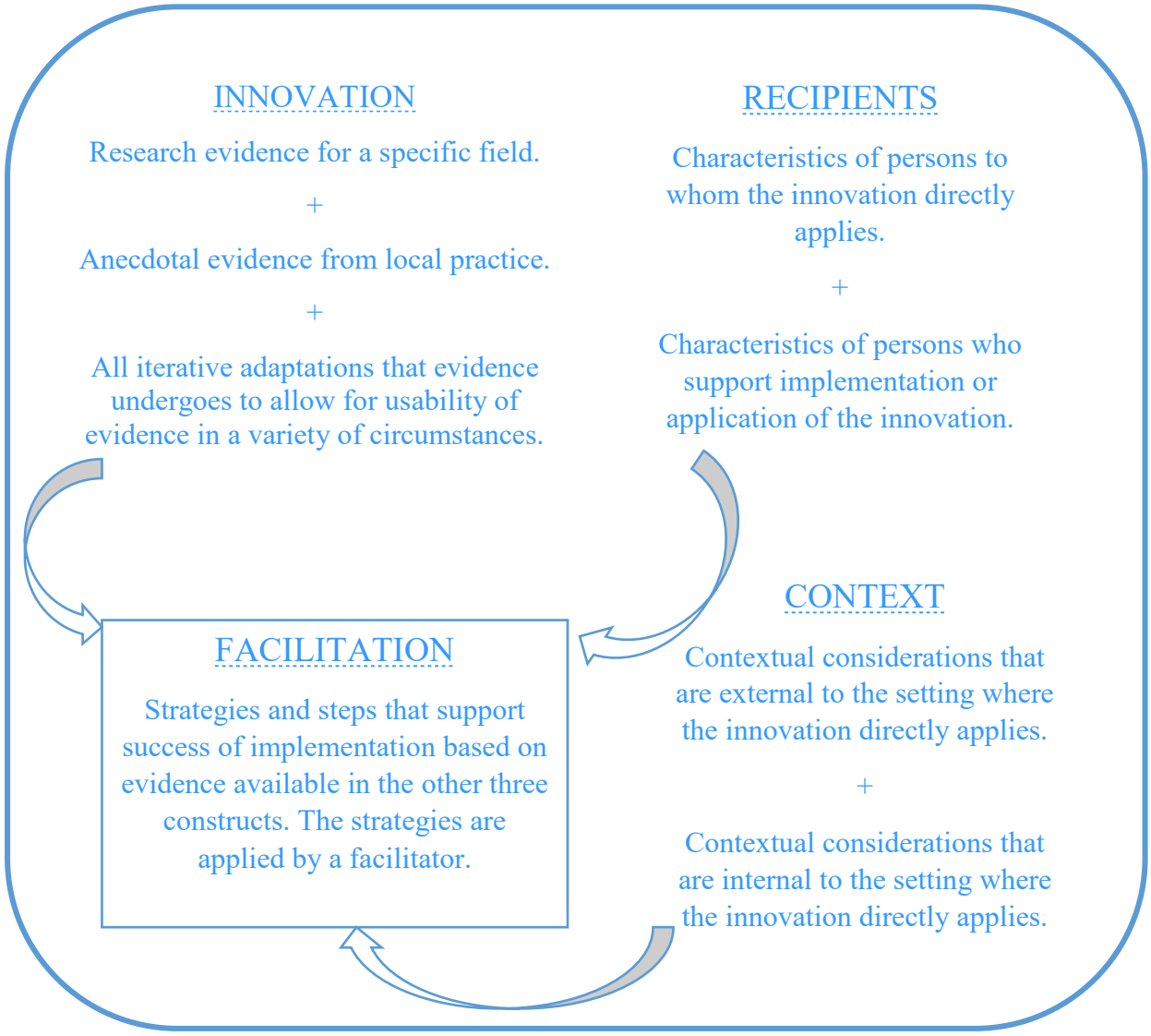


Figure 2: A Figure Summarising Key Concepts from the I-PARIHS Knowledge Translation Framework.

1.11: Summary

People living with psychosis suffer long-term impairments which affect personal, social and occupational facets of their lives (6). These impairments contribute to the occurrence of extremely poor physical health, and CVD contributes notably to the health disparity experienced (1, 2, 30, 37-41). Cardiovascular disease is a comorbidity of psychosis and presents at a younger age than in the general population (48, 49). Core factors that contribute to higher incidence and prevalence of CVD among people with psychosis are lifestyle risk factors—poor nutrition/diet, inadequate physical activity and smoking (1, 114, 133, 135). Heightened risk of CVD among people with psychosis is also moderated by additional intrinsic and environmental factors, which could confound the relationship between lifestyle risk factors and CVD risk markers (10, 43, 147). The effect of these confounding

variables needs to be accounted for when quantifying the effect of lifestyle risk among people with psychosis (10, 43, 147). Lifestyle risk factors have the propensity to cluster in those presenting with these behaviours in the general population (146). Risk factor clustering is also likely to present among those with psychosis, and identifying these patterns along with any correlated sociodemographic characteristics could inform the development of appropriate CVD interventions for this cohort (146).

Cardiovascular risk in people with psychosis is primarily managed through pharmacotherapy (10). This approach is not effective for the complete eradication of CVD because underlying lifestyle risk factors are not eliminated (51). Lifestyle change is superior for effecting pleiotropic benefits on physical health, thus, it could be argued that lifestyle modification is the most important strategy for the prevention of CVD (21, 51). Small scale interventions that target modifiable cardio metabolic risk among people with psychosis take the form of community health programs and research trials (172, 173). A review of the Australian situation on community health programs for people with psychosis reveals that much still needs to be uncovered; utilisation and efficacy of programs targeting nutrition and physical activity are some of the areas that require further investigation (9). Research trials targeting lifestyle risk are otherwise known as lifestyle interventions; they successfully minimise CVD lifestyle risk factors, weight-related outcomes, blood lipid and blood glucose levels in people with psychosis through behaviour change strategies (172). Available literature indicates a scarcity of reviews that thoroughly describe lifestyle intervention content, identify efficacious intervention characteristics, and report on clinical robustness of dietary information provided (121, 164).

Existing lifestyle interventions do not show continuity because they are not translated to different service delivery settings (190, 194, 221). Considerations involved when translating evidence-based lifestyle interventions into different settings within the Australian community context are thus unknown (214, 222-224). The i-PARIHS knowledge translation framework can guide this research by identifying factors which require further local investigation prior to implementation of lifestyle interventions into Australian CMO settings (227). Information on factors that could affect lifestyle intervention implementation into CMOs is useful for the prospective uptake of these trials (222, 223, 227).

Chapter 2: Literature Gaps, Thesis Outline and Publications

2.1: Literature Gaps Addressed in this PhD

Study 1

1. **Gap**: Although the relationship between CVD lifestyle risk factors (poor diet, smoking and low physical activity) and modifiable risk factors (dyslipidaemia, hypertension and hyperglycaemia) is established, potential confounders that are unique to people with psychosis have not been assessed and controlled for in such analyses.

   Research question: In people with psychosis, what impact do CVD lifestyle risk factors have on modifiable risk factors after controlling for potential population-specific confounders?

   Hypothesis: Increased CVD lifestyle risk factors will lead to a significant increase in modifiable risk factors in people with psychosis after controlling for potential population-specific confounders like antipsychotic medications.

   Aim: A cross-sectional data-analysis was performed which aimed to describe the relationship between lifestyle risk factors for CVD—poor nutrition, smoking and low physical activity levels—and dyslipidaemia, hypertension and hyperglycaemia in 1,825 people from the Survey of High Impact Psychosis (SHIP) in Australia, while controlling for potential confounding factors.
2. **Gap:** The clustering or co-occurrence patterns of lifestyle risk factors among people with psychosis has not been assessed previously. Furthermore, demographic factors that are associated with clustering of lifestyle risk factors have not been identified in this cohort.

   Research question: Do clustering patterns exist between the different lifestyle risk factors in people with psychosis? (If so) What demographic factors are associated with the different clusters of lifestyle risk factors in people with psychosis?

   Hypothesis: Lifestyle risk factors in people with psychosis will exhibit clustering or patterns of co-occurrence which will correlate to specific participant demographic characteristics.

   Study 1 aim: The cross-sectional data-analysis aimed to identify clustering patterns of lifestyle risk factors (using the two-step cluster in SPSS—a mode of hierarchical cluster analysis) in study participants and described the demographic characteristics associated with different clusters of lifestyle risk factors.

Research output: Mucheru D, Hanlon MC, Campbell LE, McEvoy M, and MacDonald-Wicks L. *Cardiovascular disease lifestyle risk factors in people with psychosis: a cross-sectional study.* BMC Public Health. 2018; 18(1): 742.

Study 2

3. **Gap**: Utilisation rates of community health programs targeting nutrition and physical activity among Australians with psychosis is unknown. It is also not clear whether participation in these programs yields tangible benefits in this target group.

   Research question: What are the utilisation or attendance rates of community nutrition and physical activity programs among Australians with psychosis? Is attendance of community nutrition and physical activity programs associated with improved nutrition and physical activity outcomes in people with psychosis?

   Hypothesis: Community program attendance will show a significant relationship with improved nutrition and physical activity outcomes.

   Study 2 aim: The cross-sectional data analysis aimed to describe the self-reported attendance of community nutrition and physical activity programs in the government and non-government sectors among 1,825 people from the Survey of High Impact Psychosis (SHIP), and to identify demographics associated with overall self-reported program attendance. This study also aimed to assess whether improved nutrition and physical activity outcomes were associated with program attendance.

   Research output: Mucheru D, Hanlon MC, Campbell LE, McEvoy M, MacDonald-Wicks L. *Self-Reported Nutrition and Physical Activity Program Utilisation among Australians with Psychosis: A Cross-Sectional Analysis of Data*. J Community Med Public Health. 2019; 3: 155.

Study 3

4. **Gap:** Strategies that contributed to efficacy of available lifestyle interventions need further investigation as this is unclear in existing systematic reviews.

   Research question: What strategies contribute to the efficacy of lifestyle intervention trials in people with psychosis?

   Study 3a aim: A systematic review and network meta-analysis aimed to pool and rank the efficacy of lifestyle intervention strategies that target weight, body mass index, waist-circumference, and waist-to-hip ratio in people with psychosis by comparing the effect size on these weight outcomes.

5. **Gap:** Clinical robustness of dietary information offered in previous lifestyle interventions studies has not been established. The Australian Dietary Guidelines (ADGs) are suitable for this appraisal because they base recommendations on the most superior evidence in the field.

   Research question: Does dietary information in available lifestyle interventions for people with psychosis adhere to the ADGs?

   Study 3a aim: The systematic-review also aimed to stratify lifestyle interventions according to their inclusion of dietary information that adheres with the Australian Dietary Guidelines.

   Research output: Mucheru D, Hanlon MC, McEvoy M, and MacDonald-Wicks L. *Comparative efficacy of lifestyle intervention strategies on weight outcomes in people with psychosis: a systematic review and network meta-analysis protocol.* JBI Database System Rev Implement Rep. 2017; 15(6): 1593-601.

   And;

   Mucheru D, Hanlon MC, McEvoy M, Thakkinstian A and MacDonald-Wicks L. *Comparative efficacy of lifestyle intervention strategies that target weight outcomes in people with psychosis: a systematic review and network meta-analysis*. In JBI Database System Rev Implement Rep. 2019. doi: 10.11124/JBISRIR-2017-003943.

6. **Gap:** Poor reporting in lifestyle intervention reports for people living with psychosis was identified as an issue of concern when completing the systematic review on this topic. Adherence of lifestyle interventions to reporting guidelines designed for nonpharmacologic interventions needs assessing so that problems are highlighted, and suggestions made where appropriate.

   Research question: Do lifestyle intervention trials in people with psychosis adhere to reporting standards proposed in the Consolidated Standards of Reporting Trials (CONSORT) statement for randomised trials of nonpharmacologic interventions?

   Study 3b aim: The final aim of the systematic review was to critically appraise lifestyle intervention studies that target weight outcomes for people with psychosis against the methods component of the Consolidated Standards of Reporting Trials (CONSORT) statement for randomised trials of nonpharmacologic treatments.

   Research output: Mucheru D, Hanlon MC, McEvoy M, and MacDonald-Wicks L. *An Appraisal of Methodology Reporting in Lifestyle Interventions among People with Psychosis using the*

CONSORT Statement for Randomised Trials of Nonpharmacologic Treatments: A Systematic Review. In Health Promot J Austr. 2019. doi:10.1002/hpja.293

Study 4

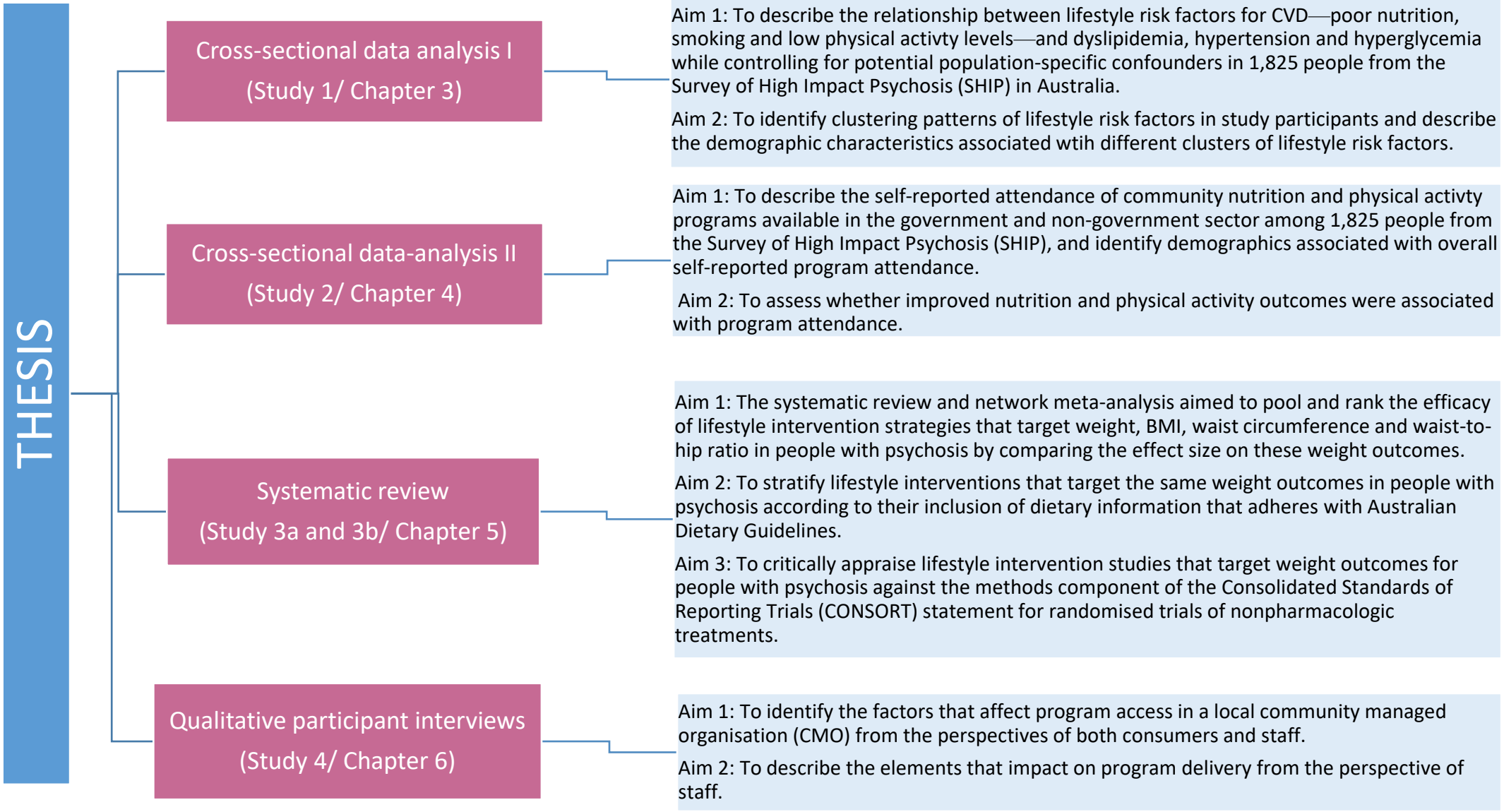
7. **Gap**: Available literature reveals a lack of information on the factors that would affect translation of lifestyle interventions for people with psychosis into the Australian community setting. These would primarily entail the considerations for program access and delivery in an Australian community managed organisation (CMO) delivering mental health services.

   Research questions: What are the factors that affect program access in a local CMO delivering programs for people with mental illness? What are the elements that impact on program delivery in the CMO?

   Study 4 aim: An interview-based qualitative study was completed that aimed to identify the factors that affect program access in a local CMO from the perspectives of both consumers and staff. Secondary to this, was to describe the elements that impact on program delivery from the perspective of staff.

   Research output: Mucheru D, Ashby S, Hanlon MC, McEvoy M, and MacDonald-Wicks L. *Factors to Consider during the Implementation of Nutrition and Physical Activity Trials for People with Psychosis into an Australian Community Setting.* BMC Health Serv Res (under review). 2019.

2.2: Thesis Outline



2.3: Publications in this Thesis

2.3.1: Manuscripts Published in Peer-Reviewed Journals

1. Chapter 3: Mucheru D, Hanlon MC, Campbell LE, McEvoy M, and MacDonald-Wicks L. *Cardiovascular disease lifestyle risk factors in people with psychosis: a cross-sectional study.* BMC Public Health. 2018; 18(1): 742.
2. Chapter 4: Mucheru D, Hanlon MC, Campbell LE, McEvoy M, MacDonald-Wicks L. *Self-Reported Nutrition and Physical Activity Program Utilisation among Australians with Psychosis: A Cross-Sectional Analysis of Data*. J Community Med Public Health. 2019; 3: 155.
3. Chapter 5.1 paper 1: Mucheru DW, Hanlon MC, McEvoy M, and MacDonald-Wicks L. *Comparative efficacy of lifestyle intervention strategies on weight outcomes in people with psychosis: a systematic review and network meta-analysis protocol.* JBI Database System Rev Implement Rep. 2017; **15**(6): 1593-601.3.
4. Chapter 5.1 paper 2: Mucheru D, Hanlon MC, McEvoy M, Thakkinstian A and MacDonald-Wicks L. *Comparative efficacy of lifestyle intervention strategies that target weight outcomes in people with psychosis: a systematic review and network meta-analysis*. JBI Database System Rev Implement Rep. 2019. doi: 10.11124/JBISRIR-2017-003943
5. Chapter 5.3: Mucheru D, Hanlon MC, McEvoy M, and MacDonald-Wicks L. *An Appraisal of Methodology Reporting in Lifestyle Interventions among People with Psychosis using the CONSORT Statement for Randomised Trials of Nonpharmacologic Treatments: A Systematic Review.* In Health Promot J Austr. 2019. doi:10.1002/hpja.293.

2.3.2: Manuscripts Currently Under Review in Peer-Reviewed Journals

1. Chapter 6: Mucheru D, Ashby S, Hanlon MC, McEvoy M, and MacDonald-Wicks L. *Factors to Consider during the Implementation of Nutrition and Physical Activity Trials for People with Psychosis into an Australian Community Setting.* BMC Health Serv Res (under review). 2019.

Chapter 3: Cardiovascular Disease Lifestyle Risk Factors in People with Psychosis: A Cross-sectional Study

3.1: Study Overview

This study was inspired by the increased susceptibility of cardiovascular disease (CVD) in people with psychosis, who have a 53% higher risk than the general population (43). Research in this field highlights that people with psychosis are more likely to exhibit modifiable cardiovascular risk factors including dyslipidaemia, hypertension, hyperglycaemia, metabolic syndrome, type 2 diabetes, overweight and obesity, which ultimately increases their risk of CVD (1, 64, 79, 80). Poor nutrition/diet, inadequate physical activity and smoking directly lead to the development of these modifiable CVD risk factors (1, 41, 51). However, the effect of potential confounders like antipsychotic medications needs to be accounted for when assessing this relationship (10, 43, 147). Additionally, lifestyle risk factors often present in certain clusters or patterns in the general population; so understanding the corresponding clustering patterns in people with psychosis would help inform development of appropriate interventions (146). Therefore, a cross-sectional data-analysis was performed which aimed to describe the relationship between lifestyle risk factors for CVD—poor nutrition, smoking and low physical activity levels—and dyslipidaemia, hypertension and hyperglycaemia in 1,825 people from the Survey of High Impact Psychosis (SHIP) in Australia, while controlling for potential confounding factors. The second aim was to identify clustering patterns of lifestyle risk factors in study participants, and describe the demographic characteristics associated with different clusters of lifestyle risk factors.

The research findings were presented orally at the Society for Mental Health Research (SMHR) in Canberra, in December 2017, and at the Dietitians Association of Australia (DAA) in Sydney, in May 2018. Both presentations were made by Miss Doreen Mucheru.

Study results were published in BMC Public Health: Mucheru D, Hanlon MC, Campbell LE, McEvoy M, and MacDonald-Wicks L. *Cardiovascular disease lifestyle risk factors in people with psychosis: a cross-sectional study*. BMC Public Health. 2018; 18(1): 742.

Mucheru et al. BMC Public Health (2018) 18:742
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BMC Public Health

RESEARCH ARTICLE Open Access

Cardiovascular disease lifestyle risk factors in people with psychosis: a cross-sectional study

Doreen Mucheru[1], Mary-Claire Hanlon[1,2,3,4], Linda E. Campbell[2,5,6], Mark McEvoy[1,7] and Lesley MacDonald-Wicks[1,2,8*]

Abstract

Background: People with psychosis die on average 25 years earlier than those in the general population, with cardiovascular disease (CVD) contributing to much of the excess mortality. This cross-sectional study aimed to identify the relationship between lifestyle risk factors for CVD – poor nutrition, smoking and low physical activity levels – and dyslipidaemia, hypertension and hyperglycaemia while controlling for potential confounders in 1825 people from the Survey of High Impact Psychosis (SHIP) in Australia. We also aimed to identify clustering patterns of lifestyle risk factors and associated demographic variables.

Methods: Three logistic regressions were used to predict the effect of nutrition, smoking and physical activity on dyslipidaemia, hypertension and hyperglycaemia while controlling for clozapine use, sex and age. Clustering patterns of nutrition, smoking and physical activity were examined using the two-step cluster method which is based on hierarchical cluster analysis. Demographic variables associated with different clusters were identified using measures of association.

Results: Smoking status had a positive association with dyslipidaemia (adjusted odds ratio = 0.50; 95% confidence interval = 0.32–0.78; $p = 0.002$). Other cardiovascular disease lifestyle risk factors did not have a significant relationship with dyslipidaemia, hypertension and hyperglycaemia. Clustering patterns of lifestyle risk factors showed that younger men, with low education levels, and relying on a government pension, were most likely to display the poorest lifestyle risk behaviours. The largest cluster (42%) of participants was characterised by a mixed demographic profile and were most likely to display poor nutrition and low physical activity levels but less likely to smoke.

Conclusions: Only smoking status had a significant positive association with dyslipidaemia which could indicate that there are additional factors affecting the relationship between other cardiovascular lifestyle risk factors and dyslipidaemia, hypertension and hyperglycaemia in people with psychosis. Unknown confounders and traditional lifestyle risk factors may explain the high rates of CVD in this group. Clustering of lifestyle risk factors and their demographic profiles could help the design of intervention programs in people with psychosis.

Keywords: Psychosis, Nutrition, Physical activity, Smoking, Lifestyle risk factors, Cardiovascular disease, Lifestyle interventions

* Correspondence: lesley.wicks@newcastle.edu.au
[1]Faculty Health and Medicine, The University of Newcastle, Callaghan 2308, Australia
[2]Brain and Mental Health Program, Hunter Medical Research Institute, New Lambton 2305, Australia
Full list of author information is available at the end of the article

Background

Cardiovascular disease (CVD) is the collective term for all conditions which affect heart and blood vessels [1]. In 2016, CVD was the leading cause of death in 190 countries around the world and on average claims about 17.3 million lives per year with this number expected to rise to more than 23.6 million by 2030 [2]. CVD is a prominent comorbidity among people with psychosis, contributing to much of the excess mortality in this group; worldwide estimates of mortality show people with psychosis die, on average, 25 years earlier than those in the general population [3, 4].

CVD is exceedingly prevalent in people with psychosis because of the high prevalence of risk factors [5]. Non-modifiable CVD risk factors are inborn and include having a family history of the condition, increasing age, ethnicity and male gender [6]. Modifiable risk factors for CVD are subject to change and constitute dyslipidaemia, hypertension, hyperglycaemia, inadequate physical activity, poor nutrition, smoking, central obesity, overweight (body mass index [BMI] of ≥25) and obesity (BMI ≥ 30) [7, 8]. Dyslipidaemia constitutes abnormally raised total or low-density lipoprotein (LDL) cholesterol or low high-density lipoprotein (HDL) cholesterol [9]. Hypertension is elevated blood pressure that is above established cut-off values while hyperglycaemia is raised blood glucose that is also above reference ranges [10, 11]. The National Health and Medical Research Council (NHMRC) considers nutrition poor if food intake is inconsistent with dietary guidelines and also defines physical activity as inadequate when one displays insufficient activity levels based on recommendations of minimum activity [12, 13]. A waist circumference of > 80 cm in women and > 94 cm in men is associated with increased risk of chronic disease and is known as central adiposity [8]. Atypical antipsychotic medications, the cornerstone of treatment in psychosis, also increase CVD risk by exacerbating weight gain, hyperglycaemia and dyslipidaemia [14].

The Survey of High Impact Psychosis (SHIP), Australia's second national psychosis survey, reported a high prevalence of modifiable CVD risk factors; more than half of the SHIP cohort (54%) presented with metabolic syndrome – a combination of hypertension, dyslipidaemia, hyperglycaemia and central obesity [15, 16]. Dyslipidaemia, hypertension and hyperglycaemia are a product of poor nutrition, smoking and inadequate physical activity, collectively known as lifestyle risk factors [17]. Pharmacological management of dyslipidaemia, hypertension and hyperglycaemia only partially decrease the risk of CVD in the presence of lifestyle risk factors [17]. The Diabetes Prevention Program research group found that metformin decreased the risk of diabetes almost twice as much in the group also receiving a lifestyle intervention [18]. In a prospective cohort study of 42,847 otherwise-healthy men taking medications for hypertension or hypercholesterolemia, 62% of deaths from coronary heart disease could have been prevented by adhering to dietary guidelines, not smoking and engaging in at least 30 min of physical activity per day [19]. Targeting lifestyle risk factors should therefore be central in CVD prevention [17].

Recently, questions have arisen as to what degree CVD lifestyle risk factors impact dyslipidaemia, hypertension and hyperglycaemia among people with psychosis [5, 20–22]. This is because people with psychosis have a 78% higher risk of developing CVD than the general population and develop the condition two decades earlier [23]. Having a psychotic disorder, in addition to medical management of psychosis, may confound the relationship between lifestyle risk factors and dyslipidaemia, hypertension and hyperglycaemia, which may increase the risk of CVD [21, 22, 24, 25]. Researchers in this field found that age, obesity, sedentary behaviour, family history of diabetes, treated hypertension and treated hypercholesterolemia show significant associations with current type 2 diabetes status among people with psychosis, however, authors acknowledge that additional unknown factors may further explain this relationship [26, 27]. Morgan, McGrath [24] and colleagues examined modifiable lifestyle risk factors with respect to metabolic syndrome and found that sedentary behaviour, overweight and obesity and smoking status all contribute to the metabolic syndrome among people with psychosis. Our research will add to this body of work by assessing the interplay of lifestyle risk factors with dyslipidaemia, hypertension and hyperglycaemia, whilst controlling for confounders [17].

In the general population, lifestyle risk factors for CVD tend to present in clusters [28]. Some suggest that a cluster of lifestyle risk factors for CVD should be treated as a single entity in intervention programs among groups likely to exhibit a cluster of all three risk factors [28]. This is because these interventions tend to be more effective and efficient at achieving intervention goals and minimize economic impact of lifestyle diseases [29–31]. People with psychosis are an ideal group to assess clustering of CVD lifestyle risk factors due to the high prevalence of the individual risk factors in this population [5, 15, 32, 33]. Correlates of physical activity and low fruit and vegetable intake – a measure of nutrition quality – have been identified in people with psychosis [32, 33]. The current paper will further this knowledge by identifying co-occurring patterns of all three lifestyle risk factors, and describe the demographic profiles of those presenting with different risk factor clusters which will be useful for the design, delivery and evaluation of lifestyle intervention programs in people with psychosis [5, 34, 35].

This study aims to describe the relationship between lifestyle risk factors for CVD – poor nutrition, smoking and low physical activity levels – and dyslipidaemia, hypertension and hyperglycaemia in a large cohort of men and women participating in SHIP, while controlling for potential confounding factors. Further, we identify clustering patterns of lifestyle risk factors in study participants, and describe the demographic characteristics associated with different clusters of lifestyle risk factors.

Methods

This is a cross-sectional analysis of data from Australian adults living with psychosis who participated in SHIP.

The survey of high impact psychosis (SHIP)

SHIP was conducted in seven catchment sites across Australia, which covered about 62,000km^2 with a total resident population of about 1.5 million of those aged 18 to 64 years. This is equivalent to almost 10% of the Australian population within the same age bracket.

The comprehensive SHIP methodology has been provided elsewhere [15, 24]. In summary, participants were considered for study inclusion if they resided in one of the seven study catchment sites and were also in contact with public specialised mental health services (MHSs) or community-managed organisations (CMOs; formerly non-government organisations) funded to support people with mental illnesses. A two-phase sampling technique was utilised to identify participants for study inclusion. Phase 1 involved a census of those in contact with MHSs and CMOs supporting people with mental illness in March 2010 as well those in contact with public MHSs 11 months prior to March 2010. A psychosis screener was used to identify psychosis-positive individuals who were then randomly selected to take part in Phase 2 of the study. In Phase 2, participants were stratified by age group and underwent a diagnostic interview, fasting blood tests, physical checks and cognitive functioning tests. Stratification by age group was to ensure adequate coverage of younger as well as older participants. Participants were excluded from the study if they resided in a nursing home or prison, or were incapable of communicating due to a language barrier or intellectual incapacity. A total of 1825 participants were included in Phase 2 and were thus part of the final sample included in SHIP.

Measures

Demographics

Demographic variables included: sex (male/female), age in years, Aboriginal or Torres Strait Islander descent (yes/no), current marital status (single or never married/married or de facto/separated or divorced/widowed), government pension as the main source of income (yes/no), highest qualification obtained (left school with no qualifications/secondary school qualification or leaving certificate/tertiary certificate/bachelor's degree/post-graduate qualifications/other), income per fortnight (AU$300 or less/AU$300-AU$499/AU$500-AU$799/AU$800-AU$1000/AU$1000 or more) and engagement in paid employment in the last 12 months (yes/no).

Diagnosis

The Diagnostic Module of the Diagnostic Interview for Psychosis (DIP-DM) was used to diagnostically describe the sample [36]. DIP-DM responses were scored and entered into a computer algorithm that employed the Operational Criteria for Psychosis (OPCRIT) to produce an International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD-10) diagnosis thus reducing the likelihood of subjective bias [36, 37]. The DIP-DM has good inter-rater reliability (kappa value of ≥ 0.6) and excellent diagnostic validity (90% consistency with the Schedules for Clinical Assessment in Neuropsychiatry) [36].

Nutrition

Retrospective responses for fruit and vegetable intake were used as measures of diet quality via items from Short Diet Questions used in the 1995 National Nutrition Survey (NNS) [38]. Fruit and vegetable intakes were measured separately for the four-week period preceding SHIP, using self-report questions [39]. Validity of 1995 NNS questions measuring fruit and vegetable intake when compared against 24-h recall data, were fair [39]. Validity assessments showed that those who reported consuming a greater number of serves of fruit and vegetables also had higher intake as per 24-h recall data; this information did not however correlate with standard serve estimates, which are the recommended portions, as serve sizes tend to be overestimated by those using the tool [39].

The Australian Dietary Guidelines (ADGs) developed by NHMRC were used as the benchmark for either meeting or not meeting fruit and vegetable recommendations [13]. The ADGs recommend consuming five serves of vegetables and two serves of fruit a day [13]. For the purposes of our analyses, fruit intake and vegetable intake scales were converted into dichotomous variables comprising 'met guidelines' and 'did not meet guidelines'.

Smoking dependence

Smoking dependence was measured using the Fagerstrom Test for Nicotine Dependence (FTND); a six-item tool used to measure addiction to smoking [40]. The FTND has acceptable test–retest reliability ($r = 0.65$) in the measurement of smoking behaviour in people with

psychosis [40]. The FTND scores were categorized into outcome categories ranging from non-smoking to high dependence [41].

Physical activity

Physical activity was measured using the International Physical Activity Questionnaire (IPAQ), which gives a retrospective self-reported measure of time in minutes spent performing moderate or vigorous activity in the 7 days prior to interview. This tool is validated in people with schizophrenia with a criterion validity of 0.37 which is similar to that of the general population [42].

Metabolic health and blood pressure

Fasting blood samples were obtained from consenting participants and analysed by an experienced hospital scientist to evaluate levels for total cholesterol, HDL-C, LDL-C and fasting blood glucose. Physical measurements inclusive of resting blood pressure were also obtained from participants. Metabolic health measures were evaluated against National Heart Foundation (NHF) targets [9]. For the purpose of this study, dyslipidaemia was indicated if total cholesterol was ≥4 mmol/L or HDL-C was ≤1 mmol/L or LDL-C was ≥2.5 mmol/L [9]. Hyperglycaemia was determined if fasting blood glucose was ≥5.6 mmol/L [16]. Finally, hypertension was indicated if systolic blood pressure was ≥140 mmHg or diastolic blood pressure was ≥90 mmHg [11].

Measurement of potential confounding variables

Based on previous literature, the following variables were tested for confounding: age, sex, psychotropic medications, diagnosis, education, income and employment [24–26]. Additional potential confounders were considered variables which, according to logistic regression analysis, were associated with the dependent variable at p level of < 0.2. Variables meeting this criterion were: clozapine use based on self-reported medications used for a period of ≥ 4 weeks in the 4 weeks preceding interview, sex and age.

Statistical analysis

Statistical tests were conducted using the Statistical Package for the Social Sciences version 23 (SPSS). Descriptive statistics were performed for all variables.

Three logistic regressions were used to predict the effect of nutrition, smoking and physical activity on i) dyslipidaemia ii) hypertension and iii) hyperglycaemia. The models were controlled for the confounding variables, clozapine use, sex and age.

Clustering of nutrition, smoking and physical activity behaviour were examined using the two-step cluster method - a mode of hierarchical cluster analysis - to assess whether lifestyle risk factor patterns were evident [43, 44]. The two-step cluster method was used for the analysis because a large number of cases can effectively be processed ($n > 1000$ is considered large for cluster analysis) as-well-as categorical and continuous data [43, 44]. The two-step cluster analysis is most effective when all variables are independent, continuous variables are normally distributed, and categorical variables have a multinomial distribution [43, 44]. Cluster analysis still produces valid results even when cluster data do not meet the identified requirements for best practice because significance levels are not calculated as part of the test [43, 44].

The two-step clustering method uses a model-based measure of distance which defines the distance between two clusters prior to merging them [45]. Step 1 in the two-step cluster analysis involves pre-cluster formation to reduce the matrix size by minimizing distances between all pairs of cases [43, 44]. All cases in the same pre-cluster are treated as a single entity following this initial step [43, 44]. Step 2 of the two-step cluster analysis is a modified hierarchical agglomerative process where pre-clusters from Step 1 are combined sequentially, to form homogenous clusters [43, 44]. The two-step cluster method thus produces clusters through minimising within-cluster variance and maximizing between-cluster variance [43, 44]. The two-step cluster procedure provides an overall goodness-of-fit measure called silhouette measure of cohesion and separation [43, 44], which is based on average distances between objects and ranges from − 1 to + 1 [43, 44]. Silhouette measures of < 0.2 indicate poor cluster quality, measures of 0.2–0.5 indicate a fair cluster quality and measures > 0.5 indicate a good cluster quality [43, 44].

To ascertain that lifestyle risk factor clusters were different from each other, as cluster analysis does not involve hypothesis testing, clusters were compared using chi-squared tests, one-way analysis of variance (ANOVA) tests, or Welch ANOVA, depending on which test assumptions the different variables satisfied [43, 44]. Where results from the ANOVA were statistically significant, a Tukey HSD post hoc was used to assess specific differences between the lifestyle risk factors. Where the Welch ANOVA produced statistically significant results, the Games-Howell post hoc test was performed to assess specific differences between the lifestyle risk factors. Demographic variables of participants were also compared across the lifestyle risk factor clusters using chi-squared tests or ANOVA depending on suitability. Variables included in the demographic comparison of clusters were: sex, age in years, current marital status, highest qualification obtained, diagnosis and government pension as main source of income.

A statistical result was considered significant if $p < 0.05$.

Results

Sample characteristics (see Table 1)

Men comprised more than half of the sample (59.6%) with a mean participant age of 38 years (SD = 11.16). Only 4.9% from the cohort were of Aboriginal or Torres Strait Islander descent and most were single or never married (61.2%). Schizophrenia was the most prevalent diagnosis (47.0%) and most of the cohort (85.0%) received a government pension as the main source of income. A significant proportion of the sample (40.5%) had at least a tertiary certificate while more than half (59.2%) earned between $500 and $799 per fortnight. Most of the sample did not meet recommendations for vegetable intake (87.8%) or for fruit intake (71.1%). Almost one fifth of the cohort did not meet NHF's target for HDL-C (22.5%) and over half did not meet the target for LDL-C (50.6%). An even greater proportion (64.8%) did not meet total cholesterol targets. Most participants were dyslipidaemic (70.7%) whereas about one-fifth displayed hyperglycaemia (21.8%). About one-third of the cohort (33.9%) had hypertension. Just under one-third of the cohort (31.6%) had moderate nicotine dependence with a slightly higher proportion being non-smokers (36.2%). The average vigorous and moderate physical activity undertaken per week was 150 min (SD = 354.3) and 120 min (SD = 383.6) respectively.

Logistic regression modelling (see Tables 2, 3 and 4)

According to logistic regression analysis, associations of fruit intake, vegetable intake, total vigorous activity and total moderate activity with dyslipidaemia were not statistically significant. However, participants who did not smoke were about 50% less likely to have dyslipidaemia than those who smoked [Odds Ratio (OR) =0.54; 95% Confidence Interval (CI): 0.35–0.83; $p = 0.005$). Adjusting the analysis for clozapine use, sex and age resulted in little difference of the effect of smoking on dyslipidaemia (OR = 0.50; 95% CI: 0.32–0.78; $p = 0.002$) (Table 2).

Smoking, fruit intake, vegetable intake, total vigorous activity and total moderate activity were not significantly associated either with hypertension (Table 3) or hyperglycaemia (Table 4).

Cluster analysis (see Table 5)

The two-step cluster analysis yielded three clusters with a silhouette measure of cohesion and separation of 0.5, indicating fair cluster quality. Cluster 1 ($n = 401$) had the fewest members and was characterised by the poorest lifestyle risk behaviours. All (100%) of cluster 1 members failed to meet recommendations for fruit or vegetable intake and had moderate dependence to nicotine. Total time per week spent engaging in vigorous physical activity was 22.5 min (SD = 80.2) whereas the total time spent engaging in moderate physical activity per week was 52 min (SD = 135.2). Cluster 2 ($n = 771$) differed from cluster 1 in that almost half of ($n = 46.8\%$) cluster 2 members did not smoke, however, like cluster 1, almost all (97.8%) cluster 2 members failed to meet recommendations for fruit intake or for vegetable intake. Activity levels in cluster 2 were also low with the average time spent engaging in vigorous and moderate physical activity per week being 29 min (SD = 85.2) and 37.1 min (SD = 91.4) respectively. Cluster 3 ($n = 653$) was characterised by higher activity levels with average time spent engaging in vigorous activity and moderate physical activity being 107 min (SD = 297.3) and 136 min (SD = 368.3) respectively. More than three-quarters (78.3%) of cluster 3 members met fruit intake recommendations, in contrast to clusters 1 and 2.

When lifestyle risk factors were assessed for difference across different clusters, statistically significant results were obtained for all behaviours. There was a statistically significant difference in fruit intake across the clusters (x^2 (4) = 1288.69, $p < 0.001$). All participants in cluster 1 (100%) failed to meet fruit intake recommendations, comparable to cluster 2 (97.8%), while in cluster 3, most met recommendations (78.3%). Similarly, vegetable intake differed across the clusters (x^2 (4) = 436.39, $p < 0.001$): all participants in cluster 1 (100%) failed to meet recommendations for vegetable intake, comparable to cluster 2 (97.8%) participants whereas 68.5% of cluster 3 participants failed to meet recommendations.

Smoking rates as measured by the FTND differed between the clusters (x^2 (8) = 1257.55, $p < 0.001$). All cluster 1 participants had a moderate dependence to nicotine (100%), compared with almost half of cluster 2 (46.8%) and cluster 3 (45.9%) participants, who did not smoke.

Time spent engaging in vigorous activity was significantly different across the clusters (F (2, 994.5) = 23.4, $p < 0.001$). Games-Howell post hoc analysis revealed statistically significant differences between clusters 2 and 3 ($p < 0.001$) and between clusters 1 and 3 ($p < 0.001$). Time spent engaging in moderate physical activity also differed across the clusters (F (2, 833.3) = 24.1, $p < 0.001$). Similarly, Games-Howell post hoc analysis also revealed statistically significant differences between clusters 2 and 3 ($p < 0.001$) and clusters 1 and 3 ($p < 0.001$). When participants' demographic characteristics were compared across the three clusters, there was a significant association between cluster membership and sex (x^2 (2) =13.75, $p = 0.001$). The largest proportion of men was in cluster 1 (66.1%), compared to cluster 2 (60.3%) and cluster 3 (54.7%).

There was also a significant difference in age of participants across the clusters (F (2, 1798) = 5.9, $p = 0.003$).

Table 1 Sociodemographic, Lifestyle and Metabolic Characteristics of Participants from the Survey of High Impact Psychosis

		N = 1825 (N %) M (SD)
Sex	Males	1087 (59.6%)
	Female	738 (40.4%)
Age	Mean	38.36 (11.16)
Aboriginal/ Torres Strait Islander descent	No	1735 (95.1%)
	Yes	90 (4.9%)
Marital Status	Single/ Never Married	1117 (61.2%)
	Married/ De facto	312 (17.1%)
	Separated/ Divorced	376 (20.6%)
	Widowed	20 (1.1%)
Diagnosis	Schizophrenia	857 (47.0%)
	Schizoaffective	293 (16.1%)
	Bipolar, mania	319 (17.5%)
	Depressive psychosis	81 (4.4%)
	Delusional disorders and other non-organic psychosis	92 (5.0%)
	Severe depression disorder	158 (8.7%)
	Screen-positive for psychosis but did not meet full criteria for ICD-10 psychosis	25 (1.4%)
Government pension, allowance or benefit as the main source of income	No	254 (13.9%)
	Yes	1551 (85.0%)
Highest qualification attained	Left school no qualifications	615 (33.7%)
	Secondary school qualification/leaving certificate	304 (16.7%)
	Tertiary Certificate	739 (40.5%)
	Bachelor's Degree	92 (5.0%)
	Postgraduate Qualifications	28 (1.5%)
	Other	32 (1.8%)
	Missing	15 (0.8%)
Income per Fortnight	Less than $300 per fortnight	58 (3.2%)
	Between $300 - $499 per fortnight	209 (11.5%)
	Between $500 - $799 per fortnight	1080 (59.2%)
	Between $800 - $1000 per fortnight	232 (12.7%)
	More than $1000 per fortnight	139 (7.6%)
	Missing	107 (5.9%)
Vegetables consumed (no of serves per day in the last 4 weeks)	Met recommendations (≥4–5 serves/day)	206 (11.3%)
	Did not meet recommendations (≤0–3 serves/day)	1602 (87.8%)
	Missing	17 (0.9%)
Fruit consumed (no of serves per day in the last 4 weeks)	Met recommendations (≥2–3 serves/ day)	511 (28.0%)
	Did not meet recommendations (≤1 serve/ day)	1297 (71.1%)
	Missing	17 (0.9%)
HDL-C level	Mean	1.18 (0.42)
	Met target > 1 mmol/L	966 (52.9%)
	Did not meet target ≤1 mmol/L	411 (22.5%)
	Missing	448 (24.5%)
LDL-C level	Mean	3.13 (1.29)
	Met target < 2.5 mmol/L	326 (20.6%)
	Did not meet target ≥2.5 mmol/L	923 (50.6%)
	Missing	526 (28.8%)
Total Cholesterol	Mean	5.09 (1.19)
	Met target < 4 mmol/L	209 (11.5%)
	Did not meet target ≥4 mmol/L	1182 (64.8%)
	Missing	434 (23.8%)
Dyslipidaemia	Not Dyslipidemic	92 (5.0%)
	Dyslipidemic	1290 (70.7%)
	Missing	443 (24.3%)
Fasting plasma glucose	Mean	5.4 (1.21)
	Not hyperglycaemic (< 5.6 mmol/L)	990 (54.2%)
	Hyperglycaemic (≥5.6 mmol/L)	397 (21.8%)
	Missing	438 (24.0%)
Systolic blood pressure	Not hypertensive (< 140 mmHg)	1520 (83.3%)
	Hypertensive (≥140 mmHg)	246 (13.5%)
	Missing	59 (3.2%)
Diastolic blood pressure	Not hypertensive (< 90 mmHg)	1273 (69.8%)
	Hypertension (≥90 mmHg)	493 (27.0%)
	Missing	59 (3.2%)
Total Hypertensive	Not hypertensive (systolic < 140 mmHg or diastolic < 90 mmHg)	1207 (66.1%)
	Hypertensive (systolic ≥140 mmHg or diastolic ≥90 mmHg)	559 (30.6%)
	Missing	59 (3.2%)

Table 1 Sociodemographic, Lifestyle and Metabolic Characteristics of Participants from the Survey of High Impact Psychosis *(Continued)*

		N = 1825 (N %) M (SD)
Smoking- Fagerstrom test for nicotine dependence	Does not smoke	661 (36.2%)
	Low dependence	74 (4.1%)
	Low to moderate dependence	187 (10.2%)
	Moderate dependence	576 (31.6%)
	High dependence	327 (17.9%)
Time in min spent engaging in vigorous physical activity/ week	Mean	150.0 (354.3)
Time in min spent engaging in moderate physical activity/ week	Mean	120.0 (383.6)

ICD: International Statistical Classification of Diseases and Related Health Problems; M (SD) - mean (standard deviation). Missing data were either not provided by participants or could not be detected in the lab in the case of metabolic health measures

Participants in cluster 1 were the youngest (36.77 ± 10.5) compared to those from cluster 2 (38.46 ± 11.5) and cluster 3 (39.23 ± 11.1). Tukey's HSD post hoc analyses revealed that there were statistically significant differences between clusters 1 and 2 (p = 0.019) and clusters 1 and 3 (p = 0.001).

There was a statistically significant difference in the highest qualifications attained by participants across the clusters (x^2 (12) = 27.02, p = 0.008). A smaller percentage of participants in clusters 1 and 2 had tertiary certificates (39.2 and 39.6% respectively) than in cluster 3 (42.4%). Finally, there was a statistically significant difference in those receiving a government pension as their main source of income across the clusters (x^2 (2) = 15.953, p < 0.001). Cluster 1 had 89.8% of participants receiving a government pension as the main source of income whereas this percentage was 86.1% for cluster 2 and 80.7% for cluster 3.

Discussion

The aim of this study was to describe the relationship between lifestyle risk factors for CVD, which are poor nutrition, smoking and low physical activity levels with dyslipidaemia, hypertension and hyperglycaemia in people living with psychosis while controlling for confounders. Smoking had a significant positive association with dyslipidaemia but showed no association with hypertension or hyperglycaemia. Fruit intake, vegetable intake, and physical activity were however not associated with dyslipidaemia, hypertension or hyperglycaemia. Clozapine use, sex and age were identified as potential confounding factors in the relationship between the lifestyle risk factors and dyslipidaemia, hypertension and hyperglycaemia, however their impact was marginal. This study also aimed to find clustering patterns of lifestyle risk factors and their associated demographic profiles and consequently identified three clusters.

Participants with who did not smoke were 50% less likely to have dyslipidaemia than those who smoked; no association was however found between fruit intake, vegetable intake, and physical activity levels with dyslipidaemia. The relationship between smoking and dyslipidaemia mirrors that of the general population [46–48]. However, research in the general population shows that consuming certain fruits and vegetables has a positive impact on markers of dyslipidaemia; nutrition tools used in our study were not specific to type of fruit or vegetables consumed, possibly explaining why our results did not reflect those from the general population [49–51]. Similarly, our results did not reflect the inverse relationship between physical activity levels and dyslipidaemia in the general population [52, 53]. Despite using a validated tool to measure physical activity levels, it is possible that factors such as participant bias, impaired memory, and confounding factors unique to this cohort impacted validity of the results in varying degrees [24, 25, 40, 42, 51, 54]. Future studies in people with psychosis can combat this by combining self-reported data with direct measures of physical activity levels [55, 56]. Lifestyle risk factors and unknown confounders are the likely cause of high rates of dyslipidaemia in people with psychosis thus, the use of lifestyle intervention efforts could be recommended [48–51].

We did not find any relationship between fruit and vegetable intake, smoking and physical activity levels with hypertension. Our results mirrored those in the general population except in the case of fruit intake and physical activity, which both have a negative relationship with hypertension [57–60]. Reasons for this are likely similar to those explained in the case of dyslipidaemia [56, 61].

Finally, fruit and vegetable intake, smoking and physical activity levels were not related to hyperglycaemia. In the general population, however, there is an inverse relationship between consumption of certain fruits and vegetables and the risk of type 2 diabetes [60]. Findings from the general population also confirm a positive relationship between smoking and risk of type 2 diabetes and a negative relationship between physical activity and type 2 diabetes risk [62, 63]. In addition to previously discussed limitations, discrepancy of our findings to those in the general population may exist because we used hyperglycaemia (≥5.6 mmol/L) to detect risk of type 2 diabetes; risk of type 2 diabetes considerably increases if fasting blood glucose is between 6.1–6.9 mmol/L or if plasma glucose is between 7.8–

Table 2 Logistic Regression Analysis of Smoking, Vegetable and Fruit Intake, and Physical Activity with Dyslipidaemia for Survey of High Impact Psychosis Participants

Independent Variables	Dependent Variable	Unadjusted Odds Ratio, (95% CI) and *p*-value	Adjusted Odds Ratio [a], (95% CI) and *p*-value
Smoking Status ([b]Non Smokers /Smokers)		0.54	0.50
		(0.35–0.83)	(0.32–0.78)
		0.005	*0.002***
Vegetable intake ([b]Did not meet recommendations/ Met recommendations)		1.09	1.01
		(0.71–1.67)	(0.66–1.54)
		0.69	0.96
Fruit intake ([b]Did not meet recommendations/ Met recommendations)	Dyslipidaemia	1.06	1.12
		(0.71–1.67)	(0.77–1.65)
		0.79	0.54
Total vigorous activity in min/ week		1.00	1.00
		(1.00–1.00)	(1.00–1.00)
		0.04	0.10
Total moderate activity in min/ week		1.00	1.00
		(1.00–1.00)	(1.00–1.00)
		0.58	0.55

[a] Adjusted for clozapine use, sex and age; [b] – reference value; ** $p < 0.05$; ***$p < 0.01$; ****$p < 0.001$; CI- Confidence interval

11.0 mmol/L based on a 2 h oral glucose tolerance test [10]. Uncontrolled hyperglycaemia can however still progress to type 2 diabetes, therefore, it is important that this risk is mitigated through lifestyle intervention [64].

Importantly, we showed that lifestyle risk factors occur in clusters among people with psychosis. The cluster with the highest prevalence of low fruit and vegetable intake, smoking and low physical activity had the highest proportion of men, who were younger, less likely to have a tertiary certificate and received a government pension as the main income. Research in the general population also found that younger men are most at risk for poor lifestyle risk behaviours [65, 66]. Younger unemployed men with psychosis are thus an important group to target in lifestyle interventions focusing all three lifestyle risk factors.

Table 3 Logistic Regression Analysis of Smoking, Vegetable and Fruit Intake, and Physical Activity with Hypertension for Survey of High Impact Psychosis Participants

Independent Variables	Dependent Variable	Unadjusted Odds Ratio, (95% CI) and p-value	Adjusted Odds Ratio [a], (95% CI) and *p*-value
Smoking Status ([b]Non Smokers /Smokers)		0.97	0.99
		(0.78–1.19)	(0.80–1.23)
		0.75	0.92
Vegetable intake ([b]Did not meet recommendations/ Met recommendations)	Hypertension	1.16	1.21
		(0.94–1.43)	(0.98–1.50)
		0.16	0.08
Fruit intake ([b]Did not meet recommendations/ Met recommendations)		0.95	0.89
		(0.78–1.15)	(0.73–1.09)
		0.60	0.26
Total vigorous activity in min/ week		1.00	1.00
		(1.00–1.00)	(1.00–1.00)
		0.68	0.71
Total moderate activity in min/ week		1.00	1.00
		(1.00–1.00)	(1.00–1.00)
		0.94	0.81

[a] Adjusted for clozapine use, sex and age; [b] – reference value; ** $p < 0.05$; ***$p < 0.01$; ****$p < 0.001$; CI- Confidence interval

Table 4 Logistic Regression Analysis of Smoking, Vegetable and Fruit Intake, and Physical Activity with Hyperglycaemia for Survey of High Impact Psychosis Participants

Independent Variables	Dependent Variable	Unadjusted Odds Ratio, (95% CI) and *p*-value	Adjusted Odds Ratio [a], (95% CI) and *p*-value
Smoking Status ([b]Non Smokers /Smokers)	Hyperglycaemia	1.09	1.15
		(0.86–1.40)	(0.89–1.48)
		0.47	0.29
Vegetable intake ([b]Did not meet recommendations/ Met recommendations)		1.07	1.15
		(0.83–1.38)	(0.88–1.49)
		0.60	0.29
Fruit intake ([b]Did not meet recommendations/ Met recommendations)		1.17	1.04
		(0.89–1.40)	(0.83–1.31)
		0.33	0.73
Total vigorous activity in min/ week		1.00	1.00
		(1.00–1.00)	(1.00–1.00)
		0.038	0.16
Total moderate activity in min/ week		1.00	1.00
		(1.00–1.00)	(1.00–1.00)
		0.60	0.62

[a] Adjusted for clozapine use, sex and age; [b] – reference value;** $p < 0.05$; ***$p < 0.01$; ****$p < 0.001$; CI- Confidence interval

Participants in this study were most likely to belong to the cluster with low fruit and vegetable intake and low physical activity levels but least likely to smoke. This information highlights that people with psychosis mainly struggle with the nutrition and physical activity aspects of their lifestyle [15]. The demographic profile of this group appears to be mixed across age, gender, education and income. Nutrition and physical activity should thus be one of the primary focus areas of lifestyle interventions delivered to people with psychosis.

The final cluster in this cohort was characterised by a significant proportion of participants meeting fruit and vegetable recommendations, lower smoking rates and higher physical activity levels. This cluster had the highest proportion of women, showed a tendency towards increasing age, a higher proportion had tertiary certificates and fewer participants relied on government pensions as the main income. Similar demographic characteristics were found in the general population among those most likely to display healthy lifestyle behaviours [66, 67]. These results imply that socioeconomic or cognitive factors may be related to engagement with healthy lifestyle behaviours [66, 67]. The socioeconomic and cognitive profile of participants should therefore be considered during the conception of lifestyle interventions not only among people with psychosis but also in the general population so that solutions offered are viable for the target population [66, 67].

Strengths and limitations

Due to the cross-sectional nature of SHIP, cause and effect relationships cannot be confirmed from our results, therefore, longitudinal research should be carried out to broaden findings from the current study [15]. SHIP is however to date the largest, representative study of people with psychosis in Australia [15]. SHIP covered a broad range of topics (in a long interview with the potential to lead to participant fatigue), thus, direct, detailed and longitudinal information on nutrition, smoking, physical activity and metabolic health could not be obtained [15]. To ameliorate this however, trained interviewers with excellent inter-rater reliability administered SHIP, using validated tools in the measurement of nutrition, smoking, physical activity, diagnosis, and metabolic health, minimizing bias [15].

Conclusions

In summary, smoking status had a significant positive association with dyslipidaemia but showed no relationship with hypertension and hyperglycaemia [38]. Fruit and vegetable intake and physical activity were however not associated with dyslipidaemia, hypertension and hyperglycaemia, which in some cases contradicted previous research [56, 61, 68]. Although this was the case, previous literature from the general population gives us reason to recommend lifestyle interventions as the primary prevention for CVD among people with psychosis [17]. Additionally, clozapine use, sex and age did not seem to have a significant impact in the relationship between lifestyle risk factors and dyslipidaemia, hypertension and hyperglycaemia - hence other confounding factors need to be identified and their impact quantified. Finally, lifestyle risk factors for CVD occurred in three

Table 5 Cluster Analysis for Fruit Intake, Vegetable Intake, Smoking and Physical Activity in Survey of High Impact Psychosis Participants and Associated Demographic Profiles

Variables used for Cluster Formation		Cluster 1 n = 401 (22% of SHIP cohort) (N %) (poorest lifestyle behaviours)*	Cluster 2 n = 771 (42% of SHIP cohort) (N %) (mixture of poor and healthy lifestyle behaviours)*	Cluster 3 n = 653 (36% of SHIP cohort) (N %) (healthiest lifestyle behaviours)*	Statistical Test
Fruit consumed (no of serves per day in the last 4 weeks)	Met recommendations (≥2–3 serves/ day)	–	2.2	78.3	x^2 (4) = 1288.69, $p < 0.001$****
	Did not meet recommendations (≤1 serve/ day)	100	97.8	21.7	
Vegetables consumed (no of serves per day in the last 4 weeks)	Met recommendations (≥4–5 serves/day)	–	2.2	31.5	x^2 (4) = 436.39, $p < 0.001$****
	Did not meet recommendations (≤0–3 serves/day)	100	97.8	68.5	
Smoking- Fagerstrom test for nicotine dependence	Does not smoke	–	46.8	45.9	x^2 (8) = 1257.55, $p < 0.001$****
	Low dependence	–	6.4	3.8	
	Low to moderate dependence	–	16.1	9.6	
	Moderate dependence	100	0.5	26.2	
	High dependence	–	30.2	14.4	
Time in min spent engaging in vigorous physical activity/ week		22.5 (80.2)[a]	29.0 (85.2)[b]	107.3 (297.3)[c]	(F (2, 994.5) = 23.4, $p < 0.001$****) GH [a vs b] $p = 0.355$ [b vs c] $p < 0.001$**** [a vs c] $p < 0.001$****
Time in min spent engaging in moderate physical activity/ week		52 (135.2)[a]	37.1 (91.4)[b]	136.6 (368.3)[c]	(F (2, 833.3) = 24.1, $p < 0.001$****) GH [a vs b] $p = 0.088$ [b vs c] $p < 0.001$**** [a vs c] $p < 0.001$****
Demographics Characteristics of Clusters					
Sex	Males	66.1	60.3	54.7	x^2 (2) =13.75, $p = 0.001$***
	Females	33.9		45.3	
Age		36.77 (10.5)[a]	38.46 (11.5)[b]	39.23 (11.1)[c]	(F (2, 1798) = 5.9, $p = 0.003$***) T-HSD [a vs b] $p = 0.019$** [b vs c] $p = 0.160$ [a vs c] $p = 0.001$***
Marital status	Single/ Never Married	66.3	59.7	59.9	x^2 (6) = 7.35, $p = 0.289$
	Married/ De facto	15.2	18.0	17.2	
	Separated/ Divorced	17.7	21.4	21.4	

Table 5 Cluster Analysis for Fruit Intake, Vegetable Intake, Smoking and Physical Activity in Survey of High Impact Psychosis Participants and Associated Demographic Profiles *(Continued)*

Variables used for Cluster Formation		Cluster 1 n = 401 (22% of SHIP cohort) (N %) (poorest lifestyle behaviours)*	Cluster 2 n = 771 (42% of SHIP cohort) (N %) (mixture of poor and healthy lifestyle behaviours)*	Cluster 3 n = 653 (36% of SHIP cohort) (N %) (healthiest lifestyle behaviours)*	Statistical Test
	Widowed	0.7	0.9	1.5	
Highest qualification obtained	Left school no qualifications	37.7	34.0	30.9	x^2 (12) = 27.02, $p = 0.008$***
	Secondary school qualification/ leaving certificate	17.7	15.2	17.8	
	Tertiary Certificate	39.2	39.6	42.4	
	Bachelor's Degree	3.0	6.7	4.3	
	Postgraduate Qualifications	0.5	1.3	2.5	
	Other	1.5	2.3	1.2	
Diagnosis	Schizophrenia	48.9	47.9	44.7	x^2 (30) = 30.66, $p = 0.432$
	Schizoaffective	17.2	14.6	17.1	
	Bipolar, mania	15.7	15.7	19.8	
	Depressive psychosis	3.5	5.4	3.8	
	Delusional disorders and other non-organic psychosis	1.2	5.1	4.5	
	Severe depression disorder	5.9	1.4	1.8	
	Screen-positive for psychosis but did not meet full criteria for ICD-10 psychosis	1.5	1.3	1.4	
Government pension, allowance or benefit as the main source of income	No	9.7	12.7	17.9	x^2 (2) = 15.953, $p < 0.001$****
	Yes	89.8	86.1	80.7	

*clusters names are attributed to the most pronounced health behaviour characteristics in each cluster;** $p < 0.05$; ***$p < 0.01$; ****$p < 0.001$; SHIP- Survey of High Impact Psychosis; x^2-Chi Square test; F- ANOVA- One-Way Analysis of Variance or Welch ANOVA; T-HSD- Tukey's honestly significant difference post hoc analysis; GH- Games-Howell- post hoc analysis

main clusters with characteristic demographic profiles which could be useful for the design and implementation of lifestyle intervention programs in people with psychosis.

Abbreviations

ADGs: Australian Dietary Guidelines; BMI: Body mass index; CMOs: Community-managed organisations; CVD: Cardiovascular disease; DIP-DM: Diagnostic Module of the Diagnostic Interview for Psychosis; FTND: Fagerstrom Test for Nicotine Dependence; HDL-C: High-density lipoprotein cholesterol; ICD: International Statistical Classification of Diseases and Related Health Problems; IPAQ: International Physical Activity Questionnaire; LDL-C: Low-density lipoprotein cholesterol; MHSs: Mental health services; NHF: National Heart Foundation; NHMRC: The National Health and Medical Research Council; NNS: National Nutrition Survey; SHIP: Survey of High Impact Psychosis; SPSS: Statistical Package for the Social Sciences; SPSS: Statistical Package for the Social Sciences

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Availability of data and materials

Data that support findings are restricted to researchers who have permission from the SHIP Study Group, and so are not publicly available. For further information regarding access, please contact Dr. Mary-Claire Hanlon (Mary-Claire.Hanlon@uon.edu.au).

Authors' contributions

LEC and M-CH were involved in implementing and reporting the SHIP; DM, M-CH and MM analysed the data; DM, LM-W, M-CH and MM contributed towards the writing of the manuscript. All authors read and approved the final manuscript.

Ethics approval and consent to participate

Ethics approval was provided for all sites by the relevant Human Research Ethics Committees (HREC) (University of Western Australia HREC- RA/4/1/2478, South Australia Health HREC- 2009179, Queensland Health HREC- 52-09, Melbourne Health HREC- 2010.011, St. Vincent's Hospital Melbourne HREC- 119/09, Hunter New England HREC- 09/11/18/5.10, Greater Western Area Health Service HREC- SSA/10/GWAHS/2). The Declaration of Helsinki was adhered to during all steps of the study. All participants provided written informed consent.

Competing interests

The authors declare that they have no competing interests.

Publisher's Note

Author details

[1]Faculty Health and Medicine, The University of Newcastle, Callaghan 2308, Australia. [2]Brain and Mental Health Program, Hunter Medical Research Institute, New Lambton 2305, Australia. [3]Priority Research Centre for Brain and Mental Health, The University of Newcastle, Callaghan 2308, Australia. [4]School of Medicine and Public Health, The University of Newcastle, Callaghan 2308, Australia. [5]Faculty of Science, The University of Newcastle, Callaghan 2308, Australia. [6]Priority Research Centre GrowUpWell, The University of Newcastle, Callaghan 2308, Australia. [7]Centre for Clinical Epidemiology & Biostatistics, Hunter Medical Research Institute, New Lambton 2305, Australia. [8]Priority Research Centre for Physical Activity and Nutrition, The University of Newcastle, Callaghan 2308, Australia.

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Chapter 4: Self-Reported Nutrition and Physical Activity Program Utilisation among Australians with Psychosis: A Cross-sectional Analysis of Data

4.1: Study Overview

This study focused on community interventions which target lifestyle risk in people with psychosis. Community nutrition and physical activity interventions were the primary area of interest because these two behaviours are most likely to cluster in people with psychosis, and can be effectively managed through lifestyle intervention strategies—an area of focus in this thesis (84) (205, 206). Although it was known that 36.5% of Australians with psychosis access different programs in the community, it was unclear what proportion utilise nutrition and physical activity programs (219). Moreover, the nutrition and physical activity effects of utilising these programs was also not known (9). A cross-sectional data analysis was therefore completed which aimed to describe the self-reported attendance of community nutrition and physical activity programs in the government and non-government sector among the 1,825 Survey of High Impact Psychosis (SHIP) participants, and identify demographics associated with overall self-reported program attendance. This study also aimed to assess whether improved nutrition and physical activity outcomes were associated with program attendance.

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Research Article

Self-Reported Nutrition and Physical Activity Program Utilisation among Australians with Psychosis: A Cross-Sectional Analysis of Data

Doreen Mucheru[1*], Mary-Claire Hanlon[1,2], Linda E. Campbell[2,3], Mark McEvoy[1,4], Lesley MacDonald-Wicks[1,5]

[1]Faculty Health and Medicine, The University of Newcastle, Australia

[2]Brain and Mental Health Program, Hunter Medical Research Institute, Australia

[3]Faculty of Science, The University of Newcastle, Australia

[4]Centre for Clinical Epidemiology & Biostatistics, Hunter Medical Research Institute, Australia

[5]Priority Research Centre for Physical Activity and Nutrition, The University of Newcastle, Australia

[*]**Corresponding author:** Doreen Mucheru, Faculty of Health and Medicine, The University of Newcastle, Callaghan NSW 2308, Australia. Tel: +61-249854928; Email: Doreen.Mucheru@uon.edu.au

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Abstract

Objective: To describe the self-reported attendance of community nutrition and physical activity programs in the government and non-government sector among 1825 people from the Survey of High Impact Psychosis (SHIP), and identify demographics associated with overall self-reported program attendance. Additionally, to assess whether improved nutrition and physical activity outcomes were associated with program attendance.

Methods: In this cross-sectional analysis of data from SHIP, descriptive statistics were generated and tests-of-association applied between program attendance, and demographics, nutrition and physical activity outcomes.

Results: Just 11.6% attended a nutrition or physical activity program. Overall attendance was associated with highest education qualifications attained (p=0.004) and diagnosed disorder (p=0.022). Non-government sector attendees were more likely to consume reduced fat milk (p=0.010), and less likely to run out of food (p=0.007).

Conclusions: There is extremely low utilisation of community nutrition and physical activity programs in Australians with psychosis which is associated with certain demographics that may act as barriers. Program attendance did not show consistent association with improved nutrition or physical activity outcomes.

Implications for public health: Nutrition and physical activity program utilisation should be encouraged in people with psychosis by addressing problems related to access. These programs should be evaluated locally to ensure usefulness.

Keywords: Community programs; Nutrition; Physical activity; Psychosis

Introduction

People living with psychosis report extremely poor nutrition and physical activity outcomes [1]. Dietary choices made by those in this group often comprise of high-fat-low-fibre foods and fewer fruits and vegetables [1,2]. They are also less likely to meet physical activity targets than the general population, and primarily engage in physical activity through light walking [3]. Poor nutrition and low physical activity are likely to coexist in people with psychosis, and show the greatest propensity of co-occurrence compared to other lifestyle risk factors [4,5].

High rates of physical illness seen in this group, are largely linked to nutrition and physical activity patterns that do not adhere to recommended guidelines [6]. Overweight, obesity, dyslipidaemia, hypertension, type 2 diabetes, metabolic syndrome and Cardiovascular Disease (CVD) are some of the resulting conditions [6]. Over one-quarter (26.8%) of participants from the Survey of High Impact Psychosis (SHIP) aged 18-64 years

reported having a cardiovascular condition and half (53.5%) had metabolic syndrome [1]. In the Australian general population, 22% of those ≥18 years reported having some form of CVD in the 2014-15 National Health Survey, and 31% of those from the AusDiab study met criteria for metabolic syndrome [7,8]. Physical health differences between people with psychosis and the Australian general population are likely to be greater than those reflected here; this is because physical health findings from the Australian general population also include those of persons ≥65 years, and they show increased susceptibility to CVD and metabolic syndrome [7,8]. Health promotion programs therefore need to target nutrition and physical activity in a way specific to those living with psychosis, so that they are empowered to have more control over their health [6,9]. Provision and utilisation of health promotion services in the community setting is crucial to ensure this [10].

Health programs available for Australians with psychosis are provided via the government and non-government sectors; targeted behaviours include nutrition and physical activity [10]. These programs are generally described as community-based or community programs to indicate that they are for those who are not inpatients [11,12].

Raudino et al. [10] described general service utilisation patterns among Australians with psychosis, however, specific emphasis on community nutrition and physical activity programs was outside the scope of this study. Overall, study findings highlighted increased use of outpatient or community services in the past decade; those accessing programs of any kind were 1.5 times more likely to live alone and 40% more likely to report unemployment [10].

Community nutrition and physical activity programs have the potential to achieve outcomes comparable to those cited in research studies assessing efficacy of nutrition and physical activity programs in people with psychosis [13]. Results from randomised controlled studies in this field highlight significant decreases in weight (4 kg) and body-mass-index (3 points) [13]. Research and evaluation of community programs would then provide a basis for exploration of factors associated with program use in people with psychosis, as they face various challenges relating to their health, employment, income, housing and social interactions [1,10,14].

Furthermore, outcomes associated with utilising community nutrition and physical activity programs ought to be identified specifically for those with psychosis, as this will clarify the kind of outcomes that can be anticipated [15]. These findings would be useful for both service users and providers, allowing for service advocacy where there is associated participant benefit, and also providing incentive for service evaluation where participant benefits are not detected [16].

Our study aimed to describe the self-reported attendance of community nutrition and physical activity programs in the government and non-government sector among 1825 people from the Survey of High Impact Psychosis (SHIP), and identify demographics associated with overall self-reported program attendance. Additionally, we aimed to assess whether improved nutrition and physical activity outcomes were associated with program attendance.

Methods

This study is a cross-sectional analysis of data from the Survey of High Impact Psychosis conducted by Morgan, et al. [1] in 2010.

Survey of High Impact Psychosis (SHIP)

SHIP was implemented across seven mental health service sites within five Australian states. The sites covered about 62,000 km^2 and 1,464,923 people aged 18-64 years. Survey inclusion criteria were, participant age between 18 and 64 years, residing in a catchment site, and contact with designated mental health services. SHIP excluded all who resided in a nursing home or prison, or those unable to sufficiently communicate in English to answer the questions. Although SHIP was a survey, an interview format was applied with participants.

The survey employed a two-phase design. Phase 1 involved a census of those in contact with designated mental health services in the government and non-government sectors. During this phase, a psychosis screener was used to identify psychosis-positive adults. Subsequent random selection of participants from the phase 1 census led to phase 2 of the study. In phase 2, participants were stratified by age to ensure adequate coverage of all age-groups who took part in diagnostic interviews, fasting blood checks, physical examinations and cognitive functioning assessments. Investigations were conducted by trained mental health professionals. Procedures applied in this survey ensured that all participants met screening criteria for psychosis. The final sample from SHIP comprised a total of 1825 participants who were interviewed. The complete summary of methods from SHIP has been published by Morgan, et al. [1].

Ethics

Ethics approval was provided for all sites by relevant local authorities; for the lead site and most others, ethics approval was granted by the Human Research Ethics Committee in 2009 (Reference Number: RA/4/1/2478). The Declaration of Helsinki was adhered to during research and written and informed consent was provided by all taking part in the study.

Data

Access to data is restricted to those who have permission from the SHIP study group. For initial inquiries regarding access please contact Dr. Mary-Claire Hanlon (Mary-Claire.Hanlon@uon.edu.au).

Study Measures

Demographics

Demographic variables examined in this analysis include, sex (male/female), age in years, Aboriginal or Torres Strait Islander descent (yes/no), current marital status (single or never married/ married or de facto/separated or divorced/widowed/NK: Not Known), highest education qualification (left school with no qualifications/secondary school qualification or leaving certificate/tertiary certificate/bachelor's degree/postgraduate qualifications/other/NK), income per fortnight (AU$300 or less/AU$300-AU$499/AU$500-AU$799/AU$800-AU$1000/AU$1000 or more/NK) and participation in paid employment in the last 12 months (employed in any job in last 12 months/home duties or caring or retired or volunteer or unpaid or student/no formal activity [includes unemployed]/NK).

Diagnosis

Diagnoses were made using the Diagnostic Module of the Diagnostic Interview for Psychosis (DIP-DM), a semi-structured clinical interview [1]. The clinical interview has good inter-rater reliability shown by a 0.80-1.00 pairwise agreement ratio for most items, and excellent diagnostic validity (9/10 agreement with Schedules for Clinical Assessment in Neuropsychiatry [SCAN]) [17]. DIP-DM was used by trained mental health professionals to obtain participant scores based on the different symptoms of illness [1]. These scores were imputed to a computer algorithm using the Operational Criteria for Psychosis (OPCRIT) to produce an ICD-10 diagnosis [18]. This procedure decreased the likelihood of subjective bias during the diagnostic process [18].

Nutrition

Retrospective measures of dietary intake from Short Diet Questions (SDQs) used in the 1995 National Nutrition Survey (NNS) were used to assess overall nutrition in this group. Questions assessing dietary intake covered 7 main aspects-meal events per day, breakfast consumption, milk consumption, vegetable intake, fruit intake, addition of salt to food and food security. All questions assessed responses for the 4-week period preceding the interview, except for food security which covered the 12-month period prior to the event. Where appropriate, response categories for the questions were merged for the purpose of analysis in the present study. Meal events measured the number of eating occasions in a day, and was collapsed from a continuous variable into a categorical variable with 4 response options (0-2 meal events/3-4 meal events /≥5 meal events/NK). Breakfast consumption assessed the number of days in a week participants normally engaged in this meal. Number of days breakfast was consumed was also collapsed from 9 response options to 3 (<4 per week/≥ 4 per week/NK). Type of milk normally consumed was the third element measured, and responses were collapsed into 5 categories from the initial 7 (does not drink milk/full cream milk/low or reduced fat or skim milk/soy or evaporated or sweetened condensed or other type of milk/NK). Intake of fruits and vegetables was assessed using 2 separate questionnaire items that asked about the usual number of serves consumed in a day. Standard serve sizes were described to participants by interviewers. Responses previously included 5 response categories which were merged into 4 for both the questions (0-1 serves/2-3 serves/4-6 serves/NK). Frequency of adding salt to cooked food was measured for the predefined period preceding the interview based on 5 options (never/rarely/sometimes/usually/NK). Finally, participants were asked whether there had been any instances during the previous 12 months when they had run out of food and could not afford to buy more (no/yes/NK).

Validity of the SDQs against 24-hour recall data indicate that questions on number of meal events and usual fruit and vegetable intake show validity that is fair, whereas validity on the assessment of breakfast consumption is poor [19]. Questions on type of milk and running out of food display good validity [19]. Validity agreement statistics were unfortunately not provided for these assessments [19].

Physical Activity

The International Physical Activity Questionnaire (IPAQ) was used to give a retrospective self-reported measure of time spent engaging in walking, moderate and vigorous activity in the 7 days prior to the interview. Moderate activities were described as requiring moderate physical effort, resulting in breathing that is somewhat harder than usual. Vigorous activities were described as requiring hard physical effort, resulting in harder than usual breathing. Moderate and vigorous activity were also described through a wide range of familiar activities that would fall into each of these two categories. Time spent engaging in any of these activities had to be at least 10 minutes in duration, and the Not Known (NK) response option was also provided. Reliability of the IPAQ in people with schizophrenia shows a correlation coefficient of 0.68 based on test-retest while criterion validity of the tool shows a correlation coefficient of 0.37 when assessed against a motion detector; both these measures are similar to that of the general population [20].

Community Rehabilitation/ Day Therapy Program Participation

SHIP participants were asked whether they had been involved in any form of community rehabilitation or day program therapy when not under hospital admission, during the 12-month period preceding interview (yes/no/NK). All participants who did not attend community rehabilitation or day therapy were marked as not applicable (NA) for prospective sections.

Participants who responded positively to attending day therapy or community rehabilitation were then asked to define this attendance based on four locations (public hospital/private hospital/ government funded community-based centre/non-government funded community-based centre). Content of programs attended in these sectors was ascertained; all programs with a focus on nutrition and physical activity were identified. Attendance at a nutrition and physical activity program was categorised for the government sector and hospitals (no/yes/NK/NA), and non-government sector (no/yes/NK/NA). Participants were then asked to specify the total duration of the program they attended in weeks, whether they completed the program (no/still on/yes/NK/NA) and if they found it of benefit (no/some/a lot/NK/NA).

Statistical Analysis

Analyses were conducted using the Statistical Package for the Social Sciences version 24 (SPSS). Descriptive statistics were run for all study variables-sex, age, Aboriginal or Torres Strait Islander descent, marital status, highest qualification, income per fortnight, participation in paid employment, diagnosis, meal events per day, breakfast consumption, milk consumption, vegetable intake, fruit intake, addition of salt to food, running out of food, walking, moderate activity, vigorous activity, attendance of community rehabilitation or day program therapy, location of community rehabilitation or day program therapy, participation in nutrition and physical activity program, program duration, completion and perceived benefit. Categorical variables were described using frequencies, and continuous variables were described using means and standard deviations. Demographic descriptive statistics were split by overall attendance of nutrition and physical activity programs. Association between demographics and attendance at a nutrition and physical activity program was assessed using chi-squared tests or independent sample t-tests depending on the suitability. In addition, chi-squared tests and Mann-Whitney U tests were conducted to highlight any associations between participation in nutrition and physical activity programs (in the government sector and hospitals, and non-government sector) and nutrition and physical activity outcomes. The specific test of association used for each group of variables was selected based on adherence to test assumptions. A p value of <0.05 was used to detect significance in all analyses.

Results

The mean age of participants was 38.4 (11.2) years and 59.6% were males. Only 4.9% of those who took part in the study identified as Aboriginal/ Torres Strait Islander descent. Most (61.2%) were single or never married. About one third (33.7%) left school without any qualifications while 40.5% reported having a tertiary qualification. Many (59.2%) had a fortnightly income between $500 and $799 while 53.2% did not participate in employment or any another formal activity in the 12 months preceding the interview. About half (47.0%) of the sample had a diagnosis of schizophrenia while 16.1% and 17.5% were affected by schizoaffective disorder and bipolar mania respectively.

Overall attendance of community rehabilitation or day therapy was 36.5%. Just 3.3% of the sample attended a community rehabilitation or day therapy program in a public hospital while only 0.3% took part in a similar type of program in the private hospital. Further, 11.2% participated in a community rehabilitation or day therapy program in a government funded community-based center whilst 25.4% attended the same type of program in a non-government funded community-based center. Participation in nutrition and physical activity programs in the government sector and hospitals was 5.3% while participation in the same kind of program within the non-government sector was 8.7%. Attendance of nutrition and physical activity programs was associated with the highest education qualifications attained (χ^2=17.394, df= 5, p=0.004) and participant diagnosis (χ^2=14.824, df=6, p=0.022). Those attending community nutrition and physical activity programs were less likely to have left school without qualifications (25.5% vs 40.9%) and more likely to have secondary school qualifications (21.7% vs 15.3%) or tertiary qualifications (44.3% vs 35.0%) than those not attending programs. They were also more likely to have schizophrenia (52.4% vs 46.4%) or delusional disorders and other non-organic psychosis (8.0% vs 4.5%) and less likely to have severe depression disorder (6.6% vs 11.8%) than those not attending programs (Table 1).

		Total Sample N = 1825 (N %) or M (SD)	Attended Nutrition and Physical Activity Program in any Sector n = 212 (n %) or M (SD)	Did not Attend Nutrition and Physical Activity Program any Sector n = 509 (n %) or M (SD)	Test
Sex	Male	1087 (59.6%)	129 (60.8%)	298 (58.5%)	X^2= 0.329, *df*= 1, *p* = 0.566
	Female	738 (40.4%)	83 (39.2%)	211 (41.5%)	
Age		38.4 (11.2)	40.0 (11.2)	38.6 (11.1)	t=-1.590, df=719, p=0.693
Aboriginal/ Torres Strait Islander descent	No	1735 (95.1%)	202 (95.3%)	479 (94.1%)	X^2= 0.396, *df*= 1, *p* = 0.529
	Yes	90 (4.9%)	10 (4.7%)	30 (5.9%)	
Marital status	Single/ Never Married	1117 (61.2%)	137 (64.6%)	341 (67.0%)	X^2= 2.527, *df*= 3, *p* = 0.470
	Married/ De facto	312 (17.1%)	22 (10.4%)	57 (11.2%)	
	Separated/ Divorced	376 (20.6%)	46 (21.7%)	103 (20.2%)	
	Widowed	20 (1.1%)	7 (3.3%)	8 (1.6%)	
Highest education qualification attained	Left school with no qualifications	615 (33.7%)	54 (25.5%)	208 (40.9%)	X^2=17.394, *df*= 5, ***p* = 0.004
	Secondary school qualifications	304 (16.7%)	46 (21.7%)	78 (15.3%)	
	Tertiary Qualifications	739 (40.5%)	94 (44.3%)	178 (35.0%)	
	Bachelor degree	92 (5.0 %)	10 (4.7%)	22 (4.3%)	
	Postgraduate qualifications	28 (1.5%)	3 (1.4%)	9 (1.8%)	
	Other	32 (1.8%)	3 (1.4%)	11 (2.2%)	
	Not known	15 (0.8%)	2 (0.9%)	2 (0.4%)	

Current net fortnightly income	Less than $300 per fortnight	58 (3.2%)	8 (3.8%)	10 (2.0%)	
	Between $300 - $499 per fortnight	209 (11.5%)	16 (7.5%)	47 (9.2%)	
	Between $500 - $799 per fortnight	1080 (59.2%)	139 (65.6%)	321 (63.1%)	X^2= 2.618, *df*= 4, *p* = 0.624
	Between $800 - $1000 per fortnight	232 (12.7%)	29 (13.7%)	71 (13.9%)	
	More than $1000 per fortnight	139 (7.6%)	9 (4.2%)	18 (3.5%)	
	Not known	107 (5.9%)	11 (5.2%)	42 (8.3%)	
Participation in paid employment	Employed in any job in last 12 months	596 (32.7%)	46 (21.7%)	134 (26.3%)	
	Home duties/ caring/ retired/ volunteer/ unpaid/ student	258 (14.1%)	30 (14.2%)	73 (14.3%)	X^2= 1.860, *df*= 2, *p* = 0.395
	No formal activity (includes unemployed)	971 (53.2%)	136 (64.2%)	302 (59.3%)	
DIP ICD-10 diagnosis	Schizophrenia	857 (47.0%)	111 (52.4%)	236 (46.4%)	
	Schizoaffective	293 (16.1%)	33 (15.6%)	74 (14.5%)	
	Bipolar, mania	319 (17.5%)	31 (14.6%)	76 (14.9%)	
	Depressive psychosis	81 (4.4%)	5 (2.4%)	26 (5.1%)	X^2=14.824, *df*= 6, **p* = 0.022
	Delusional disorders and other non-organic psychosis	92 (5.0%)	17 (8.0%)	23 (4.5%)	
	Severe depression disorder	158 (8.7%)	14 (6.6%)	60 (11.8%)	
	Screen-positive for psychosis but did not meet full criteria for ICD-10 psychosis	25 (1.4%)	1 (0.5%)	14 (2.8%)	

Participation in any community rehabilitation or day therapy program (last 12 months)		No	1133 (62.1%)	1 (0.5%)	58 (11.4%)	NA
		Yes	666 (36.5%)	211 (99.5%)	447 (87.8%)	
		Not known	26 (1.4%)	-	4 (0.8%)	
Location of community rehabilitation or day therapy program (last 12 months)	**Public hospital**	No	605 (33.2%)	189 (89.2%)	408 (80.2%)	NA
		Yes	60 (3.3%)	21 (9.9%)	39 (7.7%)	
		Not known	27 (1.5%)	1 (0.5%)	4 (0.8%)	
		Not applicable	1133 (62.1%)	1 (0.5%)	58 (11.4%)	
	Private hospital	No	659 (36.1%)	210 (99.1%)	441 (86.6%)	NA
		Yes	6 (0.3%)	-	6 (1.2%)	
		Not known	27 (1.5%)	1 (0.5%)	4 (0.8%)	
		Not applicable	1133 (62.1%)	1 (0.5%)	58 (11.4%)	
	Government funded community-based centre	No	460 (25.2%)	152 (71.7%)	301 (59.1%)	NA
		Yes	205 (11.2%)	58 (27.4%)	146 (28.7%)	
		Not known	27 (1.5%)	1 (0.5%)	4 (0.8%)	
		Not applicable	1133 (62.1%)	1 (0.5%)	58 (11.4%)	
	Non-government funded community-based centre	No	203 (11.1%)	67 (31.6%)	135 (26.5%)	NA
		Yes	464 (25.4%)	143 (67.5%)	314 (61.7%)	
		Not known	25 (1.4%)	1 (0.5%)	2 (0.4%)	
		Not applicable	1133 (62.1%)	1 (0.5%)	58 (11.4%)	

Participation in Nutrition and Physical Activity Program	**Government sector and hospitals**	No	170 (9.3%)	-	-	NA
		Yes	97 (5.3%)	-	-	
		Not known	23 (1.3%)	-	-	
		Not applicable	1535 (84.1%)	-	-	
	Non-government sector	No	379 (20.8%)	-	-	NA
		Yes	159 (8.7%)	-	-	
		Not known	29 (1.6%)	-	-	
		Not applicable	1258 (68.9%)	-	-	

M (SD): Mean (Standard Deviation); ICD: International Statistical Classification of Diseases and Related Health Problems; X^2: Chi Square test; t: Independent Sample T test; $^{*}p<0.05$; $^{**}p<0.01$; $^{***}p<0.001$; NA: Not Applicable.

Table 1: Demographic Characteristics of Participants from the Survey of High Impact Psychosis by Attendance at a Nutrition and Physical Activity Program.

Almost half (45.3%) the participants reported engaging in 3-4 meal events in a day while 51.5% reported consuming breakfast on 4 or more days in a week. A greater proportion (55.8%) of the sample consumed full cream milk. Almost three quarters (71.1%) and 48.1% of participants reported consuming 0-1 serves of fruits and vegetables a day respectively. Over one third (35.6%) of those who took part in the study never added salt to cooked food. Over one-quarter (28.4%) reported running out of food and not being able to buy more. The average time participants spent walking was 214.8 (334.7) minutes per week. The mean time spent in moderate and vigorous activity was 76 (241.0) and 55.6 (193.8) minutes per week respectively.

There was no association between attendance of nutrition and physical activity programs, either in the government sector and hospitals or in the non-government sector with meal frequency, breakfast consumption, fruit and vegetable consumption, and addition of salt to food. However, attendance of programs in the non-government sector and milk consumption displayed a statistically significant association (χ^2=11.366, *df*=3, *p*=0.010), with 39.2% of those who attended a program in this sector consuming low, reduced fat or skim milk in contrast to 25.0% among those who do not did attend. This was not replicated in those attending the government sector and hospitals. Additionally, attendance of programs in the non-government sector was significantly associated with food security (χ^2=7.232, *df*=1, *p*=0.007); more participants (31.6%) not attending programs in this sector reported running out of food and not being able to buy more, compared to attendees (20.1%). This relationship was not replicated in those attending programs in the government sector and hospitals.

Assessments between measures of physical activity including walking, moderate and vigorous activity, and attendance of programs did not show a statistically significant association with either the government sector and hospitals, or non-government sector. Nevertheless, participation in vigorous activity and attendance of programs in the non-government sector neared statistical significance (U=28017, Z=-1.89, *p*=0.058); those who reported attending programs in the non-government sector had a higher mean rank of minutes spent in vigorous physical activity per week (282.79) than those who did not attend (263.92) (Table 2).

		Total Sample N = 1825 (N %) or M (SD)	Nutrition and Physical Activity Program Attendance in the Government Sector and Hospitals		Nutrition and Physical Activity Program Attendance in the Non-Government Sector		Tests of Association with Nutrition and Physical Activity Program Participation in the Government Sector and Hospitals	Tests of Association with Nutrition and Physical Activity Program Participation in the Non-Government Sector
			No n=170	Yes n=97	No n=379	Yes N=159		
Meal events per day (last 4 weeks)	0-2 meal events	548 (30.0%)	48 (28.2%)	20 (20.6%)	112 (29.6%)	36 (22.6%)		
	3-4 meal events	826 (45.3%)	80 (47.1%)	52 (53.6%)	157 (41.4%)	71 (44.7%)	X^2= 2.120, *df*= 2, *p* = 0.347	X^2= 2.781, *df* = 2, *p* = 0.249
	≥ 5 meal events	437 (23.9%)	39 (22.9%)	25 (25.8%)	107 (28.2%)	51 (32.1%)		
	Not known	14 (0.8%)	3 (1.8%)	-	3 (0.8%)	1 (0.6%)		
Eats breakfast (days per week in last 4 weeks)	0-3 days per week	877 (48.1%)	72 (42.4%)	40 (41.2%)	180 (47.5%)	66 (41.5%)		
	≥ 4 days per week	939 (51.5%)	95 (55.9%)	57 (58.8%)	198 (52.2%)	93 (58.5%)	X^2= 0.088, *d f*= 1, *p* = 0.766	X^2= 1.683, *df* = 1, *p* = 0.195
	Not known	9 (0.5%)	3 (1.8%)	-	1 (0.3%)	-		
Milk consumed (serves per day in last 4 weeks)	Does not drink milk	98 (5.4%)	6 (3.5%)	4 (4.1%)	21 (5.5%)	7 (4.4%)		
	Full cream milk	1018 (55.8%)	82 (48.2%)	43 (44.3%)	228 (60.2%)	76 (47.8%)		
	Low or reduced fat or skim milk	575 (31.5%)	70 (41.2%)	45 (46.4%)	93 (24.5%)	62 (39.0%)		
	Soy or evaporated or sweetened condensed or other type of milk	114 (6.2%)	9 (5.3%)	5 (5.2%)	30 (7.9%)	13 (8.2%)	X^2= 0.629, *df*= 3, *p* = 0.890	X^2= 11.366, *df* = 3, **p* = 0.010
	Not known	20 (1.1%)	3 (1.8%)	-	7 (1.8%)	1 (0.6%)		

Vegetables consumed (serves per day in last 4 weeks)	0-1 serves	887 (48.6%)	78 (45.9%)	46 (47.4%)	189 (49.9%)	74 (46.5%)		
	2-3 serves	715 (39.2%)	68 (40.0%)	40 (41.2%)	142 (37.5%)	65 (40.9%)	X^2= 0 .088, *df*= 2, *p* = 0.957	X^2= 0.601, *df* = 2, *p* = 0.741
	4-6 serves	206 (11.3%)	21 (12.4%)	11 (11.3%)	44 (11.6%)	19 (11.9%)		
	Not known	17 (0.9%)	3 (1.8%)	-	4 (1.1%)	1 (0.6%)		
Fruit consumed (serves per day in last 4 weeks)	0-1 serves	1297 (71.1%)	99 (58.2%)	63 (64.9%)	265 (69.9%)	102 (64.2%)		
	2-3 serves	452 (24.8%)	62 (36.5%)	31 (32.0%)	97 (25.6%)	49 (30.8%)	X^2= 0.831, *df*= 2, *p* = 0.660	X^2= 1.952, *df* = 2, *p* = 0.377
	4-6 serves	59 (3.2%)	6 (3.5%)	3 (3.1%)	13 (3.4%)	7 (4.4%)		
	Not known	17 (0.9%)	3 (1.8%)	-	4 (1.1%)	1 (0.6%)		
Salt added to food (last 4 weeks)	Never	650 (35.6%)	62 (36.5%)	28 (28.9%)	152 (40.1%)	57 (35.8%)		
	Rarely	252 (13.8%)	33 (19.4%)	19 (19.6%)	47 (12.4%)	26 (16.4%)		
	Sometimes	348 (19.1%)	27 (15.9%)	23 (23.7%)	71 (18.7%)	38 (23.9%)	X^2= 3.090, *df*= 3, *p* = 0.378	X^2= 4.013, *df* = 3, *p* = 0.260
	Usually	560 (30.7%)	45 (26.9%)	27 (27.8%)	104 (27.4%)	37 (23.3%)		
	Not known	15 (0.8%)	3 (1.8%)	-	5 (1.3%)	1 (0.6%)		
Ran out of food (last 12 months)	No	1296 (71.0%)	114 (67.1%)	75 (77.3%)	258 (68.1%)	127 (79.9%)		
	Yes	519 (28.4%)	53 (31.2%)	22 (22.7%)	119 (31.4%)	32 (20.1%)	X^2= 2.474, *df* = 1, *p* = 0.116	X^2= 7.232, *df*= 1, ***p*= 0.007
	Not known	10 (0.5%)	3 (1.8%)	-	2 (0.5%)	-		

Physical activity (min/ week)	Walking	214.8 (334.7)	211.3 (342.5)	167.3 (174.9)	227.1 (376.3)	220.5 (279.9)	Mean rank for No=135.55 & Yes=131.28 U= 7981, Z= -0.436 p= 0.663	Mean rank for No=264.42 & Yes=281.62 U= 28204, Z= -1.174 p= 0.240
	Moderate activity	76 (241.0)	74.2 (191.4)	51.5 (107.5)	51.3 (180.5)	42.5 (123.2)	Mean rank for No=133.97 & Yes=134.05 *U*= 8240, *Z*= -0.010 *p*= 0.992	Mean rank for No=266.08 & Yes=277.64 U= 28835.50, Z= -1.003 *p*= 0.316
	Vigorous activity	55.6 (193.8)	34.0 (110.5)	43.5 (96.8)	35.4 (127.8)	43.4 (106.5)	Mean rank for No=130.25 & Yes=140.57 *U*=7607.50, *Z*= -1.508 *p*= 0.131	Mean rank for No=263.92 & Yes=282.79 U= 28017, Z= -1.893 *p*= 0.058

M (SD): Mean (Standard Deviation); X^2: Chi Square test; U: Mann-Whitney U test; df: Degrees of Freedom; $^{*}p<0.05$; $^{**}p<0.01$; $^{***}p<0.001$

Table 2: Nutrition and Physical activity Characteristics by Nutrition and Physical Activity Program Attendance in the Government Sector and Hospitals, and Non-Government Sector.

The sub-sample attending nutrition and physical activity programs in the government sector and hospitals reported an average program duration of 19.4 (19.6) weeks. Most had either completed the program (49.5%) or were still undertaking the program (40.2%) at the time of interview. Many reported experiencing "a lot" of benefit (52.6%) or "some" (39.2%) benefit.

The sub-sample accessing nutrition and physical activity programs in the non-government sector reported an average program duration of 31.6 (21.1) weeks. Many from this group were either still undertaking (63.5%) the program or had completed the program (18.9%) at the time of interview. The benefit of attending the program was described as "a lot" by 61.6% of this sub-sample while 30.8% reported experiencing "Some" benefit (Table 3).

		Government Sector and Hospitals n = 97 (n %) M (SD)	**Non-government Sector n = 159 (n %) M (SD)**
Duration of program in weeks		19.4 (19.6)	31.6 (21.1)
Completed program	No	10 (10.3%)	20 (12.6%)
	Still on	39 (40.2%)	101 (63.5%)
	Yes	48 (49.5%)	30 (18.9%)
	Not known	-	8 (5.0%)
Benefit	No	8 (8.2%)	6 (3.8%)
	Some	38 (39.2%)	49 (30.8%)
	A lot	51 (52.6%)	98 (61.6%)
	Not known	-	6 (3.8%)

Table 3: Characteristics of Nutrition and Physical Activity Program Attendance in the Government Sector and Hospitals, and Non-Government Sector.

Discussion

We aimed to describe self-reported attendance of nutrition and physical activity programs in the government and non-government sector among Australians with psychosis, and discovered that majority of the sample did not attend programs in either sector. Overall program attendance differed based on participant diagnosis, and was greater for those who attained a minimum of high school qualifications or higher. Assessments between program attendance, and nutrition and physical activity outcomes highlighted that only non-government program attendees showed increased consumption of reduced fat or skim milk in preference to other varieties. They were also less likely to run out of food and not have the financial capacity to purchase more. Meal frequency, breakfast consumption, fruit and vegetable intake, adding salt to food and physical activity participation were not related to program attendance.

Reasons for differing program attendance across participant diagnostic groups are unclear because practice guidelines for physical health service referral are consistent for the various psychotic disorders [21]. Appropriate application of these guidelines may promote increased service use across different diagnostic groups [21]. Conversely, the positive relationship between program attendance and attainment of education qualifications could indicate that skills obtained through education may equip persons to overcome personal hindrances related to health service access [22]. Service access support may thus be necessary for those with low education attainment, to ensure that problems related to access are addressed.

Other factors not covered in this study that may influence program attendance include illness, cognitive limitations, financial problems, transport hindrances and participant preferences [23-25]. Designing services that alleviate these difficulties may help improve utilisation of existing services [25,26]. Admittedly, illness related factors are more difficult to address, however, other concerns like transport and financial limitations can be minimised through providing organised program transport and designing low cost activities [10,25,26]. With proper investment and planning, cognitive needs and client preferences can be incorporated into available programs by engaging clients in program design [10,25,26].

The structure of the Australian health system may also affect attendance of existing programs [23,24]. Mental and physical health are treated via different avenues in the government sector, private sector, and community managed organisations [23,24]. A community-based model of care for those with mental illness is currently lacking, and this spread of services may result in service access gaps [23,27]. Fortunately, integrated community-based mental health services and teams are being piloted [23]. Meanwhile, the role of nutrition and physical activity programs needs advocating among Australians with psychosis [23]. General Practitioners (GPs) and case managers are well positioned for this [23,24]. GPs make referrals to other health services while case managers support those with more severe forms of illness to access appropriate treatments [28,29]. These groups act as a gateway to the larger health system for many with psychosis, hence should be informed by service providers on available programs so that they can relay this to clients [23,24].

Current program durations seemed to suggest that community nutrition and physical activity services were designed for persons who could commit on a longer-term basis. This may encourage commitment and engagement in a group not likely to be involved in other formal activities or employment, or may act as a deterrent to those who are unable or unwilling to commit for long durations [1]. Provision of multiple program options for people with psychosis may promote accommodation of needs and preferences which may encourage utilisation of services [26,30].

Rates of perceived program benefit seen in this study could indicate that particular needs are being met [31]. Further, those who attended programs showed increased consumption of reduced fat milk, and decreased likelihood of running out of food without the financial capacity to purchase more. However, improvements in other nutrition and physical activity characteristics were not displayed and the two positive nutrition outcomes were primarily evident in the group attending the non-government sector. The cause for differing outcomes in the government and non-government sector is unfortunately not apparent from available literature [32]. This is because distinctive service delivery characteristics pertaining to these sectors are lacking [32]. Additionally, the SDQs used in nutrition assessment may not be sensitive enough to assess behavioural outcomes related to attending health promotion programs available in the government and non-government sectors [19]. Local evaluation and monitoring of both non-government and government programs is therefore necessary, with the employment of appropriate tools so that amendments can be made when needed [15].

Strengths and Limitations

This study presents an analysis of a cross-sectional data which prevents inference of cause and effect relationships from findings [33]. This is however the largest representative cross-sectional study of Australians with psychosis, thus offers a good representation of the population [1]. Although much of the data presented is self-report, bias was minimised in the original study through applying validated tools where possible, and training interviewers [1]. Nutrition and physical activity programs were not

explored exhaustively because of the wide range of topics assessed in SHIP, thus should be explored further in prospective longitudinal studies with a narrower focus. Finally, SHIP was conducted in 2010 hence recent changes to the parameters assessed may not be reflected in this study.

Conclusion

This study highlights extremely low utilization of community nutrition and physical activity programs among people with psychosis in Australia, with participant diagnosis and higher education attainment displaying association with program attendance [22]. Factors like low levels of education may negatively affect program access; alleviating the challenges that inhibit program access could promote attendance in people with psychosis [25,26]. Additionally, those at the front-line of treatment provision like GPs and case-managers should advocate for the role of these services to this group [23,24]. Current findings also indicate presence of some health-promoting activities in non-government program attendees which may or may not be a consequence of factors related to service delivery. Non-government and government programs should be evaluated locally so that adjustments are made where necessary [15].

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Chapter 5.1: Comparative Efficacy of Lifestyle Intervention Strategies that Target Weight Outcomes in People with Psychosis: A Systematic Review and Network Meta-analysis

5.1.1: Study Overview

This study reviewed existing lifestyle intervention trials in people with psychosis. Previous research had established the efficacy of lifestyle interventions in decreasing weight outcomes, through the use of various behaviour change strategies (172, 207, 208, 212, 231). Nonetheless, information on intervention strategies that promoted study efficacy had not been thoroughly described by previous reviewers (172, 207, 209, 212-214, 231). Important strategies previously cited were intervention delivery though an individual or one-on-one approach, or combining this with group delivery of sessions (172). Additional information is however necessary for further testing of evidence in the field, and generation of conclusions on efficacy (172, 207, 209, 212-214).

Furthermore, available lifestyle intervention studies did not clarify whether dietary information adhered to dietary guidelines (99, 126, 172, 207, 209, 212-214). The Australian Dietary Guidelines (ADGs) present a clinically robust source of dietary information (99, 121). Adoption of evidence from the Australian Dietary Guidelines (ADGs) or similar guidelines, during formulation and implementation of lifestyle intervention trials, ensures that the studies follow principles of evidence-based health promotion (99, 121).

A systematic review and network meta-analysis was thus completed aiming to pool and rank the efficacy of lifestyle intervention strategies that target weight, body mass index, waist-circumference, and waist-to-hip ratio in people with psychosis by comparing the effect size on these weight outcomes. A secondary aim was to stratify the lifestyle interventions according to their inclusion of dietary information that adheres with ADGs (99).

The systematic review was reported using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (232). Research methods were summarised into a systematic review protocol and the findings were reported in a systematic review outcome paper. Quality of findings was evaluated using the GRADE (Grading of Recommendations Assessment, Development, and Evaluation) approach, to summarise strength of practice recommendations that can be adopted from existing research (226). Development of practice guidelines facilitates the knowledge translation process as it presents available research in a usable format (226). Both papers from this study were published in Joanna Briggs Institute Database of Systematic Reviews and Implementation Reports and also presented by Miss Doreen Mucheru as a poster presentation at the Asia Pacific Conference on Clinical Nutrition in Adelaide, Australia, in November 2017. References to the papers are:

Mucheru D, Hanlon MC, McEvoy M, and MacDonald-Wicks L. *Comparative efficacy of lifestyle intervention strategies on weight outcomes in people with psychosis: a systematic review and network meta-analysis protocol.* JBI Database System Rev Implement Rep. 2017; 15(6): 1593-601.

And;

Mucheru D, Hanlon MC, McEvoy M, Thakkinstian A and MacDonald-Wicks L. *Comparative efficacy of lifestyle intervention strategies that target weight outcomes in people with psychosis: a systematic review and network meta-analysis*. JBI Database System Rev Implement Rep. 2019. doi: 10.11124/JBISRIR-2017-003943.

Comparative Efficacy of Lifestyle Intervention Strategies on Weight Outcomes in People with Psychosis: A Systematic Review and Network Meta-Analysis Protocol

Review question/objective

Review Question: What lifestyle intervention strategies targeting weight outcomes (weight, body mass index [BMI], waist circumference and waist to hip ratio) in people with psychosis compared to no treatment or various control conditions have the best efficacy; a systematic review and network meta-analysis protocol.

Objective 1: To systematically review and rank the efficacy of different types of lifestyle intervention strategies on weight outcomes (weight, BMI, waist circumference and waist to hip ratio) in people with psychosis. The efficacy of different types of lifestyle intervention strategies will be ranked by comparing the effect size on weight outcomes in people with psychotic disorders.

Objective 2: To stratify lifestyle interventions that target weight outcomes (weight, BMI, waist circumference and waist to hip ratio) in people with psychosis according to their inclusion of dietary information that adheres with Australian Dietary Guidelines (ADGs).[1]

Background

The Survey of High Impact Psychosis (SHIP) found that in 2010 the 12-month treated prevalence of psychosis in Australia was 4.5 people per 1000 in those between 18 and 64 years.[2] Other developed countries quote similar prevalence rates with a systematic review and meta-analysis in the U.K estimating the annual prevalence of psychosis between 1950 and 2009 to be 4 people per 1000 in 16-64 year olds.[3] In America, 4.2% of the population aged 18 years and over in 2014 was estimated to be living with psychosis.[4] A psychotic disorder is characterized by the experience of hallucinations, delusions or gross excitement and over activity, psychomotor retardation and catatonic behavior that causes distress and interferes with personal functions.[5] Schizophrenia spectrum disorders represent the main types of psychotic disorders.[5] While the magnitude of the figures quoted for the prevalence of psychosis may not seem high, the annual cost incurred per individual with psychosis is almost four times that by a healthy Australian.[6] Despite a significantly higher disease burden, evidence suggests that there is poorer healthcare provision and access in people with psychosis disorders which may lead to unfavorable physical health outcomes.[7,8] Morgan V.A and colleagues found that one of the biggest concerns for people with psychosis who took part in the SHIP was their physical health.[2]

The relationship between poor physical health and psychosis is well established.[9-12] Factors that contribute to poor physical health in people with psychosis through weight gain are: antipsychotic medication use, poor diet or a diet that is inconsistent with dietary recommendations and low physical activity levels.[11,13] Excessive weight gain predisposes one to developing metabolic syndrome, a cluster of metabolic abnormalities that include hypertension, central adiposity, dyslipidemia and insulin resistance which increase the risk of cardiovascular disease (CVD) two to threefold.[14,15]

Cardiovascular disease is one of the single largest contributors to high mortality in people with psychosis.[12,16] Lifestyle factors such as a poor diet and low physical activity levels are modifiable through the use of various lifestyle intervention programs.[2,15,17]. The risk of increased weight gain associated with the use of atypical anti-psychotic medications can also be mitigated by implementing lifestyle interventions.[11,18,19] The general consensus of what a lifestyle intervention entails seems to be a program that promotes improved nutrition and or increased physical activity through use of various strategies.[17,20,21]

A preliminary search of Medline revealed that lifestyle interventions in people with psychosis have been researched widely.[17,20-28] More recent systematic reviews on lifestyle interventions in people with psychosis have confirmed the efficacy of these interventions in the reduction of weight, BMI and waist circumference. [17,20,21] Some meta-analyses have attempted to decipher what aspects of lifestyle interventions in people with psychosis are most efficacious at improving weight outcomes.[17,21-23,27] . Many of these meta-analyses have not been successful at indicating efficacious characteristics of lifestyle interventions; two studies have however highlighted that lifestyle interventions characterized by an 'individual approach' are more efficacious than 'group based' lifestyle interventions.[17,22] A closer analysis of randomized controlled studies (RCTs) that were classified as those with an 'individual approach' within the systematic reviews, revealed that these studies were distinguished by their use of specific instructions or personalized goals that were reviewed regularly by a health professional because of the one-on-one attention participants received.[29-31] Studies classified as those with an 'individual approach' were also more likely to offer participants supervised exercise. [29-31] Comparatively, an analysis of RCTs that were classified as 'group based' lifestyle interventions within systematic reviews highlighted the use of generalized information on healthy diet or physical activity that lacked the structured or personalized nature of prescribed information offered within the 'individual approach'.[32-36] Subsequently, corresponding monitoring that was offered with the highly structured diet and physical activity advice within the 'individual approach' lifestyle interventions was generally not offered within the 'group based' lifestyle interventions.[32-36]

Randomized controlled studies analyzed in previous systematic reviews and meta-analyses are characterized by many features that do not exclusively fit into the dichotomous categories, 'individual approach' or 'group based' lifestyle interventions.[17,20,21] Other important sub-categories within these lifestyle interventions are: structured diet interventions, non-structured diet interventions, structured exercise interventions, non-structured exercise interventions and combination groups that merge two of the categories mentioned above such as structured diet and structured exercise interventions, structured diet and non-structured exercise interventions, non-structured diet and structured exercise interventions and finally non-structured diet and non-structured exercise interventions.[17,20,21] These eight types of lifestyle interventions identified from analyzing some of the available RCTs will be compared against each other to assess efficacy of different intervention types. The use of dichotomous categories in comparing different types of lifestyle interventions in previous meta-analyses may have masked important features of successful lifestyle interventions; this may have been the reason why many of these studies were unsuccessful at identifying characteristics of

successful lifestyle interventions.[19,21,23] The meta-analytic procedure can however only compare two intervention types therefore may not be suitable in ranking the efficacy of different types of lifestyle interventions.[37] The use of the network meta-analytic procedure would help overcome this limitation as with this method it is possible to provide a comprehensive estimate of the efficacy of multiple intervention types using both direct and indirect effects.[37] Additionally, with the network meta-analytic procedure, it is possible to rank the intervention categories from the most efficacious to the least efficacious.[37]

In addition to this, none of the available systematic reviews and meta-analyses have identified nutritionally sound lifestyle interventions.[17,20-28] In view of the current study, nutritionally sound lifestyle interventions will be defined as RCTs that offer dietary advice that complies with ADGs in terms of serves of various foods and food groups. It is important that dietary information offered to people with psychosis complies with the ADGs as these guidelines were written to promote health and wellbeing, while reducing chronic disease which are issues of concern in this population group. [1,2] The information obtained through this network analysis can be used to make recommendations on the design of future lifestyle interventions in people with psychosis who are living in the community and accessing services so as to improve health outcomes in this vulnerable group.

Inclusion Criteria

Types of participants

This review will consider studies that include community dwelling participants aged 18 years and over with a psychotic disorder. More specifically 'psychotic disorders' mainly include schizophrenia type disorders (International Statistical Classification of Diseases and Related Health Problems [ICD] codes F20-F29).

A diagnosis of a psychotic disorder will be regarded as valid for the purpose of this study if at least one of the conditions listed below are met:

I. The diagnosis was made using the Diagnostic and Statistical Manual of Mental Disorders (DSM) or the ICD.
II. The diagnosis was confirmed by consulting the participant's physician.
III. Participant's health records were accessed to confirm diagnosis.
IV. Participants were referred by their physician to take part in the study because they had a psychotic disorder.

Participants with comorbid mental or physical illnesses will also be included provided they have a psychotic disorder.

Types of intervention(s)/phenomena of interest

This review will consider studies designed to deliver lifestyle interventions/ health interventions/ health promotion lifestyle programs/ health promotion programs/ healthy living interventions/ healthy lifestyle

programs/ interventions for health risk behaviors/ weight management interventions/ diet interventions/ exercise interventions/ nonpharmacological lifestyle interventions/ nutrition interventions.

This review will exclude all lifestyle interventions that utilize the internet or mobile health (m-health) technology because lifestyle interventions that are delivered through the internet have high dropout rates and low utilization rates hence many studies are not efficacious.[38] Furthermore, well-designed high-quality RCTs that deliver lifestyle interventions using m-health technology or delivered through the internet to a population with psychosis have not been identified because research in this area is still quite new.[38] This study will also exclude all lifestyle interventions carried out inpatient settings because the needs of people in inpatient and outpatient settings differ vastly and it has been identified in a previous systematic review that weight, BMI and waist circumference were only significantly decreased in RCTs carried out in outpatient settings.[21]

Types of outcomes

This review will consider studies that include the following outcome measures: weight, BMI, waist circumference and waist to hip ratio. This is because weight was the single most reported weight outcome in previous RCTs however, experts have concluded that BMI, waist circumference and waist-to-hip ratio are more meaningful weight outcomes in relation to overall health. [17,39,40] Weight will be included as an outcome measure in this study as it was frequently reported however BMI, waist circumference and waist-to-hip ratio will also be included as outcome measures as they are more meaningful to the assessment of overall health. [39,40]

Types of studies

This review will only include RCTs for inclusion as this the highest level of evidence.[41]

Search strategy

The search strategy aims to find published studies. A three-step search strategy will be utilized in this review. An initial limited search of MEDLINE and CINAHL will be undertaken followed by analysis of the text words contained in the title and abstract, and of the index terms used to describe the article. A second search using all identified keywords and index terms will then be undertaken across all included databases. Thirdly, the reference list of all identified reports and articles will be searched for additional studies. Studies published in English will be considered for inclusion in this review. Studies published from 1985 to date will be considered for inclusion in this review. The 1985 cut off point was decided upon because in studies prior to this, undesirable contingency weight management approaches were used such as provision of cigarettes or coffee depending on whether the participants achieved the desired outcomes; these methods may currently be considered unethical in the practice of modern clinicians. In addition to this, RCTs delivering lifestyle interventions in people with psychosis have not been identified prior to the year 1985 in other systematic reviews therefore it would not be beneficial to include studies carried out before this date.[28]

The databases to be searched include: The Cochrane Library, MEDLINE/PREMEDLINE, EMBASE, CINAHL, Scopus, and PsycINFO. The Cochrane Library will be included in the database search

because previous reviews and systematic-reviews have been done on this topic; scanning reference lists of previous reviews and systematic reviews will ensure all available RCTs are included in the current study because incomplete inclusion of research papers has been identified as a common problem among authors of this topic.[19]
Initial keywords to be used will be: lifestyle interventions, nutrition interventions, weight management psychosis and schizophrenia

Assessment of methodological quality

Papers selected for retrieval will be assessed by two independent reviewers for methodological validity prior to inclusion in the review using standardized critical appraisal instruments from the Joanna Briggs Institute Meta-Analysis of Statistics Assessment and Review Instrument (JBI-MAStARI) (Appendix I). Any disagreements that arise between the reviewers will be resolved through discussion, or with a third reviewer.

Data collection

Data will be extracted from papers included in the review using the standardized data extraction tool from JBI-MAStARI (Appendix II). The data extracted will include specific details about the interventions, populations, study methods and outcomes of significance to the review question and specific objectives. Data collection of all the outcomes will be conducted simultaneously, as separate data collections do not need to be conducted for each outcome (weight, BMI, waist circumference and waist to hip ratio). Where details of the included studies are inadequate to allow accurate grouping, authors will be contacted for more detail.

Data synthesis

Papers will, where possible be pooled in network meta-analysis using STATA statistical software.[42] All results will be subject to double data entry. Effect sizes expressed as odds ratio (for categorical data) and weighted mean differences (for continuous data) and their 95% confidence intervals will be calculated for analysis. Heterogeneity is typically presented through between-study variance in network meta-analyses, hence this will be calculated and assumed to be common across the network.[43]
Results will be present in a number of ways; network plots will be used to present a weighted visual of the interventions used and direct comparisons available whereas contribution plots will be used to display the relative contribution of each intervention type to the network.[43,44] Network plots will also be used to evaluate the transitivity assumption which implies that effect modifiers do not differ across various interventions.[43] Additional assumptions will be presented using; inconsistency plots that will display differences between the direct and indirect effects of various intervention types, comparison-adjusted funnel plots that will be used to assess small study effects if appropriate and predictive interval plots will contain a summary of the relative mean effects, prediction estimates of future studies and impact of heterogeneity on each intervention.[43] A cumulative ranking probability plot will be used to rank the efficacy of all the intervention types by displaying the probability that each study type will occupy a specific rank.[43] Nutritionally sound lifestyle interventions will be identified as so by comparing the dietary information provided to the ADGs.[1] Studies will be classified as either compliant

or non-compliant. Where statistical pooling is not possible the findings will be presented in narrative form including tables and figures to aid in data presentation where appropriate.

Conflicts of interest

None

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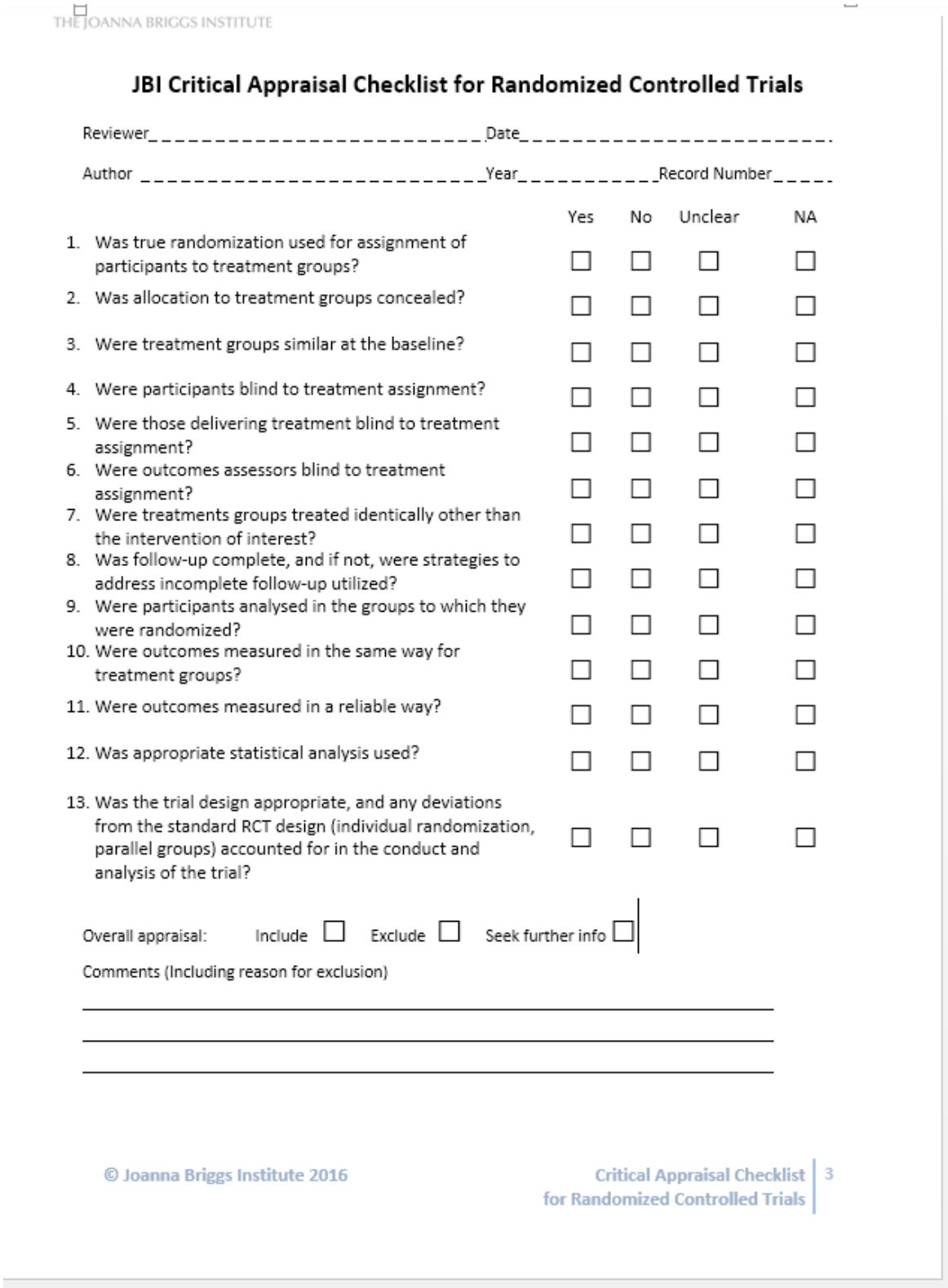
Appendix I: Appraisal instruments

MAStARI Appraisal instrument



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JBI Critical Appraisal Checklist for Randomized Controlled Trials

Reviewer_____Date_____

Author _____Year_____Record Number_____

	Yes	No	Unclear	NA
1. Was true randomization used for assignment of participants to treatment groups?	☐	☐	☐	☐
2. Was allocation to treatment groups concealed?	☐	☐	☐	☐
3. Were treatment groups similar at the baseline?	☐	☐	☐	☐
4. Were participants blind to treatment assignment?	☐	☐	☐	☐
5. Were those delivering treatment blind to treatment assignment?	☐	☐	☐	☐
6. Were outcomes assessors blind to treatment assignment?	☐	☐	☐	☐
7. Were treatments groups treated identically other than the intervention of interest?	☐	☐	☐	☐
8. Was follow-up complete, and if not, were strategies to address incomplete follow-up utilized?	☐	☐	☐	☐
9. Were participants analysed in the groups to which they were randomized?	☐	☐	☐	☐
10. Were outcomes measured in the same way for treatment groups?	☐	☐	☐	☐
11. Were outcomes measured in a reliable way?	☐	☐	☐	☐
12. Was appropriate statistical analysis used?	☐	☐	☐	☐
13. Was the trial design appropriate, and any deviations from the standard RCT design (individual randomization, parallel groups) accounted for in the conduct and analysis of the trial?	☐	☐	☐	☐

Overall appraisal: Include ☐ Exclude ☐ Seek further info ☐

Comments (Including reason for exclusion)

_____

_____

_____

Appendix II: Data extraction instruments

MAStARI data extraction instrument

JBI Data Extraction Form for Experimental / Observational Studies

Reviewer _____ Date _____

Author _____ Year _____

Journal _____ Record Number _____

Study Method

RCT	☐	Quasi-RCT	☐	Longitudinal	☐
Retrospective	☐	Observational	☐	Other	☐

Participants

Setting _____

Population _____

Sample size

Group A _____ Group B _____

Interventions

Intervention A _____

_____

Intervention B _____

_____

Authors Conclusions:

_____

_____

_____

Reviewers Conclusions:

_____

_____

_____

Study results

Dichotomous data

Outcome	Intervention ( ) number / total number	Intervention ( ) number / total number

Continuous data

Outcome	Intervention ( ) number / total number	Intervention ( ) number / total number

Comparative Efficacy of Lifestyle Intervention Strategies Targeting Weight Outcomes in People with Psychosis: A Systematic Review and Network Meta-Analysis

Abstract

Objectives: The objective of this review was to pool and rank the efficacy of lifestyle intervention strategies targeting weight, body mass index, waist circumference and waist-to-hip ratio in people with psychosis by comparing the effect size of these weight outcomes. Secondary to this, the objective was to stratify the lifestyle interventions according to their inclusion of dietary information that adheres to Australian Dietary Guidelines.

Introduction: People living with psychosis have a significantly increased risk of all-cause mortality, with cardiovascular disease a considerable contributor to this risk. Controlling lifestyle risk factors, which include smoking, poor diet and inadequate physical activity, leads to significant weight reduction and decreases cardiovascular disease risk. Previous reviews on this topic have not clearly identified essential components of lifestyle interventions in people with psychosis, mainly due to statistical limitations of analyses. This review employed the network meta-analysis, which compares more than two groups of interventions and ranks them according to efficacy, thus providing a global estimate of effect. Additionally, available reviews have not assessed compliance of dietary information offered in lifestyle interventions to established guidelines.

Inclusion criteria: This review considered randomized controlled studies that delivered lifestyle interventions to community-dwelling adults with psychotic disorders. Outcomes of interest were weight, body mass index, waist circumference and waist-to-hip ratio.

Methods: The Cochrane Library, MEDLINE/PreMEDLINE, Embase, CINAHL, Scopus and PsycINFO were searched for studies published in English from 1985 to June 2018. Data were qualitatively summarized, during which lifestyle intervention subgroups were created (based on key similarities) and then compared in direct meta-analyses and network meta-analyses. Assessments of study adherence to Australian Dietary Guidelines was conducted in a narrative format.

Results: Thirty-two randomized control studies were included, and the overall quality of these studies ranged from what appeared to be low to moderate. Lifestyle intervention studies contained both a dietary and physical activity component, with the exception of two studies that focused solely on physical activity. Delivery of dietary and physical activity information was mainly through education; however, some studies provided additional structure to the intervention by offering tailored advice or helping participants to set goals, and providing regular review of progress for diet, physical activity or both. Results from network-meta-analyses showed that only studies with a structured approach for both diet and physical activity demonstrated significant decreases in weight (effect size = -4.12, 95% confidence interval = -7.772 to -2.760, *P* = 0.000) and body mass index (effect size = -2.94, 95% confidence interval = -1.78 to -0.357, *P* = 0.003). Waist circumference subgroup comparisons mainly

comprised single studies; therefore, findings are inconclusive. Dietary information provided in studies generally complied with Australian Dietary Guidelines; however, none of the studies complied with all guidelines.

Conclusions: Lifestyle interventions incorporating both dietary and physical activity components led to the greatest decreases in weight (4.1 kg) and body mass index (2.9 points) among people with psychosis. Important intervention strategies for both components are the personalization of education through tailored advice or goal setting, and a corresponding progress review. Dietary information in the included studies appeared to comply with the Australian Dietary Guidelines. However, these findings were weakened by an increased risk of bias, complex and multicomponent study designs, and lack of clarity in reporting of study methodology.

Keywords: Diet interventions; lifestyle interventions; physical activity interventions; psychosis; weight management

Summary of Findings: Comparison of Lifestyle Intervention Subgroups with Control

[structured diet and structured physical activity lifestyle interventions] compared to [control] in [people with psychosis to decrease weight outcomes]

Bibliography: [1]

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with [control]	Risk difference with [structured diet and structured physical activity lifestyle interventions]
Weight assessed with: kilograms follow up: range 16 weeks to 24 months	541 (4 RCTs)	⨁◯◯◯ VERY LOW a,b,c,d,e	-	-	SMD **4.12 SD lower** (7.772 lower to 2.76 lower)
Body mass index (BMI) assessed with: weight in kilograms/ height in meters*height in meters follow up: range 12 weeks to 24 months	589 (5 RCTs)	⨁◯◯◯ VERY LOW b,c,f	-	-	SMD **2.94 SD lower** (1.78 lower to 0.357 lower)
Waist circumference assessed with: centimeters follow up: 12 months	280 (1 RCT)	⨁◯◯◯ VERY LOW b,c,g	-	-	SMD **0.97 SD higher** (5.741 lower to 1.941 higher)

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **SMD:** Standardised mean difference

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

Explanations

a. allocation concealment was unclear in 2 of the studies
b. the intervention effect was not consistent for all study outcomes
c. there might have been differences in the rigor of implementation and outcomes were taken at different time points
d. publication bias was detected
e. funnel plots showed assymetry
f. allocation concealment was unclear in 3 of the studies
g. it was unclear whether intervention and control groups were similar at baseline

References

1. Mucheru DW, Hanlon MC,McEvoy M,Thakkinstian A and MacDonald-Wicks L. The comparative efficacy of lifestyle intervention strategies that target weight outcomes in people with psychosis; a systematic review and network meta-analysis. 2018.

[structured diet and non-structured physical activity] compared to [control] in [people with psychosis to decrease weight outcomes]

Bibliography: [1]

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with [control]	Risk difference with [structured diet and non-structured physical activity]
Weight assessed with: kilograms follow up: range 32 weeks to 6 months	71 (2 RCTs)	⨁◯◯◯ VERY LOW a,b,c,d	-	-	SMD **0.14 SD higher** (5.565 lower to 6.416 higher)
Body mass index (BMI) assessed with: weight in kilograms/ height in meters*height in meters follow up: 6 months	51 (1 RCT)	⨁⨁◯◯ LOW [a,c]	-	-	SMD **0.24 SD lower** (2.144 lower to 2.744 higher)
Waist circumference assessed with: centimeters follow up: 6 months	51 (1 RCT)	⨁⨁◯◯ LOW [a,c]	-	-	SMD **0.12 SD higher** (7.684 lower to 8.684 higher)

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **SMD:** Standardised mean difference

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

Explanations

a. allocation concealment was unclear in 1 of the studies
b. it was unclear whether intervention and control groups were similar at baseline
c. there might have been differences in the rigor of implementation and outcomes were measured at different time points
d. funnel plot showed assymetry

References

1. Mucheru DW, Hanlon MC,McEvoy M,Thakkinstian A and MacDonald-Wicks L. The comparative efficacy of lifestyle intervention strategies that target weight outcomes in people with psychosis; a systematic review and network meta-analysis. 2018.

[non-structured diet and structured physical activity] compared to [control] in [people with psychosis to decrease weight outcomes]

Bibliography: [1]

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with [control]	Risk difference with [non-structured diet and structured physical activity]
Weight assessed with: kilograms follow up: range 12 weeks to 34 weeks	479 (4 RCTs)	⨁◯◯◯ VERY LOW a,b,c,d	-	-	SMD **0.58 SD higher** (2.589 lower to 4.76 higher)
Body mass index (BMI) assessed with: weight in kilograms/ height in meters*height in meters follow up: range 12 weeks to 34 weeks	811 (5 RCTs)	⨁◯◯◯ VERY LOW b,e	-	-	SMD **0.05 SD higher** (0.85 lower to 0.891 higher)
Waist circumference assessed with: centimeters follow up: range 12 weeks to 34 weeks	527 (4 RCTs)	⨁◯◯◯ VERY LOW b,e	-	-	SMD **0.01 SD higher** (2.156 lower to 2.183 higher)

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **SMD:** Standardised mean difference

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

Explanations

a. true randomization, allocation concealment, blinding of assessors, use of appropriate analysis and completion of follow up was not evident in all studies
b. there might have been differences in rigor of implementation and outcomes were taken at different time points
c. publication bias was detected
d. funnel plots showed asymmetry
e. true randomization, allocation concealment, blinding of assessors, use of appropriate analysis, completion of follow up and reliable outcome measurement was not evident in all studies

References

1. Mucheru DW, Hanlon MC,McEvoy M,Thakkinstian A and MacDonald-Wicks L. The comparative efficacy of lifestyle intervention strategies that target weight outcomes in people with psychosis; a systematic review and network meta-analysis. 2018.

[non-structured diet and non-structured physical activity] compared to [control] in [people with psychosis to decrease weight outcomes]

Bibliography: [1]

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with [control]	Risk difference with [non-structured diet and non-structured physical activity]
Weight assessed with: kilograms follow up: range 12 weeks to 12 months	585 (8 RCTs)	⨁◯◯◯ VERY LOW a,b,c,d,e	-	-	SMD **0.24 SD lower** (3.365 lower to 2.639 higher)
Body mass index (BMI) assessed with: weight in kilograms/ height in meters*height in meters follow up: range 8 weeks to 12 months	421 (7 RCTs)	⨁◯◯◯ VERY LOW a,b,c	-	-	SMD **0.03 SD higher** (0.936 lower to 0.962 higher)
Waist circumference assessed with: centimeters follow up: range 6 months to 6 months	217 (3 RCTs)	⨁◯◯◯ VERY LOW b,c,f	-	-	SMD **2.24 SD lower** (6.897 lower to 0.456 lower)

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **SMD:** Standardised mean difference

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

Explanations

a. true randomization, allocation concealment, similarity of groups at baseline, blinding of assessors, identical treatment of groups, completion of follow up, and reliability of outcome measurement in treatment groups could not be confirmed in all studies
b. the intervention effect was not consistent for all study outcomes
c. there might have been a difference in rigor of implementation and outcomes were taken at different time points
d. publication bias was detected
e. funnel plots showed asymmetry
f. allocation concealment, similarity of treatment groups at baseline and procedure for measuring outcomes in treatment groups was unclear in the studies

References

1. Mucheru DW, Hanlon MC,McEvoy M,Thakkinstian A and MacDonald-Wicks L. The comparative efficacy of lifestyle intervention strategies that target weight outcomes in people with psychosis; a systematic review and network meta-analysis. 2018.

[structured physical activity] compared to [control] in [people with psychosis to decrease weight outcomes]

Bibliography: [1]

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with [control]	Risk difference with [structured physical activity]
Weight assessed with: kilograms follow up: 12 weeks	28 (1 RCT)	⨁◯◯◯ VERY LOW a,b,c	-	-	SMD **0.81 SD lower** (14.754 lower to 6.154 higher)
Body mass index (BMI) assessed with: weight in kilograms/ height in meters*height in meters follow up: range 12 weeks to 6 months	91 (2 RCTs)	⨁⨁◯◯ LOW[a]	-	-	SMD **1.08 SD higher** (3.157 lower to 0.91 higher)
Waist circumference assessed with: centimeters follow up: 6 months	63 (1 RCT)	⨁⨁◯◯ LOW[a]	-	-	SMD **0.99 SD lower** (11.288 lower to 3.688 higher)

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **SMD:** Standardised mean difference

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

Explanations

a. there might have been differences in rigor of implementation and outcomes were measured at different time points
b. publication bias detected
c. funnel plot showed asymmetry

References

1. Mucheru DW, Hanlon MC,McEvoy M,Thakkinstian A and MacDonald-Wicks L. The comparative efficacy of lifestyle intervention strategies that target weight outcomes in people with psychosis; a systematic review and network meta-analysis. 2018.

Introduction *(level 1 heading)*

People in Australia living with psychosis have an all-cause mortality rate five times that of the general population, and cardiovascular disease (CVD) is largely responsible for the premature mortality.[1-6] People with psychosis have a higher prevalence of CVD lifestyle risk factors compared to the general population, leading to worse physical health outcomes.[5] The combined effects of lifestyle risk factors, including smoking, poor dietary choices and inadequate physical activity, along with atypical antipsychotic medication use in this cohort, have resulted in increased rates of weight gain, diabetes, metabolic syndrome and CVD.[7-9]

Decreasing the prevalence of CVD lifestyle risk factors is a more effective way of preventing and controlling CVD than treating the metabolic abnormalities associated with psychosis.[7] Lifestyle interventions should be the primary approach to combat CVD lifestyle risk factors, and this can be achieved through organizations that provide healthcare services for people with psychosis.[10,11] Lifestyle interventions can be defined as programs that promote improved behavioral outcomes without the employment of pharmacological aids.[10,12] In people with psychosis, lifestyle interventions that target CVD lifestyle risk factors have tended to focus on diet and physical activity and exclude smoking cessation; this is because smoking cessation programs achieve the best outcomes when pharmacotherapy is incorporated.[7,10,12-14] Lifestyle interventions that target people with psychosis are different to those offered in the general population because the impact of psychotic symptoms and cognitive challenges are considered in the design of the interventions, ensuring suitability to the target group.[15-22]

Systematic reviews and meta-analyses have confirmed that lifestyle interventions focusing on improved diet and increased physical activity among people with psychosis result in significant weight reduction, decreasing the risk of CVD.[10,12] Weight reduction, as measured by changes in body weight, is the most commonly reported outcome of lifestyle intervention studies.[10,23] Systematic reviews also confirm that benefits of lifestyle interventions extend to other parameters that are inversely associated with weight reduction, such as body mass index (BMI), waist circumference, plasma cholesterol, triglycerides, insulin and fasting blood glucose levels.[10,12,24-26] Other important findings from systematic reviews on this topic include that weight loss is greater in those with recent-onset psychosis compared to those with chronic psychosis, and that drop-out rates in lifestyle interventions are lower than those of pharmacological interventions offered in the same population.[10,12,24-26]

Despite the progress in the field and the proven success of lifestyle interventions among people with psychosis, much remains unknown about the strategies that contribute to the efficacy of these interventions.[10] Previous systematic reviews and meta-analyses have attempted to decipher the essential strategies of lifestyle interventions in people with psychosis.[10,12,24-26] This was accomplished either through reviewing effective lifestyle interventions for similarities in key characteristics after conducting meta-analyses, or through grouping lifestyle interventions into dichotomous groups based on similarities in vital elements and conducting meta-analyses.[10,12,24-26] Meta-analytic assessments of

lifestyle interventions have found that interventions with a focus on individual treatment are more efficacious than those conducted in a group setting.[24] Although this is valuable insight, a major shortcoming of these meta-analyses is that only binary groups of lifestyle intervention characteristics could be compared, which may have led to some features being over-summarized to allow for pairwise contrasts to be made, potentially masking other important information in the reviewed studies.[12,24-26] For example, a closer review of lifestyle intervention studies that focused on individual treatment highlighted i) the use of specific or personalized instructions, which were reviewed regularly by a health professional, and ii) the inclusion of supervised exercise. Similar interventions that were implemented in a group setting lacked the structured nature of personalized advice and the corresponding monitoring that was offered.[15-22] This information was not clearly described in previous meta-analyses; therefore, groupings used in analyses are difficult to justify.[12,24-26] Furthermore, studies with only some of the criteria used to create dichotomous groups for meta-analyses were not adequately catered for, as additional groups could not be included in analyses.[12,24-26]

To avoid the limitation of summarizing lifestyle interventions only according to dichotomous groups, this review employed the network meta-analytic procedure, which can assess two or more groups of available randomized controlled trials (RCTs).[27] Additionally, available RCTs were described in sufficient detail so that distinctions between any potential subcategories used for data-analyses were clear.

Finally, none of the available systematic reviews and meta-analyses identified lifestyle interventions that offered advice that adhered to the Australian Dietary Guidelines (ADGs).[28] The ADGs were written to promote health and wellbeing, and reduce rates of chronic disease; hence, it is important that any dietary advice offered to people with psychosis complies with these guidelines.[5,28,29] The ADGs are applicable to all Australian adults who do not require specialized dietary advice; therefore, they are suitable for this population.[28]

Review objectives *(level 1 heading)*

The aim of this systematic review and network meta-analysis was to pool and rank the efficacy of lifestyle intervention strategies that target weight, BMI, waist circumference and waist-to-hip ratio in people with psychosis by comparing the effect size of these weight outcomes. Secondary to this, the aim was to stratify lifestyle interventions that target the same weight outcomes in people with psychosis according to their inclusion of dietary information that adheres to ADGs.

Inclusion criteria *(level 1 heading)*

Participants *(level 2 heading)*

This systematic review considered studies that included community-dwelling participants aged 18 years and older with a psychotic disorder (mainly schizophrenia-type disorders, International Statistical Classification of Diseases and Related Health Problems [ICD] codes F20-F29).

A diagnosis of a psychotic disorder was regarded as valid for the purpose of this study if at least one of the following conditions was met:

V. The diagnosis was made using the Diagnostic and Statistical Manual of Mental Disorders (DSM) or the ICD;
VI. The diagnosis was confirmed by consulting the participant's physician;
VII. The participant's health records were accessed to confirm diagnosis; or
VIII. The participant was referred by his/her physician to take part in the study because of a psychotic disorder.

Participants with comorbid mental or physical illnesses were also included, provided they had a psychotic disorder.

Intervention(s)/phenomena of interest *(level 2 heading)*

This systematic review considered studies designed to deliver lifestyle interventions, health interventions, health promotion lifestyle programs, health promotion programs, healthy living interventions, healthy lifestyle programs, interventions for health risk behaviors, weight management interventions, diet interventions, exercise interventions, non-pharmacological lifestyle interventions or nutrition interventions.

This systematic review excluded all lifestyle interventions that utilized the Internet or mobile health (mHealth) technology because lifestyle interventions delivered through the Internet have high dropout rates and low utilization rates; hence, many studies are not efficacious.[30] Furthermore, because the research is still new, there are no identified well-designed high-quality RCTs on lifestyle interventions delivered through m-health technology or the Internet to people with psychosis.[30] This review also excluded all lifestyle interventions conducted in inpatient settings because the needs of people in inpatient and outpatient settings differ vastly. A previous systematic review found that weight, BMI and waist circumference significantly decreased only in RCTs conducted in outpatient settings.[12]

Outcomes *(level 2 heading)*

Studies were considered if they included the following outcome measures: weight (kg), BMI (kg/m^2), waist circumference (cm) and waist-to-hip ratio. These outcomes were chosen because weight was the single most reported outcome in previous RCTs; however, the consensus is that BMI, waist circumference and waist-to-hip ratio are more meaningful weight outcomes in relation to overall health.[10,31,32]

Types of studies *(level 2 heading)*

Only RCTs were considered for inclusion because of the strength in their research design.[33] This review was restricted to studies published in English from 1985 to June 2018. The language restriction was chosen because the authors are proficient in English, and difficulties may have presented in accessing and verifying information published in other languages.[34] The restriction to studies published since 1985

was chosen because earlier studies used undesirable contingency weight management approaches, such as provision of cigarettes or coffee, depending on whether the participants achieved the desired outcomes. These methods are currently considered unethical.[35] Also, RCTs delivering lifestyle interventions to people with psychosis had not been identified before 1985 in other systematic reviews; therefore, it would not be beneficial to include studies conducted before this date.[35]

Methods *(level 1 heading)*

One deviation was made from the outlined methodology in the *a priori* protocol for this review.[36] This review systematically identified all relevant RCTs from databases; however, a systematic review of previous systematic reviews on this topic was not carried out as previously stated in the protocol. This measure had been put in place to avoid incomplete inclusion of RCTs.[36] This change was made because search terms used in the current review were comprehensive. In addition, after comparing RCTs identified by our search with two of the major previous reviews on this topic, all relevant papers had been identified by our search and additional papers had also been retrieved.[10,37] A literature review of available systematic reviews on this topic was nonetheless completed to identify gaps in literature before the completion of this review.

Search strategy *(level 2 heading)*

The search strategy aimed to find published studies. The JBI three-step search strategy was utilized in this review. An initial limited search of MEDLINE and CINAHL was undertaken, followed by an analysis of the text words contained in the title and abstract, and of the index terms used to describe the article. A second search using all identified keywords and indexterms was undertaken across all databases searched. These included the Cochrane Library, MEDLINE/PreMEDLINE, Embase, CINAHL, Scopus and PsycINFO. Finally, the reference lists of identified reports and articles were searched for additional studies. Only studies published in English from 1985 to June 2018 were considered for inclusion in this review. Initial keywords included lifestyle interventions, nutrition interventions, weight management, psychosis and schizophrenia. See Appendix I for the complete search strategy.

Study selection *(level 2 heading)*

All papers identified from searching databases were independently screened by two reviewers (DM and MCH). Reviewers first screened selected titles and abstracts prior to retrieving and reviewing full texts. Full texts were assessed based on the predetermined criteria for type of participants, intervention characteristics, outcomes in focus and studies of interest. Full-text studies that did not meet the inclusion criteria were excluded, and reasons for their exclusion are provided (Appendix II).

Assessment of methodological quality *(level 2 heading)*

Papers selected for retrieval were assessed by two independent reviewers (DM and LMW) for methodological validity prior to inclusion in the review using standardized critical appraisal instruments

from JBI Meta-Analysis of Statistics Assessment and Review Instrument (JBI MAStARI; Joanna Briggs Institute, Adelaide, Australia).[38] Reviewers agreed that questions 4 and 5 in the JBI MAStARI critical appraisal instrument (relating to blinding of participants and those delivering the interventions) would be excluded from the assessment due to the nature of included studies. Any disagreements that arose between the reviewers were resolved through discussion, or with a third reviewer (MCH).

Data extraction *(level 2 heading)*

Data were extracted from papers included in the review by one reviewer (DM) using the standardized data extraction tool from JBI MAStARI.[38] The data extracted included the following specific details:

i) Study aim and methodology, comprising inclusion and exclusion criteria, intervention content, delivery format, frequency and duration, and details on follow-up
ii) Population characteristics, including age, diagnosis, medications used, sample size, compliance to the intervention and dropouts
iii) Study setting
iv) Effects of the intervention on weight, BMI, waist circumference and waist-to-hip ratio.

Data collection for the study outcomes (weight, BMI, waist circumference and waist-to-hip ratio) were conducted simultaneously. Where information from the included studies was inadequate or unclear, authors were contacted for more detail.

Data synthesis *(level 2 heading)*

Data on the different lifestyle intervention strategies used in included studies were first qualitatively summarized prior to proceeding with pooling of results (Appendix III). This process allowed for a closer analysis of studies so similarities could be identified. Lifestyle intervention categories or subgroups were thus created based on key similarities of studies. Similarities in studies were assessed based on available lifestyle intervention components (diet or physical activity or both), mode of delivery of lifestyle intervention components (strategies utilized during delivery), and the occurrence of participant review after attending intervention sessions. The use of these principles to assess lifestyle intervention studies resulted in the formation of mutually exclusive subgroups, which were then compared in meta-analyses.

Synthesis of dietary information to assess adherence with ADGs was conducted in a narrative format. Dietary information in lifestyle intervention studies was compared to the ADGs using a checklist to assess compliance or non-compliance. Tables were used to aid in data presentation (Table 1).

Table 1: Assessment of compliance to Australian Dietary Guidelines

Author	Dietary Advice	Compliance to guideline 1†	Compliance to guideline 2‡	Compliance to guideline 3§	Compliance to guideline 5¶
(Milano et al., 2007)[48]	• Dietary information encouraged a *reduction of 500 kcal/ day* with *appropriate nutritional balance.*	Compliant¢	Compliant	Insufficient detail provided¤	Insufficient detail provided
(Erickson et al., 2016)[49]	• The program aimed at a *decrease of 500-1000 kcal/ day.* • Appropriate *portion size* was taught through the food pyramid which highlighted the *5 food groups.*	Compliant	Compliant	Insufficient detail provided	Insufficient detail provided
(Daumit et al., 2013)[51]	• Participants were encouraged to consume a *variety of food* from the *5 food groups.* • The intervention promoted *portion control*, *consuming 5 serves of fruits and vegetables*, *reducing fat* content, and choosing snacks with *reduced sugar.*	Compliant	Compliant	Compliant	Insufficient detail provided
(Speyer et al., 2013)[50]	Details of dietary advice given to participants were not described.	Insufficient detail provided	Insufficient detail provided	Insufficient detail provided	Insufficient detail provided
(Khazaal et al., 2007)[24]	• *Moderate food intake* was encouraged without a prohibition of any food groups.	Compliant	Insufficient detail provided	Insufficient detail provided	Insufficient detail provided
(Weber and Wyne, 2006)[27]	• Participants were taught about healthy eating, ways to *decrease fat* and ways to *increase physical activity.*	Insufficient detail provided	Insufficient detail provided	Compliant	Insufficient detail provided
(Ratliff et al., 2015)[52]	• The intervention aimed to help participants choose healthy *foods from each food group* whilst *managing portions.*	Compliant	Compliant	Insufficient detail provided	Insufficient detail provided
(Scheewe et al., 2011)[53]	Dietary information was not given as part of this program	N/Aρ	N/A	N/A	N/A
(Font et al., 2015)[54]	• The nutrition component of the current program taught on *portion sizes*, the *food pyramid* and *dietary guidelines*.	Compliant	Compliant	Insufficient detail provided	Insufficient detail provided
(Greil et al., 2010)[55]	• Nutrition advice in this program emphasized the importance of the *food pyramid, total calorie and fat content of meals, meal planning, shopping and non-alcoholic beverages* as alternatives.	Compliant	Compliant	Compliant	Insufficient detail provided
(Verhaeghe et al., 2014)[68]	Details of dietary advice given to participants were not described.	Insufficient detail provided	Insufficient detail provided	Insufficient detail provided	Insufficient detail provided
(McKibbin et al., 2006, McKibbin et al., 2010)[26,57]	• The nutrition education emphasized the importance of *food groups, portion sizes, decreasing sugar*	Compliant	Compliant	Compliant	Insufficient detail provided

	consumption and *increasing fruit and vegetable* intake.				
(Frank et al., 2015)[70]	• Dietary education covered *nutrition guidelines*, *portion sizes* and *limiting nutrients such as fat, sugar, alcohol* and cholesterol.	Compliant	Compliant	Compliant	Insufficient detail provided
(Goldberg et al., 2013)[58]	• Nutrition education sessions covered *basics of healthy eating* and *meal planning*.	Insufficient detail provided	Insufficient detail provided	Insufficient detail provided	Insufficient detail provided
(Evans et al., 2005)[20]	• Dietary information provided to participants included information on healthy eating, label reading, energy density, fibre and maintenance of healthy eating. (Language used is non-specific/ vague in answering the current question).	Insufficient detail provided	Insufficient detail provided	Insufficient detail provided	Insufficient detail provided
(Methapatara and Srisurapanont, 2011)[59]	Details of dietary advice given to participants were not described.	Insufficient detail provided	Insufficient detail provided	Insufficient detail provided	Insufficient detail provided
(Forsberg et al., 2008)[60]	• Nutrition education sessions covered *consumption of a balanced diet, importance of main meals, snacks, fruits, vitamin, fibre as well as sugar and fat*.	Compliant	Compliant	Compliant	Insufficient detail provided
(Jean-Baptiste et al., 2007)[71]	• Education on diet included: *portion control*, healthy cooking, food choices for weight loss, label reading and healthy snacking. • Dietary advice given was based on the *food pyramid.*	Compliant	Compliant	Insufficient detail provided	Insufficient detail provided
(Mauri et al., 2008)[61]	• Nutrition education covered topics inclusive of, the importance of *balanced meals*, eating regularly and *weight maintenance upon weight loss*. A *personalised calorie controlled diet* was also prescribed.	Compliant	Compliant	Insufficient detail provided	Insufficient detail provided
(Usher et al., 2013)[62]	• Topics covered while giving dietary advice included: importance of *food groups, fruit and vegetable intake and healthy snacking.*	Compliant	Compliant	Insufficient detail provided	Insufficient detail provided
(Green et al., 2015)[65,66]	• Nutrition education topics included: *portion size, self-monitoring, calorie calculation, regular meal intake, decreasing fat and sugar intake and increasing fruit and vegetable intake*.	Compliant	Insufficient detail provided	Compliant	Insufficient detail provided
(Scocco et al., 2006)[22]	Details of dietary or physical activity advice given to participants were not described	Insufficient detail provided	Insufficient detail provided	Insufficient detail provided	Insufficient detail provided
(Kwon et al., 2006)[21]	• Dietary education covered healthy snacking, *portion control using food models, meal planning, food exchanges and low calorie meal preparation*.	Compliant	Insufficient detail provided	Insufficient detail provided	Insufficient detail provided

(Attux et al., 2013)[67]	Details of dietary or physical activity advice given to participants were not described.	Insufficient detail provided	Insufficient detail provided	Insufficient detail provided	Insufficient detail provided
(Skrinar et al., 2005)[63]	• Health seminars covered education topics such as healthy eating, weight management, stress and exercise. (Language used does not adequately describe content of the sessions)	Insufficient detail provided	Insufficient detail provided	Insufficient detail provided	Insufficient detail provided
(Battaglia et al., 2013)[64]	Dietary information was not given in this program and physical activity components were mainly practical	N/A	N/A	N/A	N/A
(Brar et al., 2005)[23]	• Nutrition education were carried out using food models so that sessions were simulated. Topics covered included *portion size*, *self-monitoring food consumption*, and *changing snacking habits and snacks*.	Compliant	Insufficient detail provided	Insufficient detail provided	Insufficient detail provided
(Erickson et al., 2017)[69]	• The nutrition curriculum covered topics including *mindful eating, portion sizes, variety during meals, managing the food environment at home and eating out of home*. Once-daily meal replacement shakes were offered when basic food and exercise changes were less effective.	Compliant	Compliant	Insufficient detail provided	Insufficient detail provided
(Gaughran et al., 2017)[72]	• Dietary information provided to participants was not specified	Insufficient detail provided	Insufficient detail provided	Insufficient detail provided	Insufficient detail provided
(Kilbourne et al., 2017)[73]	• Topics covered in the dietary component were, *portion control, identification of low fat, lower salt and sugar foods and triggers for unhealthy eating*.	Compliant	Insufficient detail provided	Compliant	Insufficient detail provided

† - Guideline 1: Maintain a healthy weight through physical activity and portion control;[29] ‡- Guideline 2: Maintain variety in diet through consuming food from the 5 food groups;[29] § - Guideline 3: Limit foods containing saturated fats, added salt and sugar and alcohol in your diet;[29] ¶ - Guideline 5: Care for your food; prepare and store it safely.[29] Guideline 4 is not relevant to the current study as it focuses on pregnant women and pregnant women were generally excluded from included studies.[29] ¢-*Compliant- information provided by the author appeared to adhere to requirements of one of the guidelines.* ¤-*Insufficient detail provided- author does not provided enough detail for us to classify information as compliant or non-compliant or language used does not clearly show compliance or non-compliance of information.* ℘-*N/A, Not applicable. Dietary advice was not offered as part of the intervention*

Stata statistical software v.14 (Stata Corp LLC, Texas, USA) was used for all statistical analyses.[39] The effect of each lifestyle intervention subgroup was summarized by pooling means and standard deviations for the individual weight outcome measures (weight in kilograms [kg], BMI, waist circumference in centimeters [cm] and waist-to-hip ratio). To allow for pooling of data from most of the available studies, means and standard deviations for weight outcomes were calculated using standard errors and confidence intervals (CIs) when the former measures were not provided.[40] Conventional pairwise meta-analyses were conducted first to allow for comparison of results with subsequent network meta-analysis.[41] Pairwise meta-analysis compared each individual lifestyle intervention category to the control condition, as listed in Appendix III. The random effects model was used for the meta-analyses, allowing for more flexibility over the fixed effects model as it carries the assumption that there are factors affecting data other than error and chance, within and between included studies.[42] Overall weighted mean differences (WMD) and corresponding CIs were obtained by combining the mean changes in weight outcomes for each study within the various subgroup analyses. Heterogeneity of studies within the various subgroups was assessed using the I^2 statistic. The I^2 statistic is calculated from meta-analysis results using the formula, $I^2 = 100\% \times (Q - df)/Q$, where Q is Cochran's heterogeneity statistic and d.f. is the degrees of freedom.[43] Low, moderate or high heterogeneity is assigned I^2 values corresponding to 25%, 50% and 75%, respectively.[43] The source of heterogeneity was explored if I^2 was ≥ 25%.

The network meta-analysis was then used to conduct comparisons between the different lifestyle intervention subgroups used in meta-analyses previously and also to rank the efficacy of different lifestyle intervention subgroups.[44] The network meta-analysis indirectly compared effects of lifestyle interventions by borrowing information from a common comparator, which was the control condition. Lifestyle interventions were coded, and the control condition was used as the reference. A two-stage multivariate meta-analysis was applied as follows: WMDs and variance-covariance were estimated for each study. These were then pooled across different subgroups using a multivariate meta-analysis. Mixed effect comparisons of lifestyle interventions were then compared using a linear combination of the multivariate meta-analysis model. Comparison-adjusted funnel plots were constructed to assess publication bias.[45] The predictive probability of being the best lifestyle intervention was estimated and ranked using surface under a cumulative ranking curve (SUCRA).[46]

Results *(level 1 heading)*

Study inclusion *(level 2 heading)*

Database searches were completed on June 1, 2018. The search recovered 6585 papers. A total of 2200 duplicates were removed. Titles and abstracts of 4385 papers were screened, and 4326 were excluded, leaving 59 papers. The remaining 59 papers received full-text screening, and 29 papers were excluded, leaving 30. Two more papers were identified in references during full-text screening and were deemed relevant for this study, giving a total of 32 papers. Figure 1 illustrates the selection process for study inclusion.

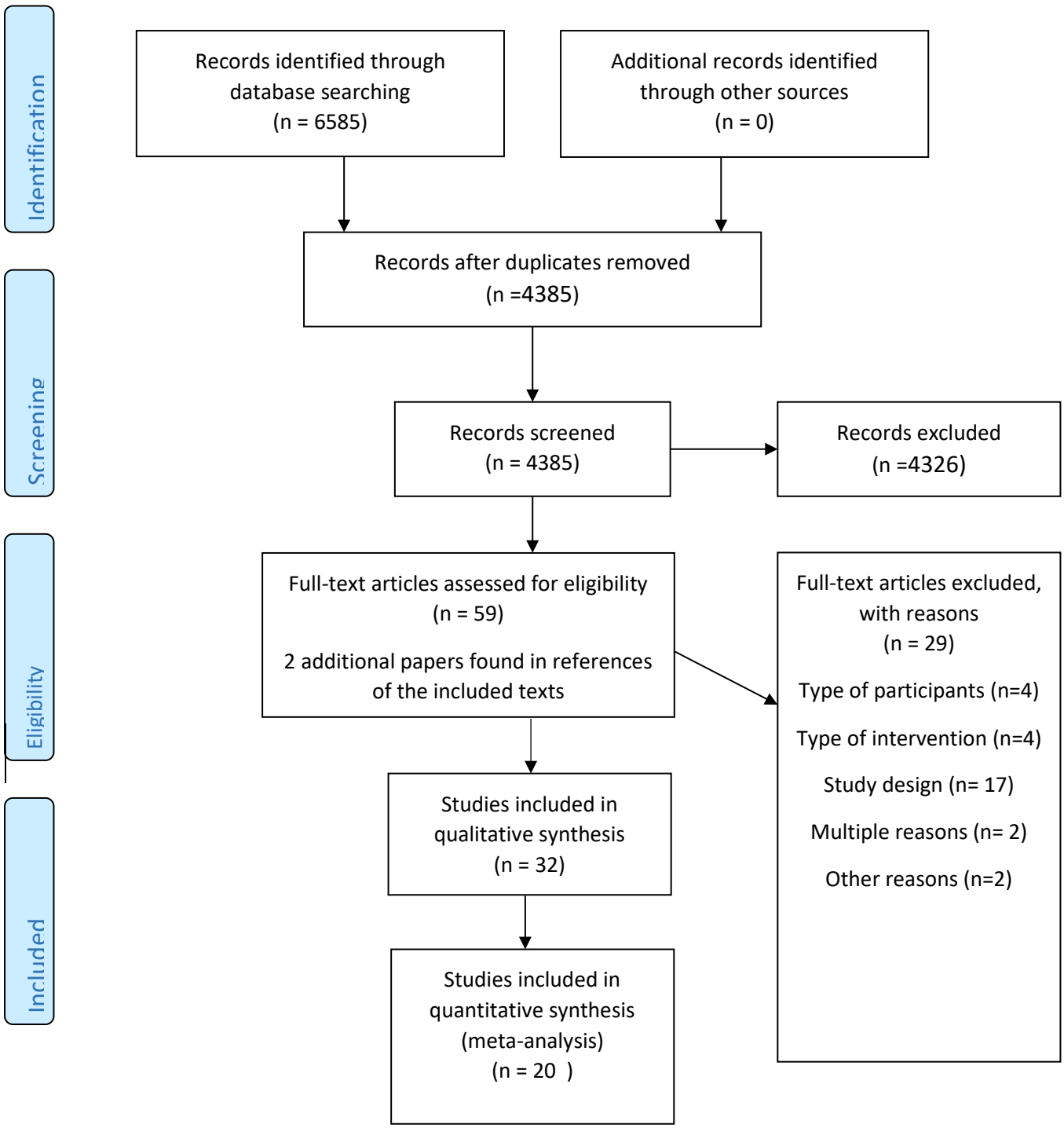

Figure 1: PRISMA flow diagram

Methodological quality *(level 2 heading)*

Two independent reviewers assessed the risk of bias in 30 studies out of 32 (two studies were follow-up studies from the parent studies). The JBI critical appraisal checklist for RCTs, a 13-item tool was

primarily used to assess risk of bias (Table 2). Overall, quality of studies ranged from low to moderate, as none of the studies met the “yes” criteria for all items on the checklist. Almost two-thirds (63%) of included studies reported using true randomization for assignment of participants to treatment groups (Q1). Many of the other studies (33%) were “unclear” on whether randomization was true, while one study (3%) had an answer of “no” to this question. One-half (50%) of RCTs reported that allocation to treatment groups was concealed (Q2). The majority (47%) of other available studies were “unclear” on allocation concealment, and 3% had an answer of “no” to using allocation concealment. More than three-quarters (77%) reported that intervention and control groups appeared similar at baseline (Q3), which was proven through statistical comparison of the groups. The remaining studies were either “unclear” (17%) or did not fulfill this criterion (3%). As previously mentioned, questions 4 and 5 were excluded from assessments due to the nature of included studies. Some studies (47%) reported that assessors of outcomes were blind to treatment group (Q6), whereas 10% stated that no blinding was used. The other studies (43%) were “unclear” on blinding of assessors. Nearly all of the studies (97%) had treatment groups being treated identically other than the intervention of interest (Q7). Only one study (3%) was “unclear” on this criterion. Most studies (93%) completed follow-up, and appropriate strategies were put in place where this was not the case (Q8). Two studies (7%), however, were “unclear” on this same question. All studies (100%) analyzed participants in the groups in which they were originally allocated (Q9). The majority (87%) of the studies measured outcomes in the same way for all treatment groups (Q10). Only 3% of studies answered “no” to this question, whereas 10% of studies were “unclear”. Many studies (73%) measured outcomes in a reliable way (Q11), whereas about one-fifth (23%) of the studies were “unclear” and 3% of studies did not fulfill this criterion. A majority of studies (83%) used appropriate statistical analyses (Q12), while in 13% of studies, it was “unclear” and one study (3%) did not use suitable analyses. Finally, all studies (100%) used an appropriately-designed RCT (Q13), and deviations were accounted for where appropriate.

Table 2: Critical appraisal results of eligible studies

Study	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13
(Milano et al., 2007)[48]	U	U	U	N/A	N/A	U	U	U	Y	U	U	U	Y
(Erickson et al., 2016)[49]	Y	Y	Y	N/A	N/A	Y	Y	Y	Y	Y	Y	Y	Y
(Daumit et al., 2013)[51]	Y	Y	Y	N/A	N/A	Y	Y	Y	Y	Y	Y	Y	Y
(Speyer et al., 2013)[50]	Y	Y	U	N/A	N/A	Y	Y	Y	Y	Y	Y	Y	Y
(Khazaal et al., 2007)[24]	U	U	N	N/A	N/A	U	N	Y	Y	Y	Y	Y	Y
(Weber and Wyne, 2006)[27]	U	U	Y	N/A	N/A	Y	Y	Y	Y	Y	Y	N	Y
(Ratliff et al., 2015)[52]	Y	Y	Y	N/A	N/A	U	Y	Y	Y	Y	Y	Y	Y
(Scheewe et al., 2011)[53]	Y	Y	Y	N/A	N/A	Y	Y	Y	Y	Y	U	Y	Y
(Font et al., 2015)[54]	Y	Y	Y	N/A	N/A	Y	Y	Y	Y	U	U	Y	Y
(Greil et al., 2010)[55]	U	U	Y	N/A	N/A	U	Y	Y	Y	U	U	Y	Y
(Verhaeghe et al., 2014)[68]	N	N	Y	N/A	N/A	U	Y	Y	Y	Y	Y	Y	Y
(McKibbin et al., 2006, McKibbin et al., 2010)[26,57]	Y	U	U	N/A	N/A	Y	Y	Y	Y	Y	Y	Y	Y
(Frank et al., 2015)[70]	Y	U	Y	N/A	N/A	Y	Y	Y	Y	Y	Y	Y	Y
(Goldberg et al., 2013)[58]	Y	U	Y	N/A	N/A	U	Y	Y	Y	Y	Y	N	Y

(Evans et al., 2005)[20]	U	U	Y	N/A	N/A	U	Y	Y	Y	Y	Y	Y	Y
(Methapatara and Srisurapanont, 2011)[59]	Y	Y	Y	N/A	N/A	N	Y	Y	Y	Y	Y	Y	Y
(Forsberg et al., 2008)[60]	Y	Y	Y	N/A	N/A	N	Y	Y	Y	Y	Y	Y	Y
(Jean-Baptiste et al., 2007)[71]	U	U	Y	N/A	N/A	U	Y	Y	Y	Y	Y	N	Y
(Mauri et al., 2008)[61]	U	U	Y	N/A	N/A	U	Y	Y	Y	Y	Y	Y	Y
(Usher et al., 2013)[62]	Y	Y	Y	N/A	N/A	N	Y	Y	Y	Y	Y	Y	Y
(Green et al., 2015)[65,66]	Y	Y	U	N/A	N/A	Y	Y	Y	Y	Y	Y	Y	Y
(Scocco et al., 2006)[22]	Y	U	U	N/A	N/A	U	Y	N	Y	Y	Y	Y	Y
(Kwon et al., 2006)[21]	U	U	Y	N/A	N/A	U	Y	Y	Y	Y	Y	Y	Y
(Attux et al., 2013)[67]	Y	Y	Y	N/A	N/A	Y	Y	Y	Y	Y	U	Y	Y
(Skrinar et al., 2005)[63]	U	U	Y	N/A	N/A	U	Y	U	Y	Y	Y	N	Y
(Battaglia et al., 2013)[64]	Y	Y	Y	N/A	N/A	Y	Y	Y	Y	Y	Y	Y	Y
(Brar et al., 2005)[23]	U	U	Y	N/A	N/A	U	Y	Y	Y	N	N	Y	Y
(Erickson et al., 2017)[69]	Y	Y	Y	N/A	N/A	Y	Y	Y	Y	Y	U	Y	Y
(Gaughran et al., 2017)[72]	Y	Y	Y	N/A	N/A	Y	Y	Y	Y	Y	U	Y	Y
(Kilbourne et al., 2017)[73]	Y	Y	Y	N/A	N/A	Y	Y	Y	Y	Y	Y	Y	Y

Total Y	**19 (63%)**	**15 (50%)**	**23 (77%)**	**0**	**0**	**14 (47%)**	**29 (97%)**	**28 (93%)**	**30 (100%)**	**26 (87%)**	**22 (73%)**	**25 (83%)**	**30 (100%)**
Total N	**1 (3%)**	**1 (3%)**	**1 (3%)**	**0**	**0**	**3 (10%)**	**0**	**0**	**0**	**1 (3%)**	**1 (3%)**	**1 (3%)**	**0**
Total U	**10 (33%)**	**14 (47%)**	**5 (17%)**	**0**	**0**	**13 (43%)**	**1 (3%)**	**2 (7%)**	**0**	**3 (10%)**	**7 (23%)**	**4 (13%)**	**0**
Total N/A	**0**	**0**	**0**	**30 (100%)**	**30 (100%)**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**

Y = Yes, N = No, U = Unclear, N/A = not applicable; JBI critical appraisal checklist for randomized controlled trials: Q1 = Was true randomization used for assignment of participants to treatment groups?; Q2 = Was allocation to treatment groups concealed?; Q3 = Were treatment groups similar at baseline?; Q4 = Were participants blind to treatment assignment?; Q5 = Were those delivering treatment blind to treatment assignment?; Q6 = Were outcome assessors blind to treatment assignment?; Q7 = Were treatment groups treated identically other than the intervention of interest?; Q8 = Was follow-up complete, and if not, were strategies to address incomplete follow-up utilized?; Q9 = Were participants analyzed in the groups to which they were randomized?; Q10 = Were outcomes measured in the same way for treatment groups?; Q11 = Were outcomes measured in a reliable way?; Q12 = Was appropriate statistical analysis used?; Q13 = Was the trial design appropriate, and any deviations from the standard RCT design (individual randomization, parallel groups) accounted for in the conduct and analysis of the trial.

Publication bias *(level 2 heading)*

Funnel plots were used to examine bias in studies. Funnel plots for studies reporting on BMI and waist circumference did not show asymmetry, whereas the funnel plot for studies reporting on weight showed asymmetry, indicating potential bias (see Figures 2 through 4).

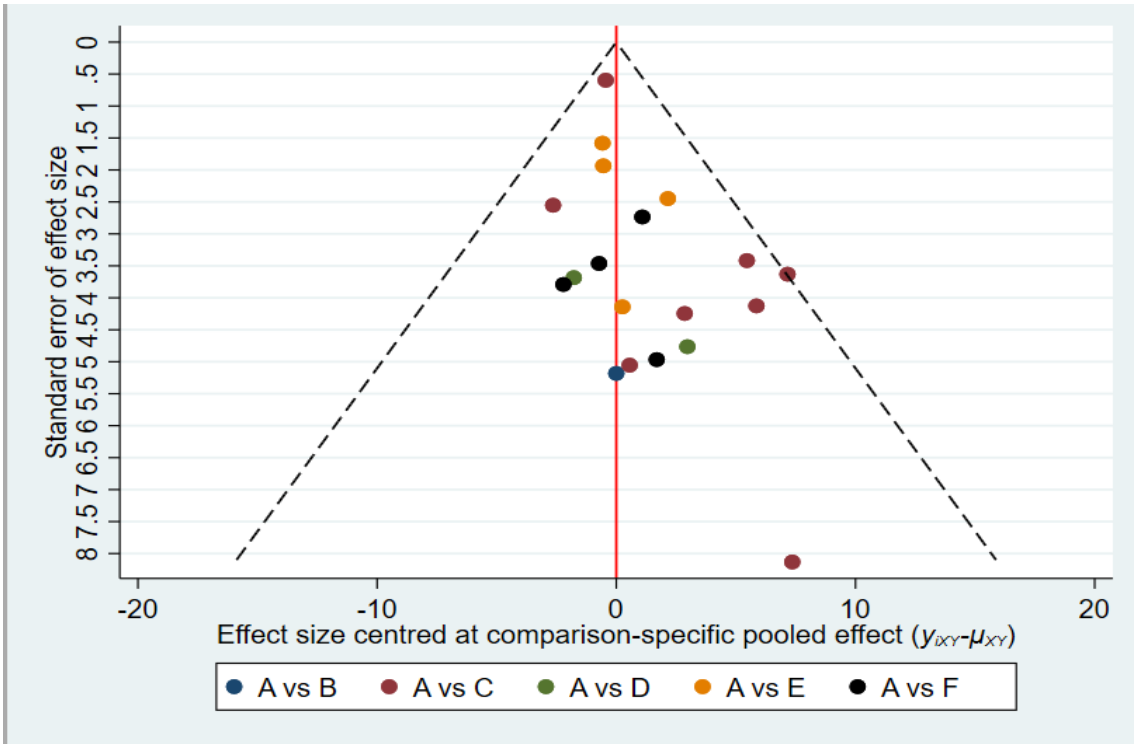

Figure 2: Funnel plot for studies reporting on weight. Key; A= Usual care, placebo I-III; B= Structured physical activity lifestyle interventions; C = Non-structured diet and non-structured physical activity lifestyle interventions; D= Structured diet and non-structured physical activity lifestyle interventions; E = Structured diet and structured physical activity lifestyle interventions; F = Non-structured diet and structured physical activity lifestyle interventions.

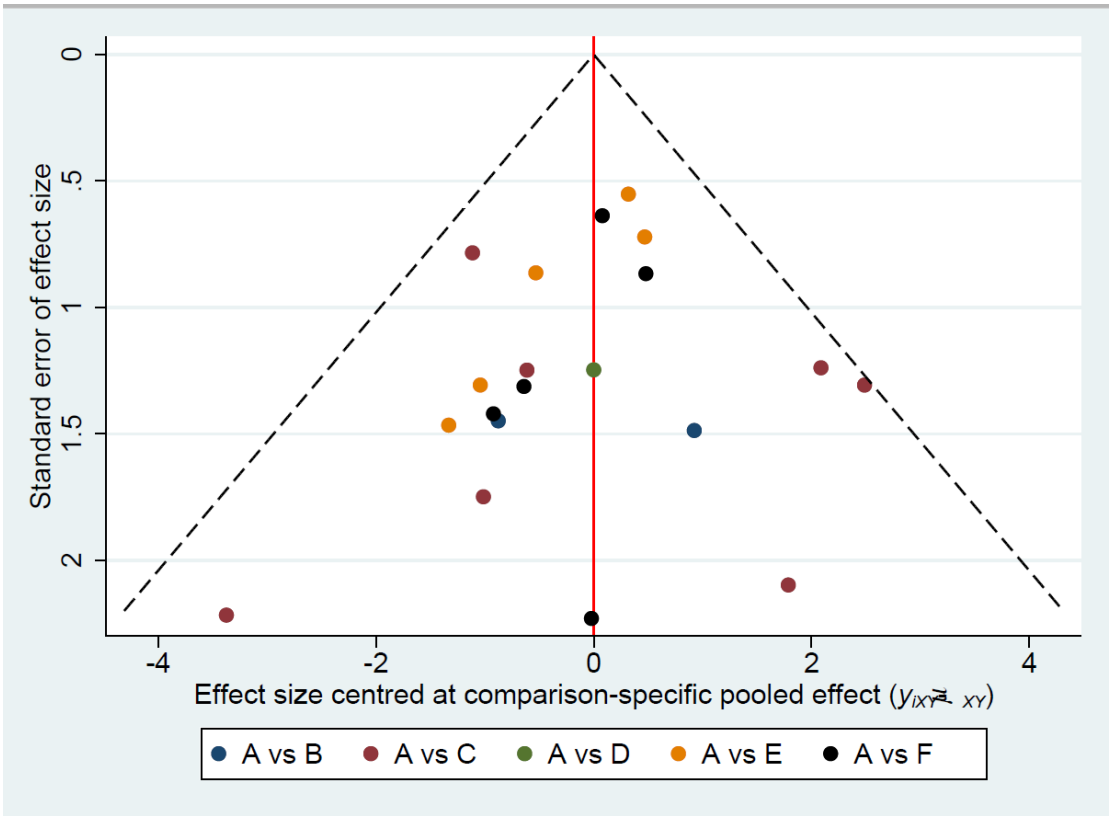

Figure 3: Funnel plot for studies reporting on BMI. Key; A= Usual care, placebo I-III; B= Structured physical activity lifestyle interventions; C = Non-structured diet and non-structured physical activity lifestyle interventions; D= Structured diet and non-structured physical activity lifestyle interventions; E = Structured diet and structured physical activity lifestyle interventions; F = Non-structured diet and structured physical activity lifestyle interventions

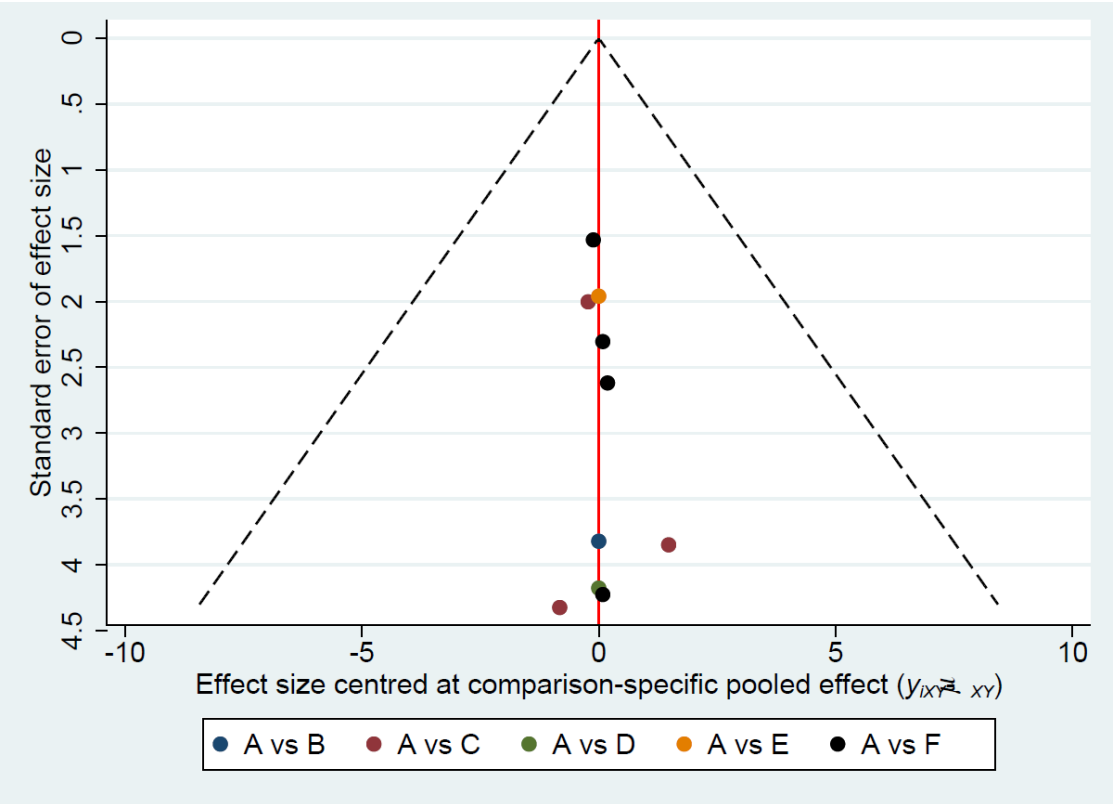

Figure 4: Funnel plot for studies reporting on waist circumference. Key; A= Usual care, placebo I-III; B= Structured physical activity lifestyle interventions; C = Non-structured diet and non-structured physical activity lifestyle interventions; D= Structured diet and non-structured physical activity lifestyle interventions; E = Structured diet and structured physical activity lifestyle interventions; F = Non-structured diet and structured physical activity lifestyle intervention

Characteristics of included studies *(level 2 heading)*

Overall, 30 of the 32 included studies reported the effect of the intervention on at least one of the outcome measures of interest.[15-19,21,22,47-69] Four of the 32 studies reporting on the effects of the intervention on the outcome measures of interest did not include standard deviations.[47,50,54,66] Body mass index and weight were the most-reported outcome measures.[15-19,21,22,47-65] Twenty-six studies reported the intervention's effect on BMI (24 with standard deviations).[15,16,18,19,21,22,47,49,51-56,58-69] Similarly, 23 studies also reported the intervention's effect on weight (20 with standard deviations).[15-19,21,22,47,48,50,54-65,67] Seventeen studies reported the effect of the intervention on waist circumference (15 with standard deviations).[15,21,48,49,52-56,58,59,61,64,65,67,70,71] Only one study reported on the intervention's effect on waist-to-hip ratio, and the standard deviation was reported.[22] Two studies did not report on the effect of the intervention, despite reporting on baseline weight outcomes.[66,72]

The most prevalent diagnoses among participants in included studies were schizophrenia,[15-19,47-50,52,53,56-59,61,63,64,67-72] schizoaffective disorder[15-19,47-50,52,53,56-59,61,63,64,67-72] and bipolar disorder.[19,47,48,50,53,54,61,66,68,69,71] Resident countries of participants were Brazil,[67] Italy,[17,47,60,63] United States of America,[18,22,48,50,51,56,57,62,64,66,68,69,72] Denmark,[49] Switzerland,[19] Netherlands,[52] Spain,[53] Germany,[54] Belgium,[70] Australia,[15,61] Thailand,[58] Sweden,[59] United Kingdom[68] and Korea.[16]

All studies included both a dietary and physical activity component in the lifestyle intervention, except for two.[15-19,21,22,47-51,53,54,56-62,64-66,68,70-72] The remaining two studies focused on physical activity as the main form of intervention.[52,63] Durations of interventions ranged from five weeks to 24 months, inclusive of study follow-up.[15-19,21,22,47-54,56-66,68-72] The lifestyle interventions were delivered by a wide range of professionals including case managers, nurses, dietitians, lifestyle coaches, nutritionists, mental health support workers, psychomotor therapists, care-coordinators, health educators and health coaches.[15-19,21,22,47-54,56-66,68-72] All interventions were manualized and delivery of intervention components tended to vary.[15-19,21,22,47-54,56-66,68-72]

Delivery of dietary and physical activity information was mainly through education in the studies that comprised both components.[15-19,21,22,47,51,53,54,58-62,64,66,67,69-72] Studies solely focusing on physical activity were mainly delivered as organized exercise sessions.[52,63] In addition to dietary and physical activity education, some studies enforced personalization of the intervention by offering tailored advice[16,22,49,60,66] or helping participants set goals specific to diet, physical activity or both, and provided regular review of progress.[15-17,48,50,52,60,61,64,66,69,71,72] Food and physical activity records were sometimes utilized to help participants keep track of their progress.[16,48,50,52,60,64,66,72] As an alternative or in addition to setting physical activity goals, some studies offered regular supervised exercise.[48,52,53,62-64,70]

Additional strategies to encourage behavior change in dietary or physical activity patterns included motivational interviewing,[19,49,50,58,71] cognitive behavior therapy[18,19,22,71] and psychoeducation.[21,60,70] In

two studies, cognitive behavior therapy and motivational interviewing were used in combination, and in one of these studies, these were the only intervention components.[19,71]

In some cases, small financial incentives were used to reward weight loss or compliance to the intervention.[21,48,51] One program sought to enhance learning in participants with psychosis by using strategies such as repetition, multiple teaching techniques and skill-building assignments.[50,64] Self-monitoring of progress was also encouraged in one of the interventions.[50]

Some studies not only incorporated dietary and physical activity components into the intervention but also offered other lifestyle components such as smoking cessation,[49,68] care coordination,[49] diabetes management,[21] emotional well-being,[67] management of alcohol and illegal substance use,[68] and psychotherapy or psychiatric treatment for symptom management.[54,66] One study focused on self-management of mental health symptoms but also incorporated a diet and physical activity education component.[69]

All the included studies had a control group.[15-19,21,22,47-54,56-66,70-72] Control interventions included the following: treatment as usual,[17,18,22,47,49,51,53,54,60,62-64,66,67,69,70] standard dietary and physical information,[16,21,48,50,57,58,61] standard dietary information only,[15,19,72] and placebo treatment in the form of occupational therapy.[49,52,59] See Appendix III for further details of the included studies.

Lifestyle intervention subgroups *(level 2 heading)*

Studies that delivered education on dietary and physical activity information without personalization of any of the components, and consequent lack of progress review, were identified as “non-structured diet and non-structured physical activity” lifestyle interventions.[18,19,21,22,47,51,54,57,59,67] This was due to the less rigorous approach in the delivery of both of these components.[18,19,21,22,47,51,54,57,59,67]

In contrast, studies offering personalization of both dietary and physical activity education, as well as consistent review of progress for both of these components, were identified as “structured diet and structured physical activity” lifestyle interventions.[16,48,50,52,60,64,66,71,72] Additional strategies that were commonly utilized in structured diet and structured physical activity lifestyle interventions were the use of food and physical activity records and supervised group exercise.[16,48,50,52,60,64,66,72] Comparable to this were lifestyle intervention studies offering personalization of education and progress review for either the dietary or the physical activity component of the intervention. “Structured diet and non-structured physical activity” lifestyle interventions comprised studies where only the dietary component followed the pattern identified for structured interventions.[15,17,72] When only the physical activity component of the intervention followed the structured approach, then the intervention was identified as a “non-structured diet and structured physical activity” lifestyle intervention.[58,61,62,70,73]

Lifestyle interventions that did not contain a dietary component and focused on physical activity alone mainly comprised regular manualized and supervised exercise, and hence were classified as “structured physical activity” lifestyle interventions.[52,63]

Two studies did not have characteristics corresponding to any of the subgroups. One of these studies focused on self-management of mental health symptoms but incorporated a dietary and physical activity education session, while the other study did not include education as part of the intervention but utilized motivational interviewing and cognitive behavioral therapy as the main form of intervention.[68,69]

Review findings *(level 2 heading)*

Direct meta-analysis *(level 3 heading)*

Weight

Twenty studies included complete data for weight; however, data from only 18 studies could be used in subgroup pooling because meta-analyses subgroups require data from at least two studies. The overall effect size (ES) of lifestyle intervention studies taking a non-structured approach for both diet and physical activity (n = 8) on weight was not statistically significant (ES = 0.39, 95% CI = -2.308 to 3.098, p = 0.777) and the I^2 statistic was 38.4% (chi square = 11.36, d.f. =7, p = 0.124) showing low to moderate heterogeneity (Figure 5). Treatment duration, age and sex were used to explore source of heterogeneity (Tables 3 through 5). Only male sex showed a significant relationship with weight for the non-structured diet and non-structured physical activity intervention (p < 0.042). Studies with a structured diet and a non-structured physical activity approach (n = 2; Figure 6) did not attain statistical significance (ES = 0.377, 95% CI = -5.335 to 6.098, p = 0.897, I^2 = 0%). Structured diet and structured physical activity lifestyle interventions (n = 4; Figure 7) attained statistical significance (ES = -5.356, 95% CI = -7.431 to -3.282, p = 0.000, I^2 statistic = 0%), although studies that had a non-structured diet and structured physical activity approach did not (n = 4; Figure 8) (ES = 1.111, 95% CI = -2.315 to 4.538, p = 0.525, I^2 = 0%). Structured physical activity lifestyle interventions were not included in direct meta-analyses due to inadequacy in the number of studies (n = 2) necessary for pooling.

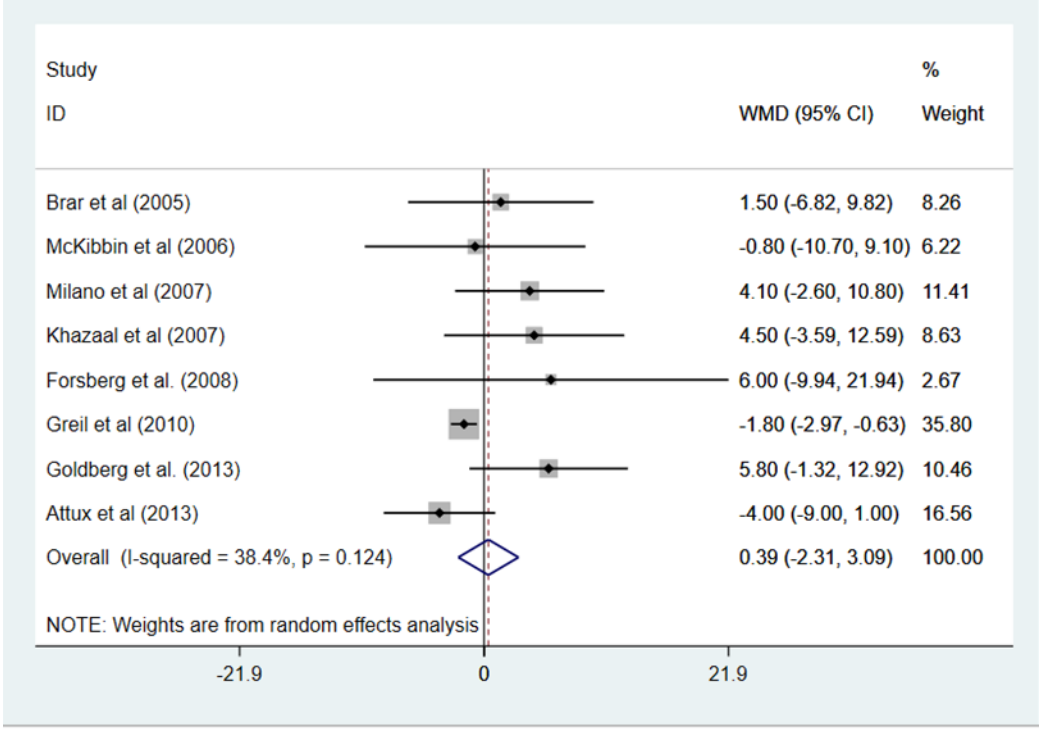

Figure 5: Meta-analysis for the effect of non-structured diet and non-structured physical activity lifestyle interventions on weight (kg). The vertical unbroken line represents the null effect. The vertical broken line represents effect of treatment (z = 0.28, P = 0.777). Heterogeneity: x^2 = 11.36 (d.f. 7) P = 0.124, I^2 = 38.4%, r^2=4.94. (WMD: weighted mean difference; CI: confidence interval.)

Table 3: Heterogeneity assessments for the effect of non-structured diet and non-structured physical activity lifestyle interventions on weight (kg) using treatment duration.

Model	Coefficient	Standard Error	t statistic	P>|t|	95% Confidence Interval	
Duration in months	.4730559	.8463451	0.56	0.596	-1.597876	2.543988
Constant	-1.493303	4.095753	-0.36	0.728	-11.51525	8.528643

Table 4: Heterogeneity assessments for the effect of non-structured diet and non-structured physical activity lifestyle interventions on weight (kg) using age.

Model	Coefficient	Standard Error	t statistic	P>|t|	95% Confidence Interval	
Mean age in years	.1078476	.2848777	0.38	0.718	-.589223	.8049182
Constant	-4.143009	13.03273	-0.32	0.761	-36.03295	27.74693

Table 5: Heterogeneity assessments for the effect of non-structured diet and non-structured physical activity lifestyle interventions on weight (kg) using gender.

Model	Coefficient	Standard Error	t statistic	P>|t|	95% Confidence Interval	
Percentage of males	.218594	.0848344	2.58	0.042	.0110116	.4261764
Constant	-10.893	3.740882	-2.91	0.027	-20.04661	-1.739396

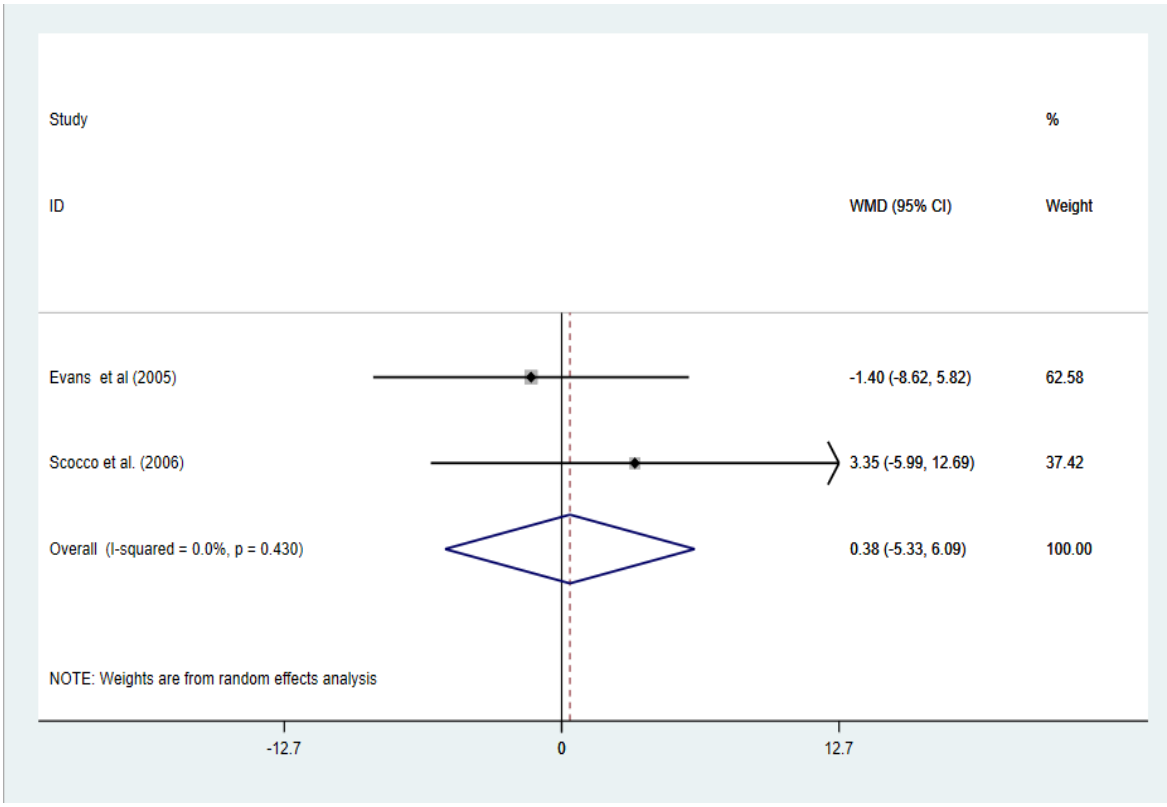

Figure 6: Meta-analysis for the effect of structured diet and a non-structured physical activity lifestyle interventions on weight (kg). The vertical unbroken line represents the null effect. The vertical broken line represents effect of treatment (z=0.13, P=0.897). Heterogeneity: x^2=0.62 (d.f.=1) P=0.430, I^2=0.0%, r^2=0.00. (WMD: weighted mean difference; CI: confidence interval.)

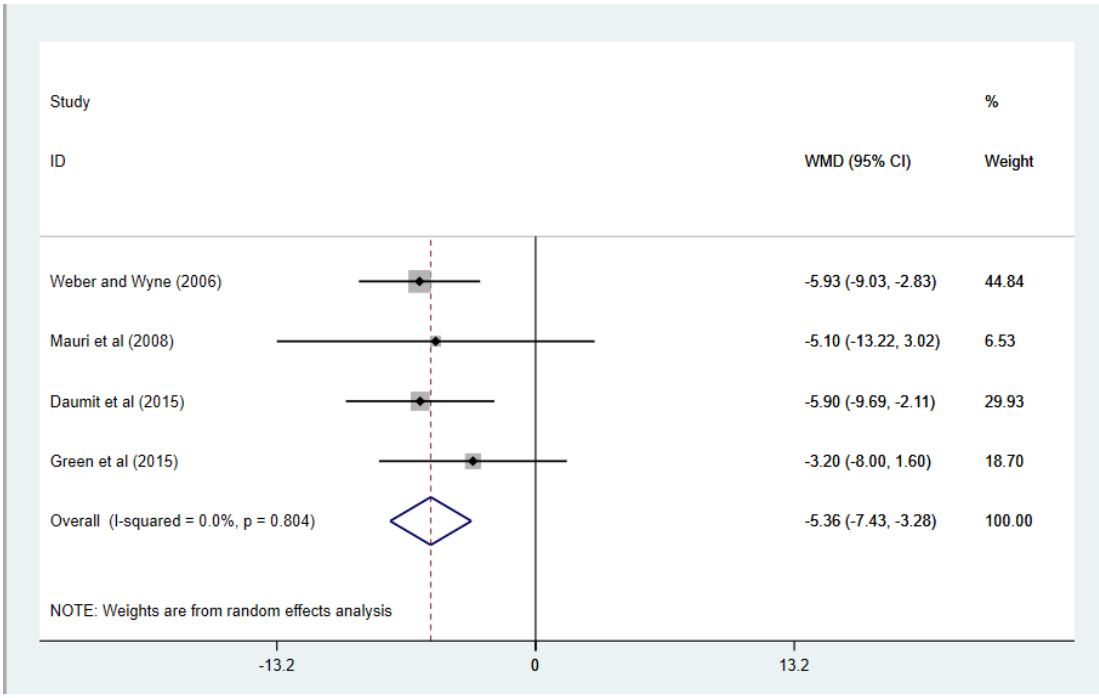

Figure 7: Meta-analysis for the effect of structured diet and structured physical activity lifestyle interventions on weight (kg). The vertical unbroken line represents the null effect. The vertical broken line represents effect of treatment (z=5.06, P=0.000). Heterogeneity: x^2=0.99 (d.f.=3) P=0.804, I^2=0.0%, t^2=0.00. (WMD: weighted mean difference; CI: confidence interval.)

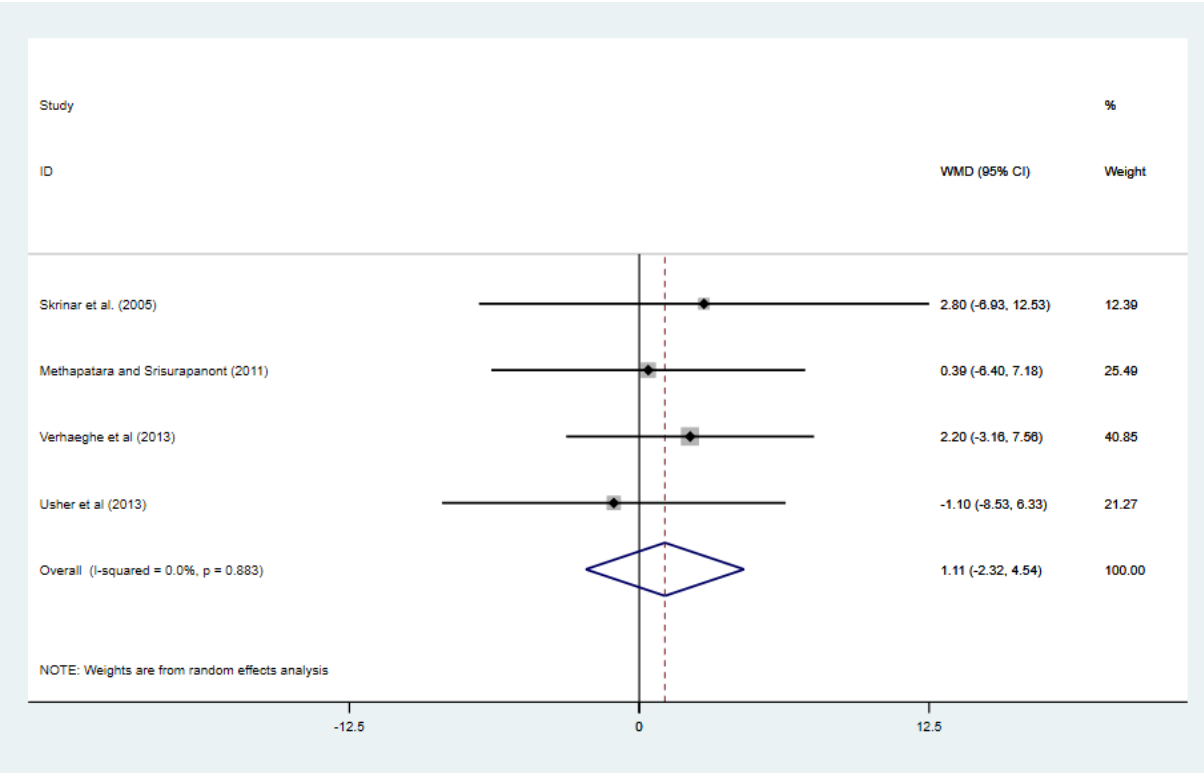

Figure 8: Meta-analysis for the effect of non-structured diet and structured physical activity lifestyle interventions on weight (kg). The vertical unbroken line represents the null effect. The vertical broken line represents effect of treatment (z=0.64, P=0.525). Heterogeneity: x^2=0.66 (d.f.=3) P=0.883, I^2=0.0%, r^2=0.00. (WMD: weighted mean difference; CI: confidence interval.)

Body mass index

Twenty-one studies included complete data for BMI; however, data from only 19 studies could be used in subgroup pooling because meta-analyses subgroups require data from at least two studies. Structured physical activity lifestyle interventions (n = 2; Figure 9) did not achieve a statistically significant effect on BMI (ES = -1.123, 95% CI = -3.157 to 0.910, p = 0.279, I^2 = 0%). Non-structured diet and non-structured physical activity interventions (n = 7; Figure 10) also did not attain statistical significance (ES = 0.161, 95% CI = -1.302 to 1.624, p = 0.829); the I^2 statistic was 50.4%, which shows moderate to high heterogeneity. Treatment duration, age and sex were used to explore source of heterogeneity, although none of these parameters had a significant impact on heterogeneity (Tables 6 through 8). Conversely, studies with both a structured diet and structured physical activity component (n = 5; Figure 11) attained statistical significance (ES = -1.068, 95% CI = -1.780 to -0.357, p = 0.003, I^2 = 0%). Finally, non-structured diet and structured physical activity interventions did not show statistically significant changes in BMI (n = 5; Figure 12) (ES = 0.021, 95% CI = -0.850 to 0.891, p = 0.962, I^2 = 0%). Structured diet and non-structured physical activity lifestyle interventions were not included in direct meta-analyses due to inadequacy in the number of studies (n = 2) necessary for pooling.

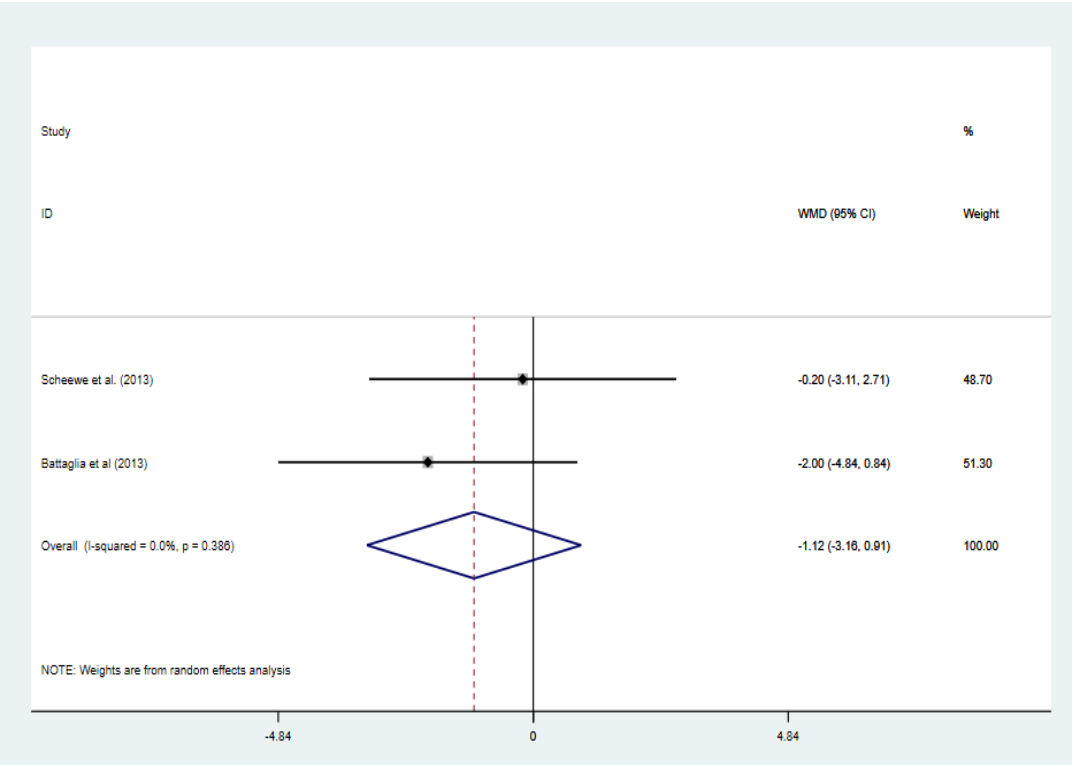

Figure 9: Meta-analysis for the effect of structured physical activity lifestyle interventions on body mass index (kg/m2). The vertical unbroken line represents the null effect. The vertical broken line represents effect of treatment (z=1.08, P=0.279). Heterogeneity: x^2=0.75 (d.f.=1) P=0.386, I^2=0.0%, r^2=0.00. (WMD: weighted mean difference; CI: confidence interval.)

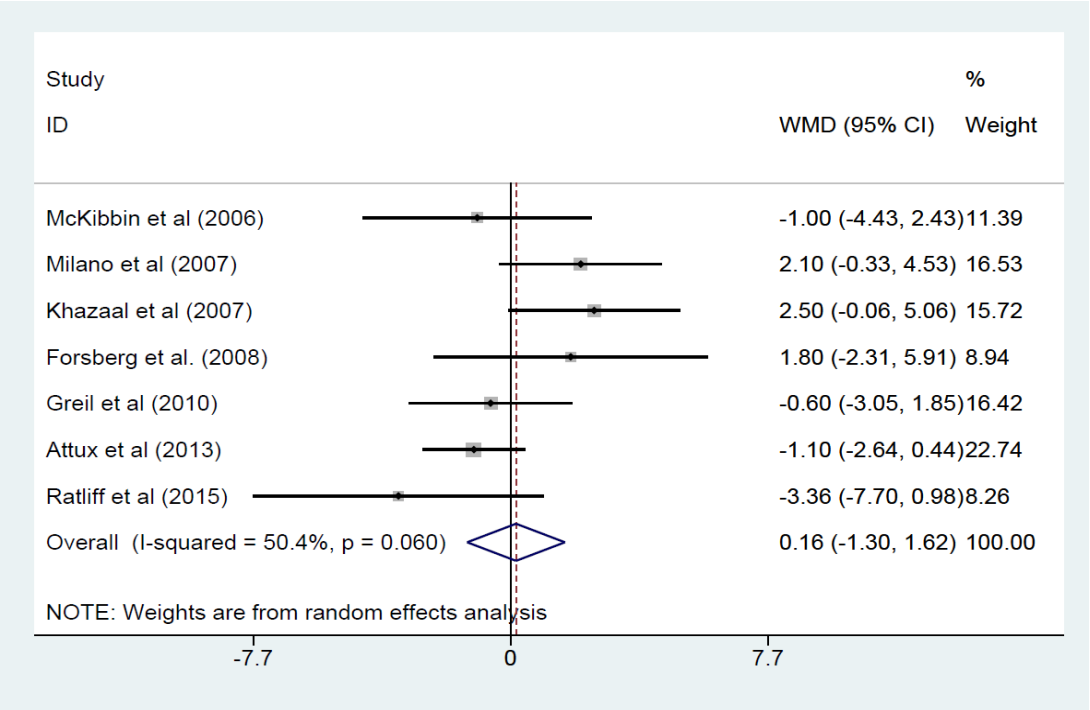

Figure 10: Meta-analysis for the effect of non-structured diet and non-structured physical activity lifestyle interventions on body mass index (kg/m2). The vertical unbroken line represents the null effect. The vertical broken line represents effect of treatment (z=0.22, P=0.829). Heterogeneity: x^2=12.09 (d.f.=6) P=0.060, I^2=50.4%, t2=1.84. (WMD: weighted mean difference; CI: confidence interval.)

Table 6: Heterogeneity assessment for the effect of non-structured diet and non-structured physical activity lifestyle interventions on BMI using treatment duration.

Model	Coefficient	Standard Error	t statistic	P>|t|	95% Confidence Interval	
Duration in months	.1411811	.2980684	0.47	0.656	-.625028	.9073903
Constant	-.4661957	1.550118	-0.30	0.776	-4.450902	3.518511

Table 7: Heterogeneity assessment for the effect of non-structured diet and non-structured physical activity lifestyle interventions on BMI using age.

Model	Coefficient	Standard Error	t statistic	P>|t|	95% Confidence Interval	
Mean age in years	-.1263792	.1609826	-0.79	0.468	-.5401982	.2874399
Constant	5.738795	7.158011	0.80	0.459	-12.66146	24.13905

Table 8: Heterogeneity assessment for the effect of non-structured diet and non-structured physical activity lifestyle interventions on BMI using gender.

Model	Coefficient	Standard Error	t statistic	P>|t|	95% Confidence Interval	
Percentage of males	.0864133	.0580907	1.49	0.197	-.0629135	.2357402
Constant	-4.159162	2.973561	-1.40	0.221	-11.80294	3.484619

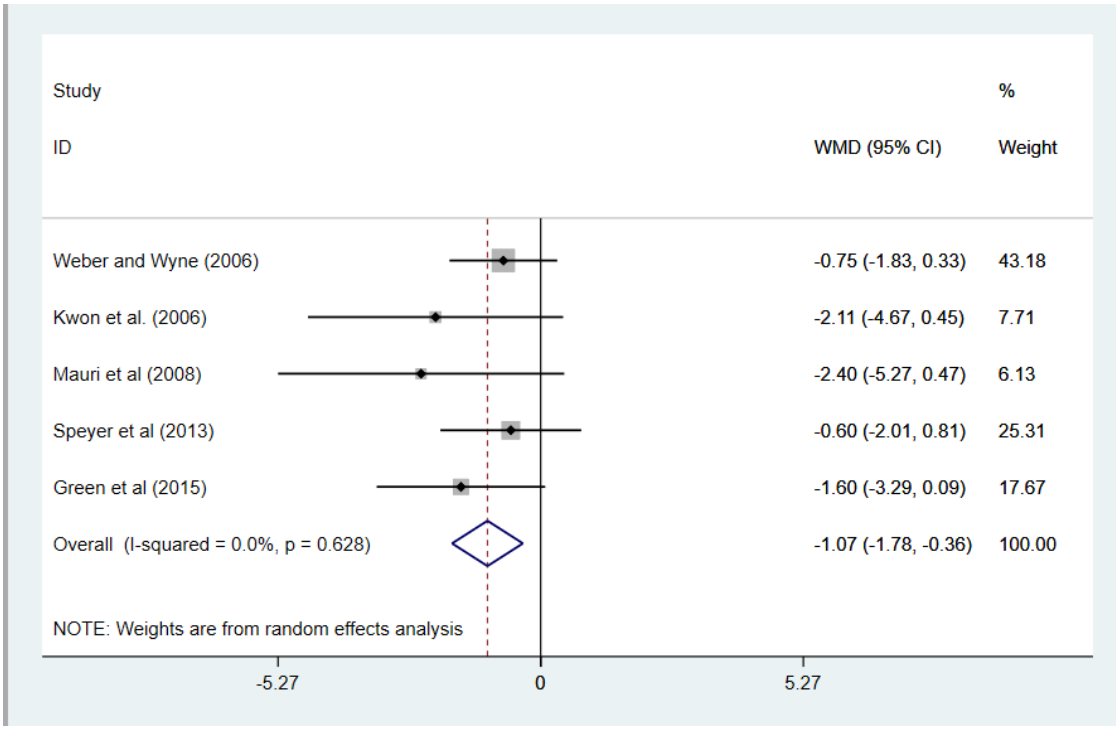

Figure 11: Meta-analysis for the effect of structured diet and structured physical activity lifestyle interventions on body mass index (kg/m2). The vertical unbroken line represents the null effect. The vertical broken line represents effect of treatment (z=2.94, P=0.003). Heterogeneity: x^2=2.59 (d.f.=4) P=0.628, I^2=0.0%, r^2=0.00. (WMD: weighted mean difference; CI: confidence interval.)

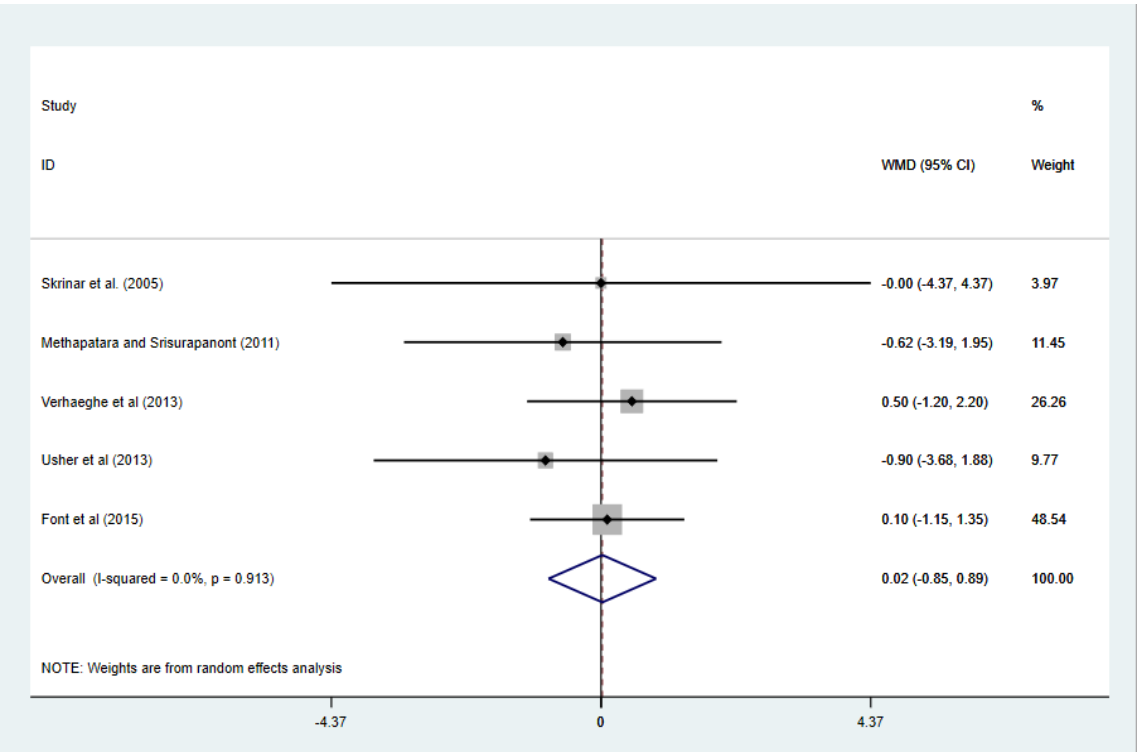

Figure 12: Meta-analysis for the effect of non-structured diet and structured physical activity lifestyle interventions on body mass index (kg/m2). The vertical unbroken line represents the null effect. The vertical broken line represents effect of treatment (z=0.05, P=0.962). Heterogeneity: x^2=0.98 (d.f.=4) P=0.913, I^2=0.0%, t^2=0.00. (WMD: weighted mean difference; CI: confidence interval.)

Waist circumference

Fourteen studies included complete data for waist circumference, but data from only seven studies could be pooled into meta-analyses because meta-analyses subgroups require data from at least two studies. Studies taking a non-structured approach for both diet and physical activity (n = 3; Figure 13) attained a statistically significant effect on waist circumference (ES = -3.677, 95% CI = -6.897 to -0.456, p = 0.025, I^2 = 0%). In contrast, studies with a non-structured diet and structured physical activity approach (n = 4; Figure 14) did not achieve statistical significance (ES = 0.013, 95% CI = -2.156 to 2.183, p = 0.990), I^2 statistic = 0%). Structured physical activity, structured diet and non-structured physical activity, and structured diet and structured physical activity lifestyle interventions were not included in direct meta-analyses due to inadequacy in the number of studies (n = 2) necessary for pooling in each subgroup.

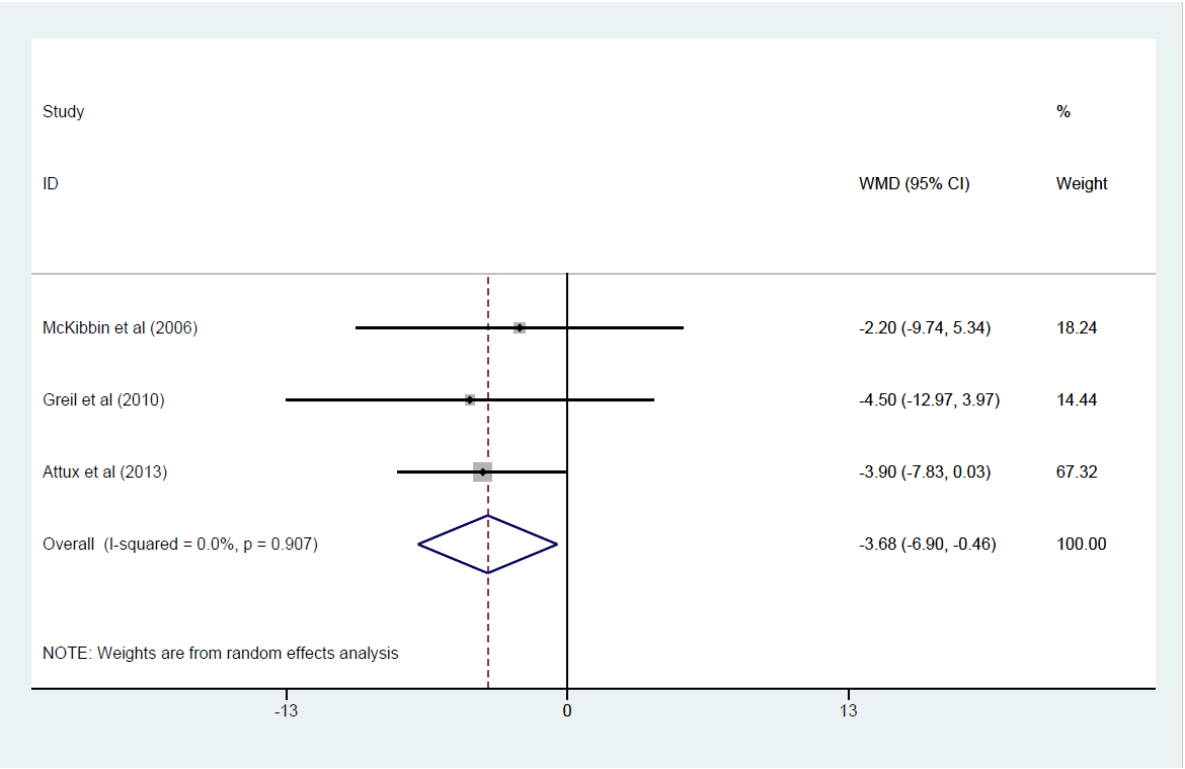

Figure 13: Meta-analysis for the effect of non-structured diet and non-structured physical activity lifestyle interventions on waist circumference (cm). The vertical unbroken line represents the null effect. The vertical broken line represents effect of treatment (z=2.24, P=0.025). Heterogeneity: x^2=0.20 (d.f.=2) P=0.907, I^2=0.0%, t^2=0.00. (WMD: weighted mean difference; CI: confidence interval.)

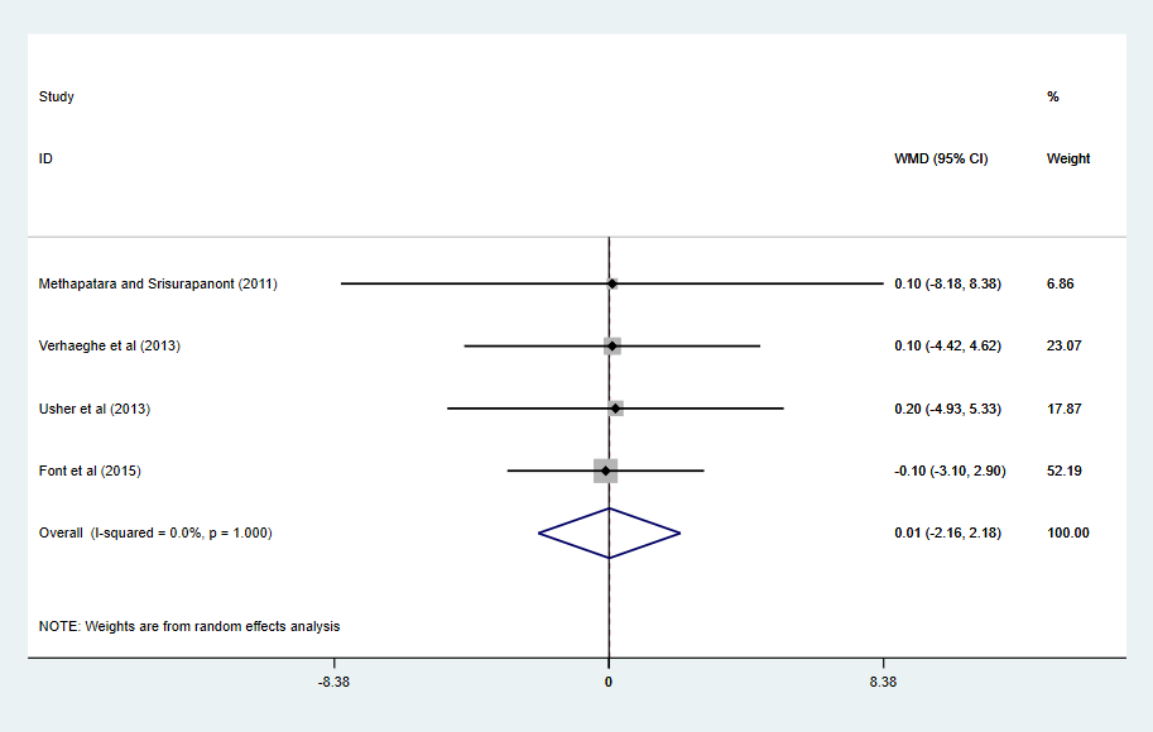

Figure 14: Meta-analysis for the effect of non-structured diet and structured physical activity lifestyle interventions on waist circumference (cm). The vertical unbroken line represents the null effect. The vertical broken line represents effect of treatment (z=0.01, P=0.990). Heterogeneity: x^2=0.01 (d.f.=3)P=1.000, I^2=0.0%, r^2=0.00. (WMD: weighted mean difference; CI: confidence interval.)

Network meta-analysis *(level 3 heading)*

Weight

Data from 19 studies were used to pool the effect of different lifestyle intervention subgroups on weight in a network meta-analysis. Contrasting lifestyle intervention subgroups that were available for comparison were mapped in a network plot (Figure 15; Tables 9 and 10). The control condition was compared to the following lifestyle intervention subgroups: structured physical activity; non-structured diet and non-structured physical activity; structured diet and non-structured physical activity; structured diet and structured physical activity; and non-structured diet and structured physical activity. Overall, weight in kg decreased the most in the intervention group with both a structured diet and structured physical activity (n = 4) approach, and this was also the only intervention group that attained statistical significance (ES = -4.12, 95% CI = -7.772 to -2.760, p = 0.000). The intervention that ranked second was structured physical activity (n = 1, ES = -0.81, 95% CI = -14.754 to 6.154, p = 0.420). The intervention that ranked third was the non-structured approach for both diet and physical activity (n = 8, ES = -0.24, 95% CI = -3.365 to 2.639, p = 0.813). The control condition ranked fourth (n = 19). The fifth in rank was interventions with a structured diet and non-structured physical activity component (n = 2, ES = 0.14, 95% CI = -5.565 to 6.416, p = 0.889). Interventions showing the least efficacy were non-structured diet and structured physical activity interventions (n = 4, ES = 0.58, 95% CI = -2.589 to 4.760, p = 0.563). All lifestyle intervention subgroups were included in network meta-analysis.

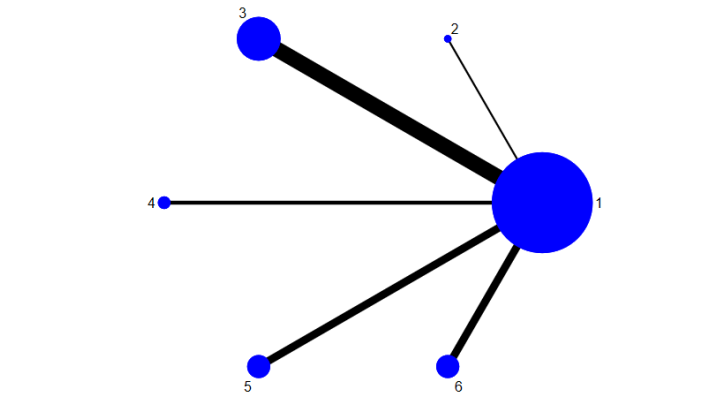

Figure 15: Network plot for lifestyle intervention subgroups reporting on weight. Circles represent the different lifestyle intervention subgroups (represented by the numbers) as a node in the network; lines represent direct comparisons using RCTs; thickness of lines represents the number of RCTs included in each comparison. Key; 1= Usual care, placebo I-III; 2= Structured physical activity lifestyle interventions; 3 = Non-structured diet and non-structured physical activity lifestyle interventions; 4 = Structured diet and non-structured physical activity lifestyle interventions; 5 = Structured diet and structured physical activity lifestyle interventions; 6 = Non-structured diet and structured physical activity lifestyle interventions.

Table 9: Network meta-analysis for the effect of lifestyle intervention subgroups on weight (kg).

Model	Coefficient	Standard Error	z statistic	P>|z|	95% Confidence Interval	
Structured physical activity	-4.299998	5.333922	-0.81	0.420	-14.75429	6.154297
Non-structured diet and non-structured physical activity	-.3630154	1.531663	-0.24	0.813	-3.365019	2.638988
Structured diet and non-structured physical activity	.4256332	3.056322	0.14	0.889	-5.564647	6.415914
Structured diet and structured physical activity	-5.265781	1.278501	-4.12	0.000	-7.771597	-2.759964
Non-structured diet and structured physical activity	1.08557	1.87475	0.58	0.563	-2.588873	4.760012

Table 10: Ranking of lifestyle intervention subgroup effects on weight.

Treatment	Surface Under the Cumulative Ranking (SUCRA)	Probability as the Best	Mean Rank

Usual care or placebo	38.0	0.0	4.1
Structured physical activity	71.3	41.9	2.4
Non-structured diet and non-structured physical activity	43.0	0.2	3.8
Structured diet and non-structured physical activity	33.7	2.5	4.3
Structured diet and structured physical activity	90.6	55.3	1.5
Non-structured diet and structured physical activity	23.5	0.1	4.8

Body mass index

Data from 20 studies were used to pool the effect of different lifestyle intervention subgroups on BMI in a network meta-analysis. A network plot was used to show all the different lifestyle intervention subgroups that were being analyzed (Figure 16; Tables 11 and 12). The control condition was compared to the following lifestyle intervention subgroups: structured physical activity; non-structured diet and non-structured physical activity; structured diet and non-structured physical activity; structured diet and structured physical activity; and non-structured diet and structured physical activity. Body mass index only decreased significantly in interventions that used a structured diet and structured physical activity approach (n = 5, ES = -2.94, 95% CI = -1.780 to -0.357, p = 0.003). Interventions that ranked second were those with a structured physical activity approach (n = 2, ES = -1.08, 95% CI = -3.157 to 0.910, p = 0.279). Interventions that were third in rank were those that applied a non-structured diet and structured physical activity approach (n = 5, ES = 0.05, 95% CI = -0.850 to 0.891, p = 0.962), and these studies had the same effect size with the control condition (n = 20) and those with a non-structured approach for both diet and physical activity (n = 7, ES = 0.03, 95% CI = -0.936 to 0.962, p = 0.978). Finally, interventions with the least efficacy were those that took a structured diet and non-structured physical activity component (n = 1, ES = 0.24, 95% CI = -2.144 to 2.744, p = 0.810). All lifestyle intervention subgroups were included in network meta-analysis.

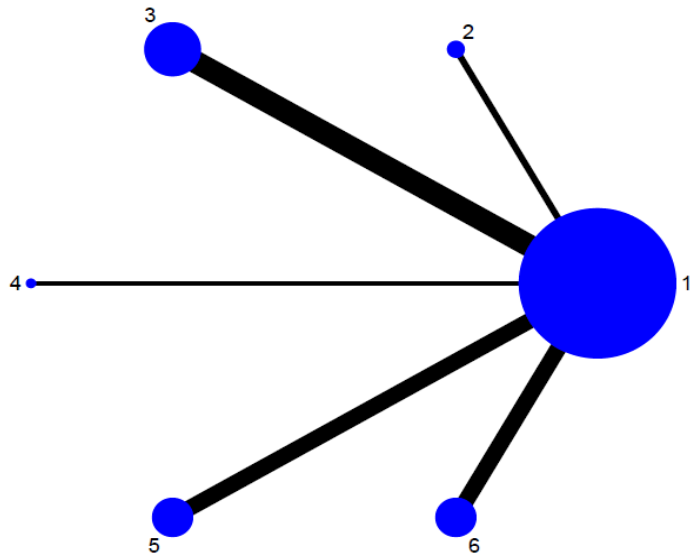

Figure 16: Network plot for lifestyle intervention subgroups reporting on BMI. Circles represent the different lifestyle intervention subgroups (represented by the numbers) as a node in the network; lines represent direct comparisons using RCTs; thickness of lines represents the number of RCTs included in each comparison. Key; 1= Usual care, placebo I-III; 2= Structured physical activity lifestyle interventions; 3 = Non-structured diet and non-structured physical activity lifestyle interventions; 4 = Structured diet and non-structured physical activity lifestyle interventions; 5 = Structured diet and structured physical activity lifestyle interventions; 6 = Non-structured diet and structured physical activity lifestyle interventions.

Table 11: Network meta-analysis for the effect of lifestyle intervention subgroups on BMI.

Model	Coefficient	Standard Error	z statistic	P>|z|	95% Confidence Interval	
Structured physical activity	-1.123431	1.037454	-1.08	0.279	-3.156803	.9099413
Non-structured diet and non-structured physical activity	.0130889	.4843339	0.03	0.978	-.936188	.9623658
Structured diet and non-structured physical activity	.3	1.246871	0.24	0.810	-2.143822	2.743822
Structured diet and structured physical activity	-1.068274	.3629083	-2.94	0.003	-1.779561	-.3569869
Non-structured diet and structured physical activity	.0209092	.4441358	0.05	0.962	-.8495809	.8913993

Table 12: Ranking of lifestyle intervention subgroup effects on BMI.

Treatment	Surface Under the Cumulative Ranking (SUCRA)	Probability as the Best	Mean Rank
Usual care or placebo	35.5	0.0	4.2
Structured physical activity	76.9	47.5	2.2
Non-structured diet and non-structured physical activity	35.4	1.1	4.2
Structured diet and non-structured physical activity	31.5	9.1	4.4
Structured diet and structured physical activity	85.6	41.5	1.7
Non-structured diet and structured physical activity	35.1	0.9	4.2

Waist circumference

Data from 10 studies were used to pool the effect of different lifestyle intervention subgroups on waist circumference. Lifestyle intervention subgroups that were included in analyses were mapped in a network plot (Figure 17; Tables 13 and 14). The control condition was compared to the following lifestyle intervention subgroups: structured physical activity; non-structured diet and non-structured physical activity; structured diet and non-structured physical activity; structured diet and structured physical activity; and non-structured diet and structured physical activity. Waist circumference only decreased significantly in interventions that used a non-structured approach for both diet and physical activity (n = 3, ES = -2.24, 95% CI = -6.897 to -0.456, p = 0.025). The structured physical activity approach (n = 1) ranked second, and this study type along with studies in subsequent ranks did not attain statistical significance (ES = - 0.99, 95% CI = -11.288 to 3.688, p = 0.320). Following in rank were studies with a structured diet and structured physical activity component (n = 1, ES = - 0.97, 95% CI = -5.741 to 1.941, p = 0.332). Studies with a structured diet and non-structured physical activity approach (n = 1) ranked fourth (ES = 0.12, 95% CI = -7.684 to 8.684, p = 0.905). Interventions with a non-structured diet and structured physical activity approach (n = 4, ES = 0.01, 95% CI = -2.156 to 2.183, p = 0.990) followed in rank with similar efficacy to the control condition (n = 10). All lifestyle intervention subgroups were included in network meta-analysis.

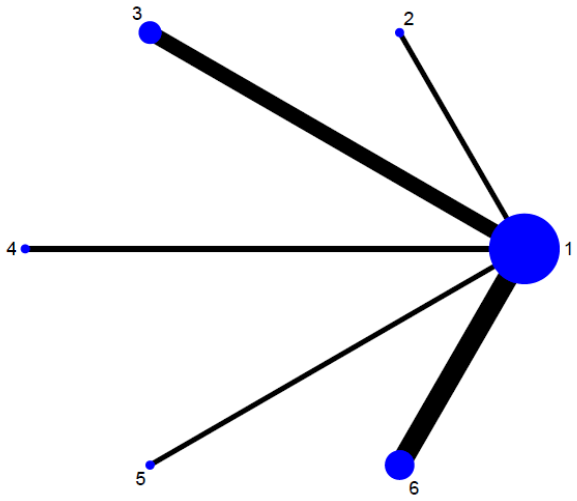

Table 13: Network meta-analysis for the effect of lifestyle intervention subgroups on waist-circumference (cm).

Model	Coefficient	Standard Error	z statistic	P>|z|	95% Confidence Interval	
Structured physical activity	-3.8	3.82053	-0.99	0.320	-11.2881	3.688102
Non-structured diet and non-structured physical activity	-3.676628	1.643097	-2.24	0.025	-6.897039	-.4562172
Structured diet and non-structured physical activity	.5	4.175783	0.12	0.905	-7.684384	8.684384
Structured diet and structured physical activity	-1.9	1.959699	-0.97	0.332	-5.740939	1.940939
Non-structured diet and structured physical activity	.013482	1.106936	0.01	0.990	-2.156073	2.183038

Table 14: Ranking of lifestyle intervention subgroup effects on waist circumference.

Treatment	Surface Under the Cumulative Ranking (SUCRA)	Probability as the Best	Mean Rank
Usual care or placebo	28.0	0.0	4.6
Structured physical activity	72.2	44.0	2.4
Non-structured diet and non-structured physical activity	80.3	34.7	2.0
Structured diet and non-structured physical activity	32.2	10.0	4.4
Structured diet and structured physical activity	58.3	11.1	3.1
Non-structured diet and structured physical activity	29.0	0.2	4.6

Compliance of dietary information provided in studies to the Australian Dietary Guidelines *(level 2 heading)*

Of the 32 papers included in the current systematic review, two focused solely on physical activity and did not provide dietary advice, and two were follow-up studies from the parent studies and did not differ methodologically from the parent studies.[52,56,63,65] A total of 28 papers thus provided the necessary information which allowed for comparison of dietary advice to ADGs.[28]

The included papers were compared to four guidelines instead of five because one of the guidelines (guideline 4) is specific to women who are breastfeeding, which was not relevant to participants in the current review.[28] Guideline 1 recommends maintenance of a healthy weight through physical activity and portion control; guideline 2 advocates variety in the diet through consuming food from the five food groups; guideline 3 prescribes limiting foods containing saturated fats, added salt, sugar and alcohol; and guideline 5 encourages caring for food through proper preparation and storage.[28]

All dietary information provided in the included studies complied to some degree with the ADGs (see Table 1).[28] In all cases, insufficient detail or vague descriptions were the reasons why studies were not classified as compliant. Five studies were compliant with guidelines 1, 2 and 3. Eight studies were compliant to guidelines 1 and 2, while two were compliant to guidelines 1 and 3. Three studies were only compliant to guideline 1, while another study was only compliant to guideline 3. Nine studies did not provide sufficient details on dietary advice to rate compliance to the guidelines.

Discussion *(level 1 heading)*

Lifestyle interventions with a structured diet and structured physical activity approach appear to be the most efficacious form of intervention for weight loss in people with psychosis, leading to decreases in

weight of about 4 kg and reductions in BMI by about 2.5 points. The main strategies utilized in these studies were education, personalized plans or goals, and progress review.[16,48,50,52,60,64,66,72] Waist circumference outcomes showed that non-structured diet and non-structured physical activity interventions that utilized education as the main strategy were the only study type to attain statistically significant decreases (~2 cm). The fact that very few studies reported on waist circumference may be a contributing factor to why statistical comparisons of waist circumference differed to those of weight and BMI. When dietary advice given to participants was compared to the ADGs, it was found that most studies complied in some degree to guidelines; however, insufficient description of dietary advice limited assessments.[15-19,21,22,47,51,53,54,58-62,64,66,67,70,72]

This research confirmed previous work, which highlighted that both dietary and physical activity components are essential to attain weight loss in lifestyle interventions among these participants.[24] Findings from the general population also highlight this, indicating that both dietary and physical activity components may be of benefit in weight loss lifestyle interventions for people with psychosis.[16,48,50,52,60,64,66,72,74]

Authors of previous studies on this topic found that interventions delivered with an individualized approach achieved more weight loss than interventions with a focus on groups of individuals.[10] This systematic review furthered these findings by discovering that studies with an individualized approach personalized education through providing tailored advice[15-17,24,48,50,52,60,61,64,66,72] or supporting participants with goal setting.[16,48,50,52,60,64,66,72] These interventions also provided review of progress on a regular basis.[16,48,50,52,60,64,66,72] The current review classified these interventions as “structured”, and interventions incorporating a structured approach for both diet and physical activity attained the most significant losses in weight (4.1 kg) and BMI (2.9 points) in network meta-analyses.[16,48,50,52,60,64,66,72] Although we completed both meta-analyses and network meta-analyses, the latter will be the reference, as this measure provides a global estimate of efficacy based on all relevant studies.[75]

Personalized lifestyle interventions cater to the unique needs of each individual.[76,77] Interventions can be personalized through the provision of tailored advice or setting individual goals.[76,77] Goals are used when individuals are dissatisfied with present circumstances and value certain outcomes over others, thus requiring incentive to direct efforts towards goal-relevant activities.[78] Studies in this review that personalized both dietary and physical activity intervention components offered an advantage over those that did not, as participants were empowered to make changes offered through education.[79] These studies also offered progress review, which typically entailed appraisal of pre-specified milestones.[16,48,50,52,60,64,66,72] Progress review is always incorporated into clinical dietary care, and it would be appropriate to employ the same strategy whenever dietary advice is delivered with the intention of behavior change.[80] Evidence on the utility of progress review for physical activity interventions is lacking, although outcomes from the current study favor this strategy.[10] Diet and physical activity lifestyle interventions among people with psychosis should offer tailored advice and assist with individual goal-setting in both intervention components and couple this with progress reviewing.[76-80]

Food and physical activity records were kept to track progress in many of the structured diet and structured physical activity interventions but were not the basis for subgroup creation.[48,50,60,64,66] Similarly, some of these interventions also provided supervised group exercise.[48,50,64] A strong correlation has been found between keeping food records and weight loss in the general population; in contrast, research on the correlation between physical activity records and weight loss still needs to be explored.[81-83] Benefits of supervised group exercise, however, include consistency in exercise schedule, accountability, exposure to a sociable environment and increased motivation.[84-86] The inclusion of food and physical activity records and supervised group exercise have the potential to improve diet and physical activity lifestyle interventions for people with psychosis, although further research is needed to confirm this.[48,50,60,64,66,84,86]

Waist circumference only decreased significantly in non-structured diet and non-structured physical activity interventions by about ~2 cm: the main format of delivery was education, and additional strategies were not consistently used across this subgroup.[18,19,21,22,47,51,54,57,59,67] A significant consideration to the interpretation of this positive finding is that waist circumference results were in contrast to weight and BMI findings.[15,21,48,49,52,53,56,58,59,61,64,65,67,70] Bias may have played a role, as studies in this subgroup with positive outcomes were the main ones reporting on waist circumference.[15,21,48,49,52,53,56,58,59,61,64,65,67,70] Finally, the positive findings are based on only three studies from this subgroup, and comparator subgroups mostly had one study.[15,21,48,49,52,53,56,58,59,61,64,65,67,70] For these reasons, conclusions cannot be made on the utility of education as the main lifestyle intervention strategy in this group.[18,19,21,22,47,51,54,57,59,67]

Other lifestyle intervention subgroups identified within the current study did not attain statistical significance in any of the outcomes. Structured diet and non-structured physical activity and non-structured diet and structured physical activity interventions utilized personalization strategies and progress review for either the dietary or physical activity component.[15,17,53,58,61,62,70,72] This could have decreased intensity of the intervention in contrast to offering this structure for both diet and physical activity.[79] Structured physical activity interventions in this study provided supervised exercise and prescribed physical activity plans but lacked a dietary component, which explains why significant weight loss was not attained.[24,52,63,74] All these findings affirm previous recommendations on the necessary components of lifestyle interventions for people with psychosis.[16,48,50,52,60,64,66,72]

Other lifestyle intervention strategies that were employed but did not occur in discernable patterns across studies included motivational interviewing, cognitive behavioral therapy, psychoeducation and financial incentives.[18,19,21,22,49,50,57,58,60,70] Findings from the general population show that using these strategies in lifestyle interventions may contribute to weight loss.[37,87-92] The efficacy of these strategies in lifestyle interventions for people with psychosis is unclear at this stage because corresponding research is unavailable.[18,19,21,22,49,50,57,58,60,70] Further research focusing on each of these individual strategies is therefore warranted.

Other intervention components offered in addition to diet and physical activity were smoking cessation, care coordination, diabetes management, emotional well-being and psychiatric treatment.[21,49,54,66,67]

The efficacy of adding other components to diet and physical activity programs remains unclear.[21,49,54,66,67] The only problem noted with this approach was poor reporting of intervention content and outcomes, which can be easily rectified in future lifestyle interventions.[49]

None of the studies reported giving advice that was explicitly contrary to ADGs' principles of portion control, variety in the diet, alcohol consumption, and control of saturated fats, added salt and sugar.[15-19,21,22,28,47-51,53,54,56-62,64-66,70,72] Vague description of dietary advice was often the reason why none of the available studies were rated as compliant with all the relevant ADGs.[28] Dietary compliance to ADGs is essential as health and well-being is promoted and the risk of chronic disease is minimized through dietary intake.[28] People with psychosis are vulnerable to chronic physical health conditions; therefore, it is advisable for the dietary advice offered to minimize this risk.[2,4,6,93]

Many studies did not clearly report on the randomization procedure,[15,16,18,19,22,47,54,60,62,70,72] allocation concealment[15-19,21,22,47,54,57,60,62,66,70,72] and blinding of outcome assessors.[15-17,19,22,47,51,54,57-62,70,72] These factors impact the risk of bias in studies and need to be clearly reported.[94] Authors often reported that blinding of participants and those delivering the interventions was not possible due to the nature of lifestyle interventions.[15-19,21,22,47-51,53,54,56-62,64-66,70,72] Tools for assessing bias in behavioral interventions should be designed so that these unique dynamics are considered.[95] Conversely, researchers in this field should also consider using innovative blinding methods that are suitable for behavioral interventions, which include concealment of study hypothesis from participants and employment of external personnel in intervention delivery who are unaware of participant treatment assignments or study hypothesis.[96,97] The use of these approaches is likely to minimize study bias. [96,97]

Publication bias, selective outcome reporting and differences in intensity of interventions are some potential setbacks that could have contributed to asymmetry in funnel plot assessments, and these factors impact the strength of conclusions that can be drawn.[10,15-19,21,22,47,54,57,60,62,66,70,72,98]

Limitations *(level 2 heading)*

Poor description of study methodology and incomplete outcome information (in included studies) are some of the shortcomings of this review, but where possible, additional information was sought from authors.[18,19,22,47,49,54,57,61,62] In line with this, few studies reported on waist circumference and waist-to-hip ratio, thus conclusions cannot be made on these outcomes.[15,21,22,48,49,52,53,56,58,59,61,64,65,67,70] As a result, the present study cannot make inferences on the potential impact of lifestyle interventions on cardiovascular risk in people with psychosis as these outcomes are indicators of cardiovascular health.[31]

Our findings on the efficacious strategies of lifestyle interventions are subject to the effect of participant compliance in interventions; information on participant compliance was, however, often omitted from studies and therefore could not be accounted for here.[15-19,21,22,47-54,56-66,68,70-72] Finally, the multicomponent nature of lifestyle interventions creates difficulties during the assessment of efficacy associated with individual intervention components because it is not always possible to control for the

effect of other variables.[10] This study applied the best available procedural and synthesis methodology to ensure that many of these limitations were minimized.[10,99]

Conclusions *(level 1 heading)*

In people with psychosis, lifestyle interventions that incorporate both dietary and physical activity components lead to the greatest losses in weight (4.1kg) and BMI (2.9 points).[16,48,50,52,60,64,66,72] Dietary and physical activity intervention strategies that seem crucial for the attainment of significant decreases in weight and BMI are personalization of education through providing tailored advice or goal setting, and corresponding progress review.[16,48,50,52,60,64,66,72] Other strategies that may also contribute to weight loss are using food and physical activity records, and supervised group exercise sessions.[16,48,50,52,60,64,66,72] Dietary information offered in included studies was generally compliant with relevant ADGs.[15-19,21,22,47-54,56-65,67,70] Strength of evidence on the efficacy of different lifestyle intervention strategies and compliance of lifestyle interventions to ADGs are weakened by increased risk of bias in studies, complex and multicomponent design of lifestyle interventions and lack of clarity in reporting study methodology. Increased risk of bias and poor reporting are factors that are rectifiable in future lifestyle interventions through use of standardized methodology and appropriate reporting tools for behavioral interventions.[100] Making improvements to these elements is likely to ameliorate some of the difficulties associated with interpreting complex multicomponent lifestyle interventions.[100]

Recommendations for practice *(level 2 heading)*

This systematic review has level B evidence, based on the JBI Grades of Recommendation, indicating that the recommendations are ‘‘weak’’. Factors that contributed to this include increased risk of bias, complex and multicomponent design of lifestyle interventions and lack of clarity in the reporting of study methodology. We, therefore, conditionally recommend the incorporation of both dietary and physical activity components in lifestyle interventions targeting weight loss in community-dwelling people with psychosis. Essential strategies that may be incorporated in both of these components include education, tailored advice, goal setting and progress review. The use of food and physical activity records and supervised group exercise sessions could also be incorporated into the intervention.

Recommendations for research *(level 2 heading)*

Future diet and physical activity lifestyle intervention studies in people with psychosis ought to thoroughly describe study methodology and, if this is not possible, authors should provide a way for interested parties to access this information when necessary.[101] This will help improve the quality of future reviews.[10] Prospective research on the current topic area should also consider employing some of the creative approaches to blinding that are recommended for behavioral lifestyle interventions.[96]

Acknowledgments *(level 1 heading)*

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Conflicts of interest

There is no conflict of interest in this project.

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Appendix I: Search strategy

Ovid database for MEDLINE/PreMEDLINE (Repeated for EMBASE and PsycINFO within Ovid)

Search conducted May 2018

Search	Query
#1	health* liv* program*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
#2	health* liv* interven*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
#3	health* promot* program*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
#4	health* promot* interven*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
#5	physical health interven*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
#6	lifestyle interven*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
#7	non pharmacological lifestyle interven*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
#8	diet interven*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
#9	weight management interven*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
#10	physical activity interven*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
#11	exercise interven*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

#12	diabetes interven*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
#13	cardiovascular disease interven*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
#14	obesity interven*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
#15	psychosis.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
#16	severe mental illness.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
#17	bipolar disorder.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
#18	schizoaffective.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
#19	schizophren*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
#20	patient* taking antipsychotic*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
#21	patient* taking clozapine.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
#22	patient* taking olanzapine.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
#23	severe mental diseas*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
#24	severe mental disorder*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
#25	serious mental illness.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary

	concept word, rare disease supplementary concept word, unique identifier, synonyms]
#26	serious mental disorder*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
#27	mental disorder*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
#28	mental illness.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
#29	behavioural weight loss interven*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
#30	behavioural weight manage*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
#31	nutrition* interven*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
#32	non pharmacologic intervention*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
#33	non-pharmacological weight management.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
#34	health improv*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
#35	health improve* intervention.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
#36	health promotion educat*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
#37	health promotion lifestyle interven*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
#38	health* liv* interven*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept

	word, rare disease supplementary concept word, unique identifier, synonyms]
#39	educational interven*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
#40	exercise therapy.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
#41	physical health interven*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
#42	physical activity program*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
#43	physical exercise interven*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
#44	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43
#45	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
#46	44 and 45
Limited to #1985-May 2018, English Language, humans, adults.#	
Records retrieved: 514	

CINAHL, search conducted June 2018

Search	**Query**
#1	(diet* or weight or obesity or nutrition) N3 (intervention* or program*)
#2	(physical activity or exercise) N3 (intervention* or program*)
#3	(lifestyle or life style) N3 (intervention* or program*)
#4	(health* promot* or health* improve*) N3 (intervention* or program* or educat*)
#5	health* liv* N3 (intervention* or program*)
#6	(MH “Exercise+”)
#7	(MH “Health Promotion+”)
#8	(non-pharmacological N3 (intervention* or program*)
#9	(MH “Health Education”)
#10	(MH “Patient Education”)
#11	community garden*
#12	community garden*

#13	shopping N3 (intervention* or program*)
#14	recovery college*
#15	MH "Psychotic Disorders+")
#16	psychosis
#17	(MH "Schizophrenia") OR “Schizophrenia”
#18	"Schizophrenic Psychology"
#19	Schizophrenic Psychology"
#20	(MH "Schizoaffective Disorder”) OR “schizoaffective”
#21	(serious or severe) N2 (mental illness* or mental disorder* or mental disease*)
#22	(MH "Mental Disorders") OR
#23	(MH "Bipolar Disorder") OR “Bipolar Disorder”
#24	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14
#25	S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23
#26	S24 AND S25
Limited to #1985- June 2018, English language, adults, humans, randomized controlled trials.#	
Records retrieved: 143	

Scopus, search conducted June 2018

Search	**Query**
#1	((TITLE-ABS-KEY ("Patient Education") AND DOCTYPE (ar) AND SUBJAREA (mult OR medi OR nurs OR vete OR dent OR heal) AND PUBYEAR > 1984) OR (TITLE-ABS-KEY ("community garden*") AND DOCTYPE (ar) AND SUBJAREA (mult OR medi OR nurs OR vete OR dent OR heal) AND PUBYEAR > 1984) OR (TITLE-ABS-KEY ((shopping) W/3 (intervention* OR program*)) AND DOCTYPE (ar) AND SUBJAREA (mult OR medi OR nurs OR vete OR dent OR heal) AND PUBYEAR > 1984) OR (TITLE-ABS-KEY ("recovery college*") AND DOCTYPE (ar) AND SUBJAREA (mult OR medi OR nurs OR vete OR dent OR heal) AND PUBYEAR > 1984) OR ((TITLE-ABS-KEY (((diet* OR weight OR obesity OR nutrition*) W/3 (intervention* OR program*))) AND DOCTYPE (ar) AND SUBJAREA (mult OR medi OR nurs OR vete OR dent OR heal) AND PUBYEAR > 1984) OR (TITLE-ABS-KEY ((("physical activity" OR exercise) W/3 (intervention* OR program*))) AND DOCTYPE (ar) AND SUBJAREA (mult OR medi OR nurs OR vete OR dent OR heal) AND PUBYEAR > 1984) OR (TITLE-ABS-KEY ((lifestyle OR "life style") W/3 (intervention* OR program*)) AND DOCTYPE (ar) AND SUBJAREA (mult OR medi OR nurs OR vete OR dent OR heal) AND PUBYEAR > 1984) OR (TITLE-ABS-KEY (("health* promot*" OR "health* improve*") W/3 (intervention* OR program* OR educat*)) AND DOCTYPE (ar) AND SUBJAREA (mult OR medi OR nurs OR vete OR

	dent OR heal) AND PUBYEAR > 1984) OR (TITLE-ABS-KEY (("health* liv*") W/3 (intervention* OR program*)) AND DOCTYPE (ar) AND SUBJAREA (mult OR medi OR nurs OR vete OR dent OR heal) AND PUBYEAR > 1984) OR (TITLE-ABS-KEY (exercise OR exp "Exercise Therapy") AND DOCTYPE (ar) AND SUBJAREA (mult OR medi OR nurs OR vete OR dent OR heal) AND PUBYEAR > 1984) OR (TITLE-ABS-KEY ("Health Promotion") AND DOCTYPE (ar) AND SUBJAREA (mult OR medi OR nurs OR vete OR dent OR heal) AND PUBYEAR > 1984) OR (TITLE-ABS-KEY (("non-pharmacological") W/3 (intervention* OR program*)) AND DOCTYPE (ar) AND SUBJAREA (mult OR medi OR nurs OR vete OR dent OR heal) AND PUBYEAR > 1984) OR (TITLE-ABS-KEY ("Health Education") AND DOCTYPE (ar) AND SUBJAREA (mult OR medi OR nurs OR vete OR dent OR heal) AND PUBYEAR > 1984))) AND ((TITLE-ABS-KEY ("Bipolar Disorder" OR bipolar) AND DOCTYPE (ar) AND SUBJAREA (mult OR medi OR nurs OR vete OR dent OR heal) AND PUBYEAR > 1984) OR ((TITLE-ABS-KEY ("Psychotic Disorders") AND DOCTYPE (ar) AND SUBJAREA (mult OR medi OR nurs OR vete OR dent OR heal) AND PUBYEAR > 1984) OR (TITLE-ABS-KEY (psychosis) AND DOCTYPE (ar) AND SUBJAREA (mult OR medi OR nurs OR vete OR dent OR heal) AND PUBYEAR > 1984) OR (TITLE-ABS-KEY (schizophrenia) AND DOCTYPE (ar) AND SUBJAREA (mult OR medi OR nurs OR vete OR dent OR heal) AND PUBYEAR > 1984) OR (TITLE-ABS-KEY ("Schizophrenic Psychology") AND DOCTYPE (ar) AND SUBJAREA (mult OR medi OR nurs OR vete OR dent OR heal) AND PUBYEAR > 1984) OR (TITLE-ABS-KEY (schizoaffective) AND DOCTYPE (ar) AND SUBJAREA (mult OR medi OR nurs OR vete OR dent OR heal) AND PUBYEAR > 1984) OR (TITLE-ABS-KEY ((serious OR severe) W/0 ("mental illness*" OR "mental disorder*" OR "mental disease*")) AND DOCTYPE (ar) AND SUBJAREA (mult OR medi OR nurs OR vete OR dent OR heal) AND PUBYEAR > 1984) OR (TITLE-ABS-KEY (mental AND disorders) AND DOCTYPE (ar) AND SUBJAREA (mult OR medi OR nurs OR vete OR dent OR heal) AND PUBYEAR > 1984))) AND ((TITLE-ABS-KEY (randomized AND controlled AND trial) AND DOCTYPE (ar) AND SUBJAREA (mult OR medi OR nurs OR vete OR dent OR heal) AND PUBYEAR > 1984) OR (TITLE-ABS-KEY (controlled AND clinical AND trial) AND DOCTYPE (ar) AND SUBJAREA (mult OR medi OR nurs OR vete OR dent OR heal) AND PUBYEAR > 1984) OR (TITLE-ABS-KEY (random*) AND DOCTYPE (ar) AND SUBJAREA (mult OR medi OR nurs OR vete OR dent OR heal) AND PUBYEAR > 1984) OR (TITLE-ABS-KEY (placebo) AND DOCTYPE (ar) AND SUBJAREA (mult OR medi OR nurs OR vete OR dent OR heal) AND PUBYEAR > 1984) OR (TITLE-ABS-KEY (trial) AND DOCTYPE (ar) AND SUBJAREA (mult OR medi OR nurs OR vete OR dent OR heal) AND PUBYEAR > 1984) OR (TITLE-ABS-KEY (groups) AND DOCTYPE (ar) AND SUBJAREA (mult OR medi OR nurs OR vete OR dent OR heal) AND PUBYEAR > 1984))

	AND (LIMIT-TO (LANGUAGE , "English")) AND (LIMIT-TO (SRCTYPE , "j"))
Limited to #1985- June 2018, English language, randomized controlled trials etc.#	
Records retrieved: 3516	

Cochrane, search conducted June 2018

Search	**Query**
#1	(diet* or weight or obesity or nutrition*) near/3 (intervention* or program*):ti,ab,kw Publication Year from 1985 to 2016 (Word variations have been searched)
#2	(physical activity or exercise) near/3 (intervention* or program*):ti,ab,kw Publication Year from 1985 to 2016 (Word variations have been searched)
#3	(lifestyle or life style) near/3 (intervention* or program*):ti,ab,kw Publication Year from 1985 to 2016 (Word variations have been searched)
#4	(health* promot* or health* improve*) near/3 (intervention* or program* or educat*):ti,ab,kw Publication Year from 1985 to 2018 (Word variations have been searched)
#5	(health* liv*) near/3 (intervention* or program*):ti,ab,kw Publication Year from 1985 to 2018 (Word variations have been searched)
#6	MeSH descriptor: [Exercise] explode all trees
#7	MeSH descriptor: [Health Promotion] explode all trees
#8	non-pharmacological:ti,ab,kw and intervention* or program*:ti,ab,kw Publication Year from 1985 to 2018 (Word variations have been searched)
#9	MeSH descriptor: [Health Education] explode all trees
#10	MeSH descriptor: [Patient Education as Topic] explode all trees
#11	community garden*:ti,ab,kw (Word variations have been searched)
#12	(shopping) near/3 (intervention* or program*):ti,ab,kw Publication Year from 1985 to 2018 (Word variations have been searched)
#13	recovery college*:ti,ab,kw (Word variations have been searched)
#14	#1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13
#15	MeSH descriptor: [Psychotic Disorders] explode all trees
#16	psychosis:ti,ab,kw Publication Year from 1985 to 2018 (Word variations have been searched)
#17	MeSH descriptor: [Schizophrenia] this term only
#18	schizophrenia
#19	MeSH descriptor: [Schizophrenic Psychology] this term only
#20	"schizoaffective disorder":ti,ab,kw Publication Year from 1985 to 2018 (Word variations have been searched)
#21	(serious or severe) near/2 (mental illness* or mental disorder* or mental disease*):ti,ab,kw (Word variations have been searched)
#22	MeSH descriptor: [Mental Disorders] this term only
#23	MeSH descriptor: [Bipolar Disorder] this term only
#24	bipolar
#25	#15 or #16 or #17 or #19 or #20 or #21 or #22 or #23 or #24
#26	"randomized controlled trial":ti,ab,kw (Word variations have been searched)

#27	"controlled clinical trial":ti,ab,kw (Word variations have been searched)
#28	random*:ti,ab,kw (Word variations have been searched)
#29	"placebo":ti,ab,kw (Word variations have been searched)
#30	Trial:ti,ab,kw (Word variations have been searched)
#31	Groups:ti,ab,kw (Word variations have been searched)
#32	#26 or #27 or #28 or #29 or #30 or #31
#33	#14 and #25 and #32
Limited to #1985- June 2018, English language, randomized controlled trials.#	
Records retrieved: 640	

Appendix II: Studies excluded on full text

Looijmans A, Jörg F, Schoevers RA, Bruggeman R, Stolk RP, Corpeleijn E. Changing the obesogenic environment of severe mentally ill residential patients: ELIPS, a cluster randomised study design. BMC psychiatry. 2014; 14:293
Reason for exclusion: This is a study protocol, hence ineligible study design.

McCreadie RG, Kelly C, Connolly M, Williams S, Baxter G, Lean M, et al. Dietary improvement in people with schizophrenia: randomised controlled trial. Br J Psychiatry. 2005; 187:346-51
Reason for exclusion: Ineligible intervention/phenomena of interest.

Zhang J-P, Weiss JJ, McCardle M, Klopchin H, Rosendahl E, Maayan L, et al. Effectiveness of a cognitive behavioral weight management intervention in obese patients with psychotic disorders compared to patients with nonpsychotic disorders or no psychiatric disorders: Results from a 12-month, real-world study. J Clin Psychopharmacol. 2012; 32(4):458-64
Reason for exclusion: Ineligible study design and participants

Font RM, Sanmartin MIF, Lopez LMM, Tabuena NO, Canet SO, Echevarria LSE, et al. The effectiveness of a program of physical activity and diet to modify cardiovascular risk factors in patients with severe mental illness (CAPiCOR study). Int Arch Med. 2015; 8 (1) (no pagination)(A74).
Reason for exclusion: This is a study protocol, hence ineligible study design.

Direk N, Ucok A. Effectiveness of a structured diet program in antipsychotic-induced weight gain in patients with schizophrenia. Int J Psychiatry Clin Pract. 2008; 12(3):238-40
Reason for exclusion: Ineligible study design.

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Reason for exclusion: Ineligible participants.

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Reason for exclusion: Ineligible intervention/phenomena of interest.

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Reason for exclusion: Ineligible study design.

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Reason for exclusion: Ineligible study design.

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Reason for exclusion: Ineligible study design.

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Reason for exclusion: Ineligible study design.

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Reason for exclusion: This was not a lifestyle intervention because they used pharmacotherapy.

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Reason for exclusion: This was a conference abstract.

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Reason for exclusion: This was a conference abstract.

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Reason for exclusion: Ineligible study design.

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Reason for exclusion: The type of participants does not fit inclusion criteria as they are inpatients.

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Reason for exclusion: Ineligible intervention/phenomena of interest.

Appendix III: Characteristics of included studies

Author	Sample size	Drop outs	Diagnoses	Country	Age (M,SD)	Antipsychotic medications	Duration	Intervention	Control	Group
Non-structured diet and non-structured physical activity lifestyle interventions*										
Milano et al., 2007[47]	I=22 C=14	0	Schizophrenia and bipolar disease	Italy	I=46 C=45	Olanzapine	3 months	This was a diet and physical activity program. Dietary component comprised of simple nutritional education. Participants were encouraged to decrease intake by 500 kcal/day, with appropriate nutritional balance. A simple program of physical activity was proposed (3 times/week for 30–60 min).	Performed no organized physical activity and followed regular diet	Treatment as usual
Khazaal et al., 2007[19]	I=31 C=30	I=6 C=2	Schizophrenia, schizoaffective disorders, bipolar disorder and schizotypal disorder	Switzerl and	40.7, ±10.3	Olanzapine, risperidone, clozapine, quetiapine, amisulpride, classical antipsychotic drug	12 weeks	This was a CBT intervention focusing on diet and physical activity. Twelve 2-hour group sessions were held weekly. Dietary education was delivered by motivational interviewing and encouraged cognitive restructuring of maladapted cognitions relating to weight and food. Moderate physical activity was encouraged to promote self-care and not to decrease weight.	Participants received brief dietary advice in a 2-hour session at baseline.	Placebo II

Author	Sample size	Drop outs	Diagnoses	Country	Age (M,SD)	Antipsychotic medications	Duration	Intervention	Control	Group
Ratliff et al., 2015[51]	I=10 C=10 WC=10	I=1 C=1	Schizophrenia and schizoaffective disorder	USA	I=50.1 ±10.6 C=47. 3±8.0 WC= 49.0± 8.1	Chlorpromazine	8 weeks	The program targeted dietary and physical activity behavior. Social cognitive theory combined with financial contingency measures were the program basis. Weekly group education sessions were delivered focusing on diet and physical activity attitude change. Education topics focused on equipping participants with knowledge on healthier foods and increased physical activity. Participants received $5 for each lb lost/week from week 2 and $20 for baseline and week 8 assessments. The second intervention group received the same intervention as the first group; however, contingency rewards were given differently. Participants received financial reimbursements of $17.50 for each group session attended plus $20 for baseline and week 8 assessments.	Individuals in the waitlist control received no specific dietary or physical activity intervention for 8 weeks.	Treatment as usual
Greil et al., 2010[54]	I=26 C=24	I=1 C=2	Bipolar disorder	Switzerl and	I=48.1 ±11.5 C=48. 9±12.0	—	5 months and 6 months follow-up	The components of the current program comprised sessions on nutrition, physical activity and psychotherapy for symptoms. Four nutrition education sessions were offered, inclusive of cooking classes and nutritional advice. Weekly physical activity education instructions were given.	Standard care	Treatment as usual

Author	Sample size	Drop outs	Diagnoses	Country	Age (M,SD)	Antipsychotic medications	Duration	Intervention	Control	Group
McKibbin et al., 2006[21] McKibbin et al., 2010[21,56]	I=29 C=28	7	Schizophrenia and schizoaffective	USA	I=54.8 ±8.2 C=53. 1±10.4	—	6 months	Nutrition, physical activity, and diabetes management components were included in the current program, which was underpinned on social cognitive theory. The program was offered weekly for 90 min. Education was the main method used to deliver the nutrition component. Participants engaged in weekly weigh-ins, pedometer use and healthy food sampling. Participants also received raffle tickets for engaging in behavior change. Physical activity education was given and participants encouraged to walk 30 min/day.	Participants received brochures at baseline on diabetes education, nutrition and exercise.	Placebo I
Goldberg et al., 2013[57]	I=53 C=56	I=23 C=15	Schizophrenia, schizoaffective disorder, major depression, bipolar disorder, posttraumatic stress and anxiety disorder	USA	52.0±9 .1	Olanzapine, risperidone, quetiapine, ziprasidone, aripiprazole, fluphenazine, haloperidol and perphenazine	6 months	The program offered was a psychoeducation nutrition and physical activity intervention. Weekly nutrition and physical activity education sessions were offered.	Participants were given handouts that provided dietary and physical activity advice.	Placebo I

Author	Sample size	Drop outs	Diagnoses	Country	Age (M,SD)	Antipsychotic medications	Duration	Intervention	Control	Group
Forsberg et al., 2008[59]	I=24 C=17	I=3 C=2	Schizophrenia and bipolar disorder	Sweden	I=39.8 (23-59) C=42.8 (22-71)	—	12 months	The current healthy living program equipped participants with nutrition and physical activity skills. Handouts were given with nutrition and physical activity information. A group leader cared for 5-12 persons and met with members weekly for 2 hours. Group sessions included nutrition and physical activity education.	Participants had the opportunity to try sketching, charcoal drawing, pencil drawing, oils, batik and collage.	Placebo III
Attux et al., 2013[67]	I=81 C=79	I=8 C=13	Schizophrenia and other psychosis	Brazil	I=36.2 ±9.9 C=38.3±10.7	—	12 weeks and 3 months follow-up	This program educated participants on nutrition and physical activity and also focused on self-esteem, motivation and anxiety. Twelve 1-hour sessions were conducted weekly. Nutrition education was given over 4 sessions and importance of physical activity was discussed over 3. One session was opened to relatives.	Standard care	Treatment as usual
Brar et al., 2005[18]	I=34 C=37	I=12 C=9	Schizophrenia and schizoaffective disorder	USA	I= 40.0 ± 10.1 & 40.5 ± 10.6	Risperidone	14 weeks	This was a CBT intervention that educated participants on diet and physical activity. Participants attend biweekly sessions for the first 6 weeks and weekly sessions for the remaining 8 weeks. Nutrition and physical activity education was given during sessions.	No additional intervention	Treatment as usual
Structured diet and structured physical activity lifestyle interventions†										

Author	Sample size	Drop outs	Diagnoses	Country	Age (M,SD)	Antipsychotic medications	Duration	Intervention	Control	Group
Weber and Wyne, 2006[22]	I=8 C=9	I=1 C=1	Schizophrenia and schizoaffective disorder	USA	—	—	16 weeks	This CBT intervention focused on diet and physical activity. Weekly 1-hour sessions were held for 16 weeks. Sessions included role plays, goal setting, motivational scaling and problem solving. Presentations on low-fat, healthy diets and physical activity were held. All participants kept food and activity diaries, which were turned in at the beginning of each session. Group sessions were held of which various topics on diet and physical activity were discussed.	Participants received treatment as usual.	Treatment as usual
Erickson et al., 2016[48]	I=60 C=48	I=35 C=25	Schizophrenia, schizoaffective disorder and bipolar disorder	USA	I=49.6 ± 9.1 & 49.7 ± 6.9	Olanzapine, clozapine, risperidone, quetiapine, aripiprazole, ziprasidone	12 months	This program comprised diet and physical activity components. Participants kept food and exercise diaries that were reviewed weekly for 8 weeks and monthly thereafter. A decrease in dietary intake was encouraged by 500-1000 kcal/day. Supervised group exercises were held bi-weekly. Manualized physical activity instructions were given to encourage increased activity to 150 min/week by week 5. Healthy eating quizzes were held periodically to assess knowledge. $10 vouchers was given for achieving personal goals.	Participants were encouraged to exercise and follow a healthy diet through publicly available material.	Placebo I
Daumit et al., 2013[50]	I=144 C=147	I=11 C=5	Schizophrenia, schizoaffective disorder, bipolar disorder, major depression	USA	45.3±11.3	—	18 months	This intervention addressed both diet and physical activity. Motivational interviewing was cornerstone to delivery. The dietary component fostered self-awareness	Standard nutrition and physical activity information was given at	Placebo I

Author	Sample size	Drop outs	Diagnoses	Country	Age (M,SD)	Antipsychotic medications	Duration	Intervention	Control	Group
								through a food log. Participants were helped to set dietary goals. Intervention goals were monitored via individual review meetings. The physical activity goal was 150 min of moderate intensity activity/ week. Three 50-min supervised exercise sessions were held per week. Participants were taught to monitor their physical activity and taught exercises they could do at home.	baseline. Classes were offered quarterly, with content unrelated to weight.	
Speyer et al., 2013[49]	I=138 C=142 C=148	I=18 C=21 C=21	Schizophrenia, schizoaffective disorder and persistent delusional disorder	Denmark	I=37.8 ±12.6 C=39.5± 12.8 C=38.5±11.8	—	12 months	This manualized intervention addressed diet and physical activity, care-coordination and smoking cessation. Participants were encouraged to choose if focus should be on one or more of the four possible tracks. Theoretical bases were stages of change, motivational interviewing and assertive approach. A lifestyle coach supported patients in setting up individual goals though weekly home visits. Dietary advice was based on examining individual dietary habits, food purchases, cooking practices and offering feasible advice. The physical activity goal was 30 min/day and participants were encouraged to keep a training log, which was reviewed regularly and suggestions offered.	Control group 1: A psychiatric nurse facilitated contact with primary care to ensure patients received optimal treatment.	Placebo III
									Control group 2: no additional effort was offered in regards to a lifestyle intervention or treatment of physical disorders.	Treatment as usual

Author	Sample size	Drop outs	Diagnoses	Country	Age (M,SD)	Antipsychotic medications	Duration	Intervention	Control	Group
Frank et al., 2015[66]	I=61 C=61	I=3 C=5	Bipolar disorder	USA	41.6 ±9.5	—	24 months	The lifestyle program consisted of nutrition and physical activity components, psychiatric treatment, care coordination. Participants met the lifestyle coach at least fortnightly for 6 months and once every 6 weeks thereafter. Nutrition education was delivered through psychoeducation. A lifestyle coach aided participants in development of plan for nutrition to decrease intake by ≥ 500 kcal/day. Participants kept food diaries which were reviewed. Physical activity education was also given and participants were assisted to create plans aimed to increase activity to ≥ 30 min, 3-5 times/week. Activity goals were reviewed by their lifestyle coach.	Usual care	Treatment as usual
Mauri et al., 2008[60]	I=15 C=18	I=3 C=8	Bipolar disorder, schizoaffective disorders, psychotic depression.	USA	38.9, (19 – 60)	—	12 weeks & 12 weeks follow-up	This was a nutrition and physical activity psychoeducation program. Participants received 8 individual visits, each 30 min. As part of the dietary component, participants kept a food diary after which they received a personalized diet decreased by 500 kcal/day. Physical activity education and use of step counter was applied with the objective of 10,000 steps/day. Patients were encouraged to record weight weekly to the identification of effective dietary and physical activity strategies at review.	Usual care for 12 weeks and intervention thereafter.	Treatment as usual

Author	Sample size	Drop outs	Diagnoses	Country	Age (M,SD)	Antipsychotic medications	Duration	Intervention	Control	Group
Kwon et al., 2006[16]	I=33 C=15	I=11 C=1	Schizophrenia, schizoaffective disorder	Korea	I=32.0 ± 9.2 C=29. 8± 6.07	Olanzapine	12 weeks	The lifestyle intervention targeted diet and physical activity. Weekly consults were offered for the first 4 weeks and then fortnightly. Dietary education was given and participants were encouraged to keep a food diary, which was discussed with a dietitian who helped with diet planning at each visit. Participants were also given exercise education and received consults with an exercise coordinator who helped with exercise planning at every visit.	Participants received routine care with verbal recommendations for diet and physical activity.	Placebo I
Green et al., 2015[64]	I=104 C=96	I=22 C=29	Schizophrenia	USA	47.2± 10.6	—	6 months & 6 months follow-up	The intervention incorporated nutrition and physical activity components. The program was adapted to suit people with severe mental illness by using strategies such as repetition, multiple teaching modalities and skill building practice. Weekly meetings were held for 2 hours with a weight loss goal of 4.5-6.8 kg over 6 months. The dietary component comprised education, and participants also kept food records and were encouraged to set goals with weekly review. Physical activity education was given with an overall goal of 180 min of moderate activity/week. Participants were encouraged to record activity and individual goals were set and reviewed weekly. Weekly group exercise sessions were held.	Usual care	Treatment as usual

Author	Sample size	Drop outs	Diagnoses	Country	Age (M,SD)	Antipsychotic medications	Duration	Intervention	Control	Group
								Phone call consults were made during the follow-up period.		
Erickson et al., 2017[71]	I=62 C=58	I=9 C=9	Schizophrenia, schizoaffective disorder, Bipolar disorder	USA	I= 50.4 ±9.0 C=51. 9± 9.3	Olanzapine, clozapine, risperidone, quetiapine, aripiprazole, ziprasidone	8 weeks and 12 months follow-up	This program offered diet and physical activity education led by a dietitian. Weekly 60-min classes were offered for the first 8 weeks and monthly thereafter. Participants were also offered individual sessions with dietitians. Participants were helped to set and accomplish food and activity goals. Motivational interviewing and CBT techniques were utilized.	Self-help educational handouts on health issues were provided.	Placebo I
Structured diet and non-structured physical activity lifestyle interventions‡										
Scocco et al., 2006[17]	I=10 C=10	I=1 C=2	Schizophrenia, schizoaffective disorder	Italy	I=51.7 ±12.4 C=39. 2 ± 9.9	—	8 weeks and 24 weeks follow-up	The program offered individual consults with a dietitian on diet and physical activity. During consults, individualized food diaries were drawn up emphasizing energy intake and expenditure. Increased physical activity was also encouraged. At follow-up, food diaries were discussed and questions clarified.	Waitlist control	Treatment as usual
Jean-Baptiste et al., 2007[72]	I=8 C=9	I=1 C=3	Schizophrenia	USA	I=52.4 C=40. 7	Clozapine, olanzapine, risperidone haloperidol, perphenazine, thiothixene, fluphenazine quetiapine, ziprasidone	16 weeks with 6 months follow up	The intervention comprised nutrition and physical activity components. Nutrition education was given by a dietitian who also led a cooking demonstration and a grocery store tour. Participants kept a food record and submitted it weekly to the dietitian who reviewed it and provided individualized feedback. Exercise was encouraged by providing pedometers.	Demonstration on how to prepare healthy recipes was performed.	Placebo II

Author	Sample size	Drop outs	Diagnoses	Country	Age (M,SD)	Antipsychotic medications	Duration	Intervention	Control	Group
Evans et al., 2005[15]	I=29 C=22	I=5 C=11	Schizophrenia, schizoaffective disorder, schizophreniform psychosis, bipolar disorder, depression	Australia	I= 33.6 ±11.6 C=34.6±9.6	Olanzapine	3 months & 3 months follow-up	Participants received nutrition and physical activity education via fortnightly dietetic consultations. Nutrition education was given during consults, and participants set healthy eating goals, which were reviewed fortnightly. Participants were also encouraged to increase physical activity.	Participants received nutritional education at baseline.	Placebo II
Non-structured diet and structured physical activity lifestyle interventions§										
Masa-Font et al., 2015[73]	I=169 C=163	I=27 C=18	Schizophrenia	Spain	46.3 ±8.9 47.1 ±9.9	—	3 months	This intervention comprised diet and physical activity components. The diet intervention consisted of 16 sessions, biweekly for 20 min. Nutrition education was based on the Mediterranean diet. Knowledge gained was assessed by nurses delivering the intervention. Physical activity intervention consisted of 24 sessions, biweekly. Participants were assisted to increase activity to 10,000 steps/day through education and supervised walks.	Participants continued with regular treatment.	Treatment as usual

Author	Sample size	Drop outs	Diagnoses	Country	Age (M,SD)	Antipsychotic medications	Duration	Intervention	Control	Group
Verhaeghe et al., 2013[70]	I= 201 C=83	I=80 C=33	Schizophrenia, mood disorder, substance misuse, personality disorder	Belgium	I=46.2 ±12.5 C=46.6±11.9	—	10 weeks & 24 weeks follow-up	This health promotion program incorporated nutrition and physical activity components. Intervention theoretical frameworks were social cognitive theory, self-determination theory and control theory. Weekly psychoeducation and group discussions on healthy eating and problem solving were given. Written exercise plans were given and supervised sessions of 30 min exercise were given.	Regular treatment	Treatment as usual
Methapatara and Srisurapanont, 2011[58]	I=32 C=32	I=4 C=1	Schizophrenia	Thailand	40.4 ±10.4	Clozapine, olanzapine	12 weeks	This program promoted improved nutrition and increased physical activity through motivational interviewing. Participants were educated on nutrition and exercise in five 1-hour sessions. Pedometers were given to participants and their use taught. Physical activity goals were set with the help of a therapist with a daily minimum of 3000 steps. Regular review of exercise goals was given by therapists who helped participants adhere to the program.	Participants in the control group received a healthy lifestyle leaflet.	Placebo I
Usher et al., 2013[61]	I=51 C=50	—	Schizophrenia, depression, bipolar disorder, anxiety	USA	>18	Clozapine, olanzapine, risperidone, Seroquel, amisulpride, Abilify, Avanza	12 weeks	The lifestyle intervention comprised nutrition and physical activity components. Nutrition and physical activity education was given during weekly 1-hour meetings for 12 weeks. Weekly 30-min exercise sessions were led by the researcher.	Participants were given an education booklet at baseline with nutrition and physical activity information.	Placebo I

Author	Sample size	Drop outs	Diagnoses	Country	Age (M,SD)	Antipsychotic medications	Duration	Intervention	Control	Group
Skrinar et al., 2005[62]	I=15 C=15	I=6 C=4	DSM-IV mood or psychotic disorder diagnoses	USA	I=39.7 ± 8.17 C=36. 3±11.3	—	12 weeks	This healthy living intervention incorporated both nutrition and physical activity sessions. Five health sessions were held weekly for 30-45 min. One of the five health sessions focused on nutrition education, and four health sessions were dedicated to provision of supervised exercise.	Waitlist control	Treatment as usual
Structured physical activity lifestyle interventions‖										
Scheewe et al., 2013[52]	I=31 C=32	I=2 C=7	Schizophrenia, schizoaffective , schizophrenifo rm disorder	Netherla nds	I=29.2 ±7.2 C=30. 1±7.7	—	6 months	This was an exercise therapy intervention. The program aimed to increase physical activity to ≥ 150 min of moderate intensity exercise or ≥ 75 min of vigorous exercise/week. Exercise therapy was delivered in line with a protocol and supervised by a psychomotor therapist for 2 hrs/week. Compliance was recorded in a log book. Participants were prescribed hourly biweekly exercise to perform at home of which intensity was gradually increased.	Participants in the control group were offered occupational therapy for 1 hour 2 times per week.	Placebo III
Battaglia et al., 2013[63]	I=10 C=18	I=2 C=3	Schizophrenia	Italy	I=36.0 ± 5.0 C=35. 0 ± 4.0	—	12 weeks	This was a physical activity intervention. Participants attended 2 group exercise sessions per week with a trainer, which lasted about 2 hours. Training sessions were supervised and moderated by a trainer.	Participants did not perform any organized physical activity.	Treatment as usual
Other lifestyle interventions‖										

Author	Sample size	Drop outs	Diagnoses	Country	Age (M,SD)	Antipsychotic medications	Duration	Intervention	Control	Group
Gaughran et al., 2017[68]	I=213 C=193	I=3 C=1	Schizophrenia spectrum, bipolar disorder	UK	I= 43.8 ±10.1 C= 44.7 ±10.2	—	12 months and 3 months follow-up	This intervention addressed diet and exercise using motivational interviewing and CBT. Additional areas focused on were smoking, alcohol use and illegal substance use.	Treatment as usual	Treatment as usual
Kilbourne et al., 2017[69]	I=146 C=147	I=11 C=6	Schizophrenia, bipolar disorder, major depressive disorder	USA	I=55.1 ±10.7 C=55.3 ± 11.0	Antipsychotics, antidepressants, mood stabilizers	5 weeks and follow up until month 12	This was primarily a program focusing on self-management of severe mental illness. Comprised 5 weekly 90-minute group sessions. One session focused on nutrition and physical activity education. Participants were assisted in setting goals for their mental and physical health. Participants were contacted monthly via phone call for 6 months after the intervention to track progress.	Usual care	Treatment as usual

I: intervention group; C: control group; (—): information not available; CBT: cognitive behavioral therapy; WC: waitlist control; DSM-IV: Diagnostic and Statistical Manual of Mental Disorders; Treatment as usual: no form of placebo mentioned or given/usual care; Placebo I: standard nutrition and physical activity information provided through talks, lectures or handouts; Placebo II: standard nutrition information provided through talks, lectures or handouts; Placebo III: An action or process that does not involve provision of dietary or physical activity information e.g. occupational therapy, increased contact with a health professional.

***—Non-structured diet and non-structured physical activity lifestyle interventions:** The nutrition component is characterized by some form of education where participants are informed about healthy food or demonstrations on healthy meal preparation are given. Participants are also provided with physical activity education or encouraged to increase their physical activity. This category is characterized by provision of nutrition and physical activity education; however, individual goals in these areas are not set nor monitored regularly. Participants are therefore not assisted with integrating the education into their current lifestyle.

†**—Structured diet and structured physical activity lifestyle interventions:** The nutrition component is characterized by education and also provision of a prescribed diet or provision of assistance to set dietary goals that are regularly reviewed. Participants are also provided with education on physical activity but are also helped to set physical activity goals whose progress is monitored and reviewed regularly or are also provided with regular exercise under the supervision of a trainer. This category is characterized by the nutrition education and provision specific dietary instructions or setting of dietary goals that are reviewed regularly, and the provision of physical activity education along with provision of assistance to set physical activity goals that are reviewed regularly.

‡**—Structured diet and non-structured physical activity lifestyle interventions:** The nutrition component is characterized by some form of education and provision of a prescribed diet that is regularly reviewed, or the delivery of clearly identified goals and objectives to be met by participants that are reviewed regularly. However, participants are only provided with physical activity education and are not assisted to integrate this information into their daily life via goal setting. This category is characterized by the provision of specific dietary instructions or setting of dietary goals that are monitored and reviewed regularly; however, the physical activity component does not follow a similar approach where integration of information into daily life is offered.

§—Non-structured diet and structured physical activity lifestyle interventions: The nutrition component is characterized some form of education where participants receive information about healthy food or demonstrations on healthy meal preparation are given; however, the physical activity component is marked by not only education but also setting of physical activity goals whose progress is monitored and reviewed regularly or also the provision of regular exercise under the supervision of a trainer. This category is characterized by nutrition education coupled with a personalized physical activity component where participants are given physical activity instructions or education and are also assisted to set goals that are reviewed regularly or are also provided with regular exercise under the supervision of a trainer.

‖—Structured physical activity: No nutrition component is offered as part of the intervention. Participants are provided with education on physical activity and are also helped to set physical activity goals whose progress is monitored and reviewed or are also provided with regular exercise under the supervision of a trainer**.**

‖—Other lifestyle interventions: Did not fit into any of the identified subgroups.

Chapter 5.2: An Appraisal of Methodology Reporting in Lifestyle Interventions among People with Psychosis using the CONSORT Statement for Randomised Trials of Nonpharmacologic Treatments: A Systematic Review

5.2.1 Study Overview

A thorough review of existing lifestyle interventions highlighted that many studies omitted relevant information in the methodology which made interpretation of these studies difficult (214, 233). This was particularly evident when appraising studies against the Australian Dietary Guidelines (ADGs); none of the studies complied with all relevant guidelines, due to inadequate information or vague descriptions of the dietary approaches that were used (233). The implication for this is that specific information on efficacious dietary or nutrition advice for people with psychosis is lacking (233). Although some studies highlighted the principles that were used to promote dietary change such as portion control or limiting foods with saturated fats, specific protocols for administering this information were unavailable (233). Interpretation of this information was thus difficult due to potential variation in how dietary information was applied in the lifestyle interventions (215).

Quality of existing lifestyle intervention reports can be improved by adhering to guidelines designed for nonpharmacologic interventions (215). The Consolidated Standards of Reporting Trials (CONSORT) statement for randomised trials of nonpharmacologic interventions were designed to address challenges associated with standardisation, administration, reproduction and reporting in behavioural interventions (215). Assessing lifestyle interventions against formal reporting guidelines like the CONSORT Statement for RCTs of nonpharmacologic interventions provides insight on the quality of available research and highlights areas for improvement, in order to promote usability of research in this field (172, 207-209, 212, 215, 234). In view of this, the aim of this study was to critically appraise lifestyle intervention studies that target weight outcomes for people with psychosis against the methods component of the CONSORT statement for randomised trials of nonpharmacologic treatments.

Results from this study were published in the Health Promotion Journal of Australia. Mucheru D, Hanlon MC, McEvoy M, and MacDonald-Wicks L. *An Appraisal of Methodology Reporting in Lifestyle Interventions among People with Psychosis using the CONSORT Statement for Randomised Trials of Nonpharmacologic Treatments: A Systematic Review*. Health Promot J Austr. 2019. Doi 10.1002/hpja.293

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REVIEW

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An appraisal of methodology reporting in lifestyle interventions among people with psychosis: A systematic review

Doreen Mucheru BNutrDiet, (Hons)[1] | Mary-Claire Hanlon PhD[1,2,3,4] | Mark McEvoy PhD[1,5] | Lesley MacDonald-Wicks PhD[1,2,6]

[1]Faculty Health and Medicine, The University of Newcastle, Callaghan, NSW, Australia

[2]Brain and Mental Health Program, Hunter Medical Research Institute, New Lambton, NSW, Australia

[3]Priority Research Centre for Brain and Mental Health, Mater Hospital, Waratah, NSW, Australia

[4]Hunter Cancer Research Alliance, The University of Newcastle, Callaghan, NSW, Australia

[5]Centre for Clinical Epidemiology & Biostatistics, Hunter Medical Research Institute, New Lambton, NSW, Australia

[6]Priority Research Centre for Physical Activity and Nutrition, The University of Newcastle, Callaghan, NSW, Australia

Correspondence
Doreen Mucheru, Faculty Health and Medicine, The University of Newcastle, Callaghan 2308, NSW, Australia.
Email: Doreen.Mucheru@uon.edu.au

Abstract

Issue addressed: Lifestyle interventions use nutrition and physical activity behaviour modification techniques to decrease obesity and cardio-metabolic risk in people with psychosis. Evidence on the specific behaviour modification strategies applied to decrease obesity is weakened by inadequate methodology reporting of lifestyle interventions. A systematic review that we conducted earlier highlighted a possible deficiency in reporting; hence we aim to critically appraise lifestyle intervention studies that target weight outcomes for people with psychosis against the methods component of the CONSORT statement for randomised trials of nonpharmacologic treatments.

Methods component: We considered randomised controlled studies which delivered lifestyle interventions to community-dwelling adults with psychotic disorders, and included those with the following outcomes of interest: weight, body mass index, waist circumference and waist-to-hip ratio. The Cochrane Library, MEDLINE/PREMEDLINE, EMBASE, CINAHL, Scopus and PsycINFO were searched for English publications between 1985 and 2018. Methodology and reporting of studies were evaluated using the CONSORT statement for randomised trials of nonpharmacologic treatments.

Results: Thirty-two studies met the inclusion criteria. Critical appraisals revealed that reporting of lifestyle intervention studies was generally incomplete. Fewer than 50% provided the recommended information on trial design, participant characteristics, detail of interventions, outcomes, sample size, randomisation, blinding and statistical methods.

Conclusions: Application of guidelines, like the CONSORT statement, in future publications of lifestyle interventions for people with psychosis will improve accuracy of reporting.

So what? Enhanced reporting in lifestyle intervention studies for people with psychosis will promote guideline creation and translation of research, which is likely to positively impact physical health outcomes.

Summary

This appraisal of lifestyle interventions which target weight outcomes in people with psychosis against the CONSORT statement for randomised trials of nonpharmacologic treatments highlighted that reporting was generally incomplete in studies. Poor reporting limits the utility of lifestyle intervention research in people with psychosis; however, this can be improved with future use of the CONSORT statement or similar reporting guidelines.

1 | BACKGROUND

Lifestyle interventions are an effective obesity treatment and have been shown to reduce cardio-metabolic risk factors among people with psychosis.[1] Evidence summaries show that these interventions produce decreases in weight (−4.1 kg), changes in body mass index (BMI) (−2.9 points) and waist-circumference reductions (−2 cm) when compared to control conditions.[2] Other cited benefits include improvements in fasting blood glucose (−5.79 mg/dL), triglycerides (−61.68 mg/dL) and total cholesterol levels (−20.98 mg/dL).[3] Although impact on physical health conditions has not been established, anthropometric and metabolic changes can decrease risk of type 2 diabetes, metabolic syndrome and cardiovascular disease (CVD).[1,3,4] These interventions are superior to pharmacological treatments for CVD risk reduction because they eliminate underlying causative behaviours.[4] The Royal Australian and New Zealand College of Psychiatrists (RANZCP) therefore recommends comprehensive management of cardio-metabolic risk in people with psychosis through pharmacological treatment and lifestyle intervention.[5]

Previous lifestyle interventions incorporate nutrition and physical activity treatments, and rely on behavioural changes to modify health outcomes.[1,6] Recent focus on the efficacy of these interventions is due to the poor physical health experienced by people with psychosis, evidenced by high rates of obesity, metabolic syndrome and CVD.[1,3,7–9] These cardio-metabolic health problems contribute to the shortened life expectancy in this group, which is 10–25 years earlier than the general population. [8–11] Poor nutrition and inadequate physical activity are well-established downstream risk factors for cardio-metabolic health conditions; however, effective strategies for delivering intervention components pertaining to these behaviours in a program for people with psychosis are still being identified.[1–3,7] Consequently, there is a need for knowledge advancement in the field.[1,2] An important foundation for this is adequate lifestyle intervention reporting, thus allowing knowledge synthesis and research replication.[12]

We conducted a systematic review investigating the comparative efficacy of strategies used in lifestyle interventions in people with psychosis.[2] The findings showed that randomised controlled trials (RCTs) which utilised a structured or personalised approach in both nutrition and physical activity components of the intervention achieved the greatest decreases in weight and BMI (ES = −4.12, 95% CI = −7.772 to −2.760, $P < .000$ and ES = −2.94, 95% CI = −1.78 to −0.357, $P = .003$ respectively).[2,13] The certainty rating of this evidence was, however, very low based on the Grades of Recommendation, Assessment, Development, and Evaluation (GRADE) tool.[14,15] Reasons for this included incomplete intervention description, lack of clarity on strategies for preventing bias and high risk of bias in some studies.[2] Previous systematic reviews of lifestyle interventions among people with psychosis also reported encountering similar problems when assessing efficacy of RCTs.[1,7] Application of a standardised study design, methodology and reporting procedures should improve the quality of the reporting in these lifestyle interventions.[12]

The Consolidated Standards of Reporting Trials (CONSORT) statement is a set of guidelines designed to improve reporting of RCTs, which have been extended to cover nonpharmacologic interventions.[12] Nonpharmacologic interventions apply behavioural techniques, surgery, technical procedures, rehabilitation, devices, and complementary and alternative medicine to modify health-related outcomes.[12] Nonpharmacologic interventions are largely dependent on human behaviour in both those delivering and receiving the intervention, and consequently, can be difficult to describe, standardise, reproduce and administer.[12] The CONSORT statement for RCTs of nonpharmacologic interventions was designed to minimise the magnitude of these challenges; the statement comprises a 21-item checklist of factors considered essential for inclusion in the methods section of relevant publications.[12] The checklist necessitates the inclusion of information on the trial design, participants, interventions, outcomes, sample size, randomisation, blinding and statistical methods.[12]

Trial design as per the CONSORT statement encompasses the type of trial, allocation ratio and processes for allocating treatment.[16] Additionally, participants comprise all parties and settings involved in the delivery and receipt of the intervention, eligibility criteria for both these individuals and intervention settings, and characteristics of data collection settings.[12,17] Interventions generally include all treatments offered in the experimental and control arms, timing of administration, mode of treatment delivery and treatment standardisation procedures.[12,18] The CONSORT statement requires that outcomes cover any pre-specification details of variables, skill requirements of assessors, procedures and timing for measurement, and the presence or absence of changes to specified outcomes after research commencement.[12,16] Sample size consists of a procedural justification for the number of study participants. Moreover, the CONSORT statement calls for the inclusion of details on how bias associated with care providers or treatment centres was controlled in the sample size.[12,16,19]

Randomisation, as an element of the CONSORT statement, takes into account the procedures of sequence generation, allocation of treatment providers to trial groups and allocation concealment.[12] Personnel involved in these processes are also part of the randomisation construct.[12] Blinding not only includes the presence or absence of concealment allocation, but also to whom this procedure was applied, how this was achieved, similarity of treatments offered in the intervention and any other attempts to limit bias where blinding was not possible.[12,20] Finally, statistical methods that are consistent with the CONSORT statement incorporate data analysis processes and procedures used to control for the effect of different care providers and treatment centres in the analyses.[12]

In light of the methodological considerations proposed by the CONSORT statement, lifestyle intervention studies for people with psychosis are likely to benefit from a formal comparison to the checklist.[12] The aim of this study was to critically appraise lifestyle intervention studies that target weight outcomes for people with psychosis against the methods component of the CONSORT statement for randomised trials of nonpharmacologic treatments.[2,12]

2 | METHODS COMPONENT

2.1 | Inclusion and exclusion criteria

This systematic review considered RCTs which delivered lifestyle interventions that applied nutrition or physical activity elements aimed at weight loss or weight management among community-dwelling participants, aged 18 years and over with a diagnosed psychotic disorder (typically schizophrenia, bipolar disorder, schizoaffective disorder and major depressive disorders).[2,13,21] Outcome measures considered for inclusion were weight, BMI (kg/m^2), waist circumference and waist-to-hip ratio.[2,13] Weight was included because it was the single most reported outcome in primary RCTs and losses of ≥5% are associated with health benefits.[1,22] BMI, waist circumference and waist-to-hip ratio are however more meaningful in assessing overall health.[23]

Lifestyle interventions were excluded if they utilised the internet or mobile health (m-health) technology, due to the high dropout rates and low utilisation rates associated with these interventions.[2,13,24] In addition, all lifestyle interventions conducted within inpatient settings were also excluded because the needs of people within inpatient and outpatient settings differ greatly.[2,3,13]

2.2 | Search strategy

The search strategy aimed to find studies published in English between 1985 and June 2018 in the Cochrane Library, MEDLINE/PREMEDLINE, EMBASE, CINAHL, Scopus and PsycINFO (see Table 1 for search terms).[2,13] Reference lists of all identified reports and articles were searched for additional studies.[2,13] The restriction to studies published in English was applied due to the anticipated difficulties associated with translating studies published in other languages.[2,13,25] Studies prior to 1985 were excluded because they used strategies that may be considered unethical by modern clinicians.[2,13,26]

2.3 | Study selection

Studies identified from databases were screened by two independent reviewers based on pre-determined inclusion and exclusion criteria.[2,13] Titles and abstracts of studies were first screened prior to full-texts of included papers being retrieved.[2,13] Full-texts were then screened and studies not meeting the inclusion criteria were excluded from the final list of included papers.[2,13]

2.4 | Data extraction

Relevant data were extracted from papers included in the review by one reviewer, with checking by another reviewer. Extracted data included specific details on: study design, participants, interventions, outcomes, sample size, randomisation procedure, blinding and statistical methods applied.[12]

TABLE 1 Search strategy for lifestyle intervention studies among people with psychosis

	Combine with "AND"		
Combine with "OR"	diet* intervention* or program*	psychotic disorders (MESH heading)	randomised controlled trial (MESH heading)
	weight intervention* or program*	psychosis	controlled clinical trial (MESH heading)
	obesity intervention* or program*	Schizophrenia (MESH heading)	Random*
	nutrition intervention* or program*	schizophrenic psychology (MESH heading)	Placebo
	physical activity intervention* or program*	schizoaffective	Trial
	exercise intervention* or program*	serious or severe mental illness* or mental disorder* or mental disease*	Groups
	lifestyle intervention* or program*	mental disorders (MESH heading)	
	life style intervention* or program*	bipolar disorder (MESH heading)	
	health* promot* intervention* or program*		
	health* improve*intervention* or program*		
	health* liv* intervention* or program*		
	Exercise therapy (MESH heading)		
	Health Promotion (MESH heading)		
	nonpharmacological intervention* or program*		
	Health Education (MESH heading)		
	Patient Education as Topic (MESH heading)		
	community garden*intervention* or program*		
	Shopping intervention* or program*		
	recovery college*		

2.5 | Assessment of methodological quality

Studies selected for inclusion were assessed for methodological quality by three independent reviewers using the Cochrane Risk of Bias Tool.[27] Any disagreements between the reviewers were resolved through discussion.

2.6 | Appraisal against the CONSORT statement for randomised trials of nonpharmacologic treatments

The methods component of the CONSORT statement for randomised trials of nonpharmacologic treatments incorporates the domains of trial design, participants, interventions, outcomes, sample size, randomisation, blinding and statistical methods.[12] Studies were compared against the various domain items as a checklist, with response categories of yes, no or not applicable to the various items.

2.7 | Data synthesis

Methodological data in the included RCTs were compared to the CONSORT statement qualitatively. Results were then summarised in tables and charts.

3 | RESULTS

3.1 | Study overview

The search recovered 6585 papers of which 2200 were duplicates. Title and abstracts of 4385 papers were screened yielding 59 papers for full text review. Of these, 30 were included and 29 excluded. Studies were excluded from this study if participants, interventions, outcomes or study design did not meet the inclusion criteria. Two additional studies were identified in references of included studies, resulting in a total of 32 included papers. (See Figure 1 for PRISMA flow diagram).

3.2 | Evaluation of studies against the methods component of CONSORT statement for randomised trial nonpharmacologic treatments

Evaluations against the CONSORT statement generally yielded dichotomous outcomes (see Table 2 and Figure 2). Studies fulfilling the relevant criteria exemplified comprehensive recording of information, whereas those not fulfilling these criteria either provided incomplete or irrelevant information.

Many studies (77%) did not adhere to the principles for describing trial design, allocation ratio and procedures for allocating care providers. Most (87%) failed to account for any changes to methods after trial commencement and possible reasons for doing so. Only half of the studies (57%) met criteria for clearly stating the eligibility criteria for both participants and care providers. Settings and locations where data were collected were only comprehensively described in about half of the studies (53%).

Less than one-fifth of studies (17%) provided precise intervention details, sufficient for replication. All studies, however, indicated whether and how the intervention was standardised. Only 37% stated whether and how adherence of care providers to protocol was assessed or enhanced. Details on adherence or enhancement of participants to the protocol were, however, comprehensive in almost two-thirds of studies (63%).

Complete information for primary and secondary outcomes was provided in less than half of studies (47%). Few studies (13%) specified whether there had been changes to methods after trial commencement and reasons for doing so. Only 10% of studies provided details on how the sample size was generated, with consideration of clustering effects due to different care providers or centres. Half the studies (50%) did not convey the methods used to generate random allocation sequence. Only one-third of studies (37%) described the type of randomisation used. Techniques used to implement random allocation sequence and accounts of concealment procedures were only specified in 53% of studies. Only 17% of studies described the personnel involved in generation of allocation sequence, participant enrolment and assignment to treatment groups.

A minority of studies (20%) reported comprehensively on blinding, in contrast to a majority (80%) that gave information on the similarity of the treatments provided. Just 13% of studies demonstrated attempts to decrease bias where complete blinding was not possible. Most studies (80%) failed to provide complete details on statistical methods used, including whether and how clustering of care providers or centres were handled. Finally, additional analyses used (including subgroup and adjusted analysis) were described in 57% of studies.

3.3 | Risk of bias

Assessments of bias using the Cochrane Risk of Bias Tool yielded three mutually exclusive responses (low risk of bias, inadequate bias control/high risk of bias or information being unclear; see Table 3 and Figure 3). Half (50%) were unclear on the allocation sequence used, compared to 47% showing adequate sequence generation for low risk of bias, while 3% did not adequately generate sequences. Half the studies (53%) were unclear on allocation concealment while 43% ensured allocation was adequately concealed, indicating low risk of bias. One study (3%) was not adequately concealed. Half the studies (50%) did not provide clear methods for blinding. The other 47% reported adequate blinding while one study (3%) did not apply adequate blinding, suggesting a high risk of bias. Most studies (43%) were unclear on reasons behind incomplete outcome data, 30% adequately addressed these issues (reducing risk of bias) and 27% did not. Half the studies (53%) appeared free of selective outcome reporting, showing a low risk of bias, 33% were unclear and 13% displayed selective outcome reporting. Finally, 67% of studies reflected low risk of other forms of bias, whilst 33% were at high risk (See Table 3 and Figure 3).

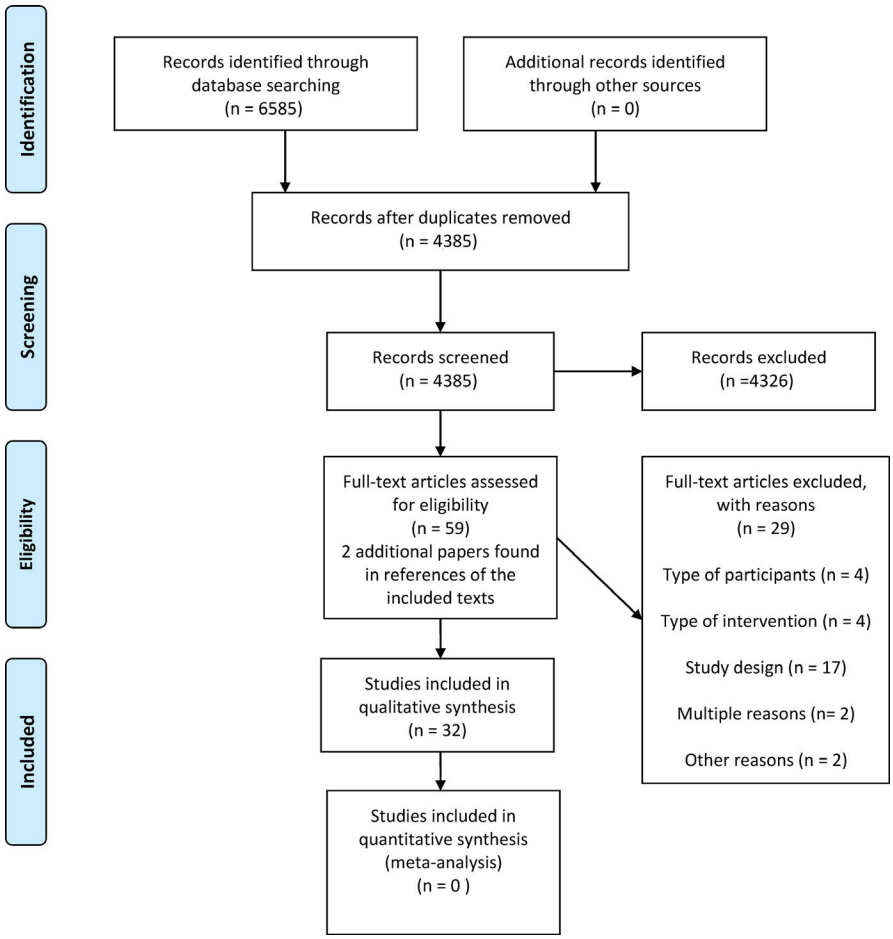

FIGURE 1 PRISMA 2009 flow diagram of studies included in the review

4 | DISCUSSION

This study critically appraised the lifestyle intervention studies that target weight outcomes among people with psychosis, for adequate reporting against the methods component of the CONSORT statement for randomised trials of nonpharmacologic treatments.[2,12] Reporting was generally poor with fewer than 50% of studies providing the recommended information on trial design, participants, interventions, outcomes, sample size, randomisation, blinding and statistical methods.[12,28–58] This limits the utility of lifestyle intervention research for people with psychosis.[1,2,7] Although the present study only focused on lifestyle interventions in people with psychosis, reviewers of similar interventions in the general population also acknowledge the prevalence of reporting omissions especially pertaining to randomisation, outcomes, intervention content, blinding and adverse events.[59–61] Barte et al[62] noted that inadequate information on interventions limited development of best-practice guidelines for weight gain prevention in the general population. Additionally, Ma et al[60] in their systematic review of 54 weight loss RCTs in the general population encouraged adherence to reporting guidelines to combat these shortcomings. This highlights the various complexities associated with describing, standardising and consistently administering behavioural intervention content, which warrants close monitoring by all stakeholders involved in the presentation of results.[12]

The most concerning of our findings were the incomplete descriptions of treatments applied. There was a large variety of treatments applied in lifestyle interventions, including education, tailored advice, goal setting, food and activity records, supervised exercise, motivational interviewing, cognitive behaviour therapy and psychoeducation.[12,28–58] Where multiple intervention components were applied, processes for ensuring efficacy of each element were not given.[12,28–58] Further, details on tailoring of treatments for different participants, treatment standardisation across the interventions and adherence protocols for care providers and participants to ascertain weight loss were not always given.[1,2,7,12,18] Consequently, assumptions cannot be made regarding how these treatments were applied where this was not explicitly stated. This hinders research appraisal and replication.[1,2,7,12,13,18,49,63] Incomplete or unusable reports of lifestyle interventions have prevented effectiveness testing, guideline development and evidence translation.[1,2,7,63–65]

Eligibility criteria for care providers were often not given in reviewed studies. It is essential that eligibility criteria of participants and care providers, data collection settings, and intervention locations are indicated in nonpharmacologic interventions due to their distinct roles.[12] Differences in care provider skills and volume of care

TABLE 2 Appraisal of reporting in lifestyle intervention studies among people with psychosis using the methods component of CONSORT statement for randomised trial nonpharmacologic treatments

Studies/Author information	Items from the methods component of the CONSORT statement for randomised trial nonpharmacologic treatments																				
	3a	3b	4a	4b	5a	5b	5c	5d	6a	6b	7a	7b	8a	8b	9	10	11a	11b	11c	12a	12b
Milano et al (2007)[28]	N	N	N	N	N	Y	N	N	N	N	N	N/A	N	N	N	N	N	Y	N	N	N/A
Khazaal et al (2007)[31]	N	N	Y	N	N	Y	N	N	Y	N	N	N/A	N	N	N	N	N	Y	N	N	Y
Ratliff et al (2015)[34]	N	N	N	Y	N	Y	N	Y	Y	N	N	N/A	Y	N	Y	N	N	Y	Y	N	Y
Greil et al (2010)[37]	N	N	N	N	N	Y	N	Y	N	N	N	N/A	N	N	N	N	N	N	N	N	Y
McKibbin et al (2006) and McKibbin et al (2010)[40,55]	N	N	N	Y	N	Y	N	Y	Y	N	N	N/A	Y	Y	Y	N	N	Y	N	N	Y
Goldberg et al (2013)[41]	N	N	Y	Y	N	Y	Y	N	N	N	N	N/A	N	Y	N	N	N	Y	N	N	Y
Forsberg et al (2008)[44]	Y	Y	Y	Y	N	Y	N	Y	N	Y	N	N/A	Y	N	Y	N	N	Y	N	N	N/A
Attux et al (2013)[79]	N	N	Y	N	N	Y	Y	Y	Y	N	N	N/A	Y	N	Y	N	N	Y	N	N	N/A
Brar et al (2005)[38]	N	N	Y	N	N	Y	N	N	N	N	N	N/A	N	N	N	N	N	Y	N	N	Y
Weber and Wyne (2006)[33]	N	N	N	N	N	Y	Y	N	Y	N	N	N/A	Y	N	Y	N	N	Y	N	N	N/A
Erickson et al (2016)[29]	Y	N	N	Y	Y	Y	N	Y	N	N	N	N/A	Y	N	Y	Y	N	Y	N	N	N/A
Daumit et al (2013)[32]	N	Y	N	Y	Y	Y	Y	Y	Y	Y	N	N/A	N	Y	N	N	N	Y	N	Y	Y
Speyer et al (2013)[30]	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	N	N/A	Y	Y	Y	Y	Y	Y	N	N	Y
Frank et al (2015)[54]	N	N	Y	Y	N	Y	Y	N	Y	N	N	N/A	N	N	N	N	N	Y	N	N	Y
Mauri et al (2008)[45]	N	N	N	N	N	Y	N	N	Y	N	N	N/A	N	N	N	N	N	Y	N	Y	Y
Kwon et al (2006)[51]	Y	N	Y	N	N	Y	N	Y	N	N	N	N/A	N	N	N	N	N	N	N	N	Y
Green et al (2015)[49]	N	N	N	Y	Y	Y	N	N	Y	N	N	N/A	Y	Y	Y	Y	N	N	Y	N	Y
Erickson et al (2017)[56]	Y	N	Y	Y	N	Y	Y	Y	N	N	N	N/A	Y	Y	Y	N	N	Y	N	N	N/A
Scocco et al (2006)[50]	N	N	Y	Y	N	Y	N	Y	Y	N	N	N/A	Y	N	Y	N	N	N	N	N	N/A
Jean-Baptiste et al (2007)[53]	N	N	Y	Y	N	Y	N	Y	N	N	N	N/A	N	N	N	N	N	Y	N	N	N/A
Evans et al (2005)[42]	N	N	Y	Y	N	Y	N	N	N	N	N	N/A	N	N	N	N	N	Y	N	N	N/A
Masa-Font et al (2015)[80]	N	Y	N	Y	N	Y	Y	Y	N	Y	N	N/A	N	N	N	N	N	Y	N	N	N/A
Verhaeghe et al (2013)[39]	Y	N	Y	Y	N	Y	Y	Y	Y	N	Y	N/A	Y	Y	Y	N	N	Y	N	Y	Y
Methapatara and Srisurapanont (2011)[43]	N	N	N	Y	N	Y	N	N	Y	N	N	N/A	Y	Y	Y	N	Y	Y	N	Y	Y
Usher et al (2013)[46]	N	N	Y	N	N	Y	N	N	N	N	N	N/A	Y	N	Y	Y	Y	Y	Y	Y	N/A
Skrinar et al (2005)[47]	N	N	N	N	N	Y	N	Y	N	N	N	N/A	N	N	N	N	N	N	N	N	N/A

(Continues)

TABLE 2 (Continued)

Studies/Author information	Items from the methods component of the CONSORT statement for randomised trial nonpharmacologic treatments																				
	3a	3b	4a	4b	5a	5b	5c	5d	6a	6b	7a	7b	8a	8b	9	10	11a	11b	11c	12a	12b
Scheewe et al (2013)[35]	N	N	Y	N	N	Y	N	Y	N	N	N	N/A	Y	Y	Y	N	Y	Y	Y	N	Y
Battaglia et al (2013)[48]	N	N	N	N	Y	Y	N	Y	Y	N	N	N/A	Y	N	Y	N	Y	Y	Y	N	N/A
Gaughran et al (2017)[57]	Y	N	Y	N	N	Y	Y	Y	N	N	Y	N/A	N	Y	N	N	N	N	N	N	Y
Kilbourne et al (2017)[58]	N	N	Y	Y	N	Y	Y	Y	N	N	Y	N/A	N	Y	Y	Y	Y	Y	N	Y	Y
Total Y	7 (23%)	4 (13%)	17 (57%)	16 (53%)	5 (17%)	30 (100%)	11 (37%)	19 (63%)	14 (47%)	4 (13%)	3 (10%)	–	15 (50%)	11 (37%)	16 (53%)	5 (17%)	6 (20%)	24 (80%)	4 (13%)	6 (20%)	17 (57%)
Total N	23 (77%)	26 (87N%)	13 (43%)	14 (47%)	25 (83%)	–	19 (63%)	11 (37%)	16 (53%)	26 (87%)	27 (90%)	–	15 (50%)	19 (63%)	14 (47%)	25 (83%)	24 (80%)	6 (20%)	26 (87%)	24 (80%)	–
Total N/A	–	–	–	–	–	–	–	–	–	–	–	30 (100%)	–	–	–	–	–	–	–	–	13 (43%)

Note: Y = Yes, N = No, N/A = Not Applicable; 2017 CONSORT checklist of information to include when reporting a randomised trial assessing nonpharmacologic treatments (NPTs)* in the Methods *(Items 3a-12b)*; *3a*—Description of trial design (such as parallel, factorial), including allocation ratio, when applicable, how care providers were allocated to each trial group; *3b*—Important changes to methods after trial commencement (such as eligibility criteria), with reasons; *4a*—Eligibility criteria for participants, when applicable, eligibility criteria for centres and for care providers; *4b*—Settings and locations where the data were collected; *5a*—Description of the different components of the interventions and, when applicable, description of the procedure for tailoring the interventions to individual participants (with sufficient details to allow replication); *5b*—Details of whether and how the interventions were standardised (with sufficient details to allow replication); *5c*—Details of whether and how adherence of care providers to the protocol was assessed or enhanced (with sufficient details to allow replication); *5d*—Details of whether and how adherence of participants to interventions was assessed or enhanced (with sufficient details to allow replication); *6a*—Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed; *6b*—Any changes to trial outcomes after the trial commenced, with reasons; *7a*—How sample size was determined, when applicable, details of whether and how the clustering by care providers or centres was addressed; *7b*—When applicable, explanation of any interim analyses and stopping guidelines; *8a*—Method used to generate the random allocation sequence; *8b*—Type of randomisation, details of any restriction (such as blocking and block size); *9*—Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned; *10*—Who generated the random allocation sequence, who enrolled participants and who assigned participants to interventions; *11a*—If done, who was blinded after assignment to interventions (eg, participants, care providers, those administering co-interventions, those assessing outcomes) and how; *11b*—If relevant, description of the similarity of interventions; *11c*—If blinding was not possible, description of any attempts to limit bias; *12a*—Statistical methods used to compare groups for primary and secondary outcomes, when applicable, details of whether and how the clustering by care providers or centres was addressed; *12b*—Methods for additional analyses, such as subgroup analyses and adjusted analyses.

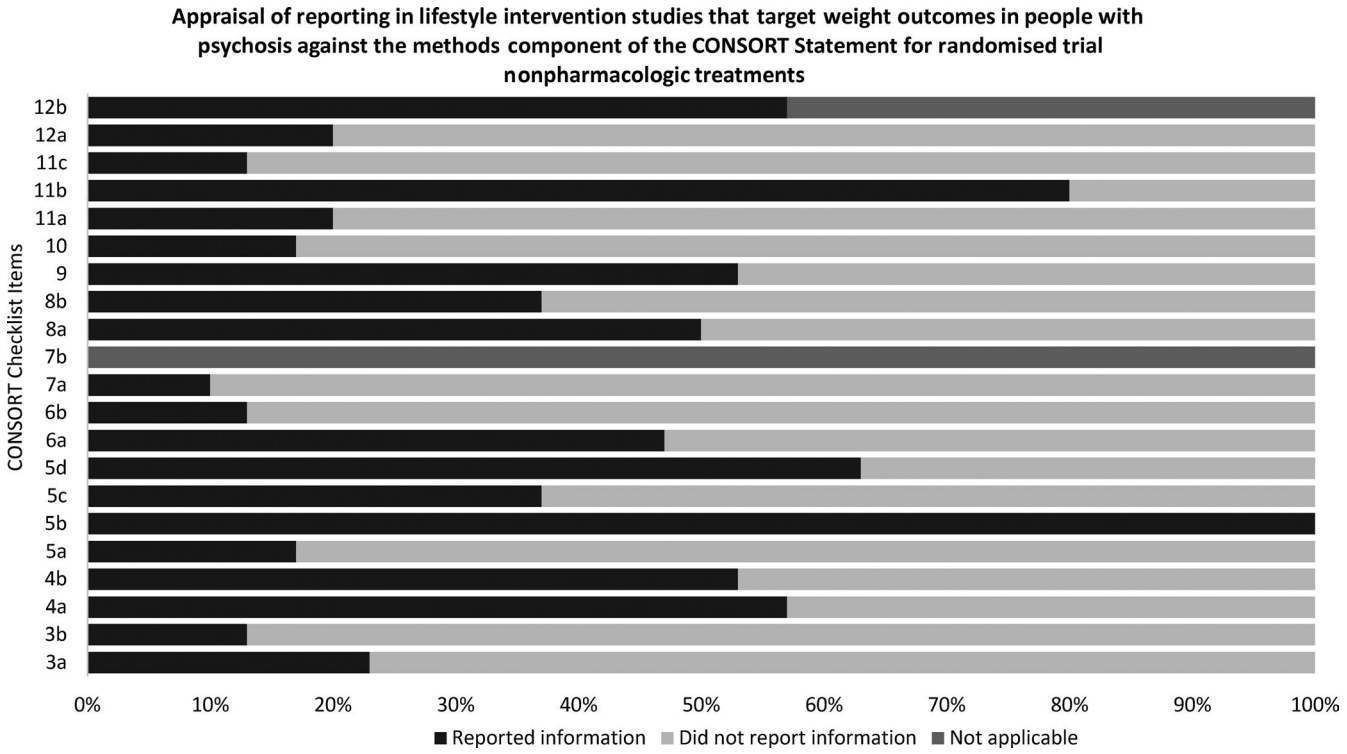

FIGURE 2 A horizontal bar chart showing an appraisal of reporting in lifestyle intervention studies among people with psychosis using the methods component of CONSORT statement for randomised trial nonpharmacologic treatments

providers in treatment centres may modify treatment success and adherence.[12,17,66] Alteration or omission of these details may seriously inhibit treatment safety and future effectiveness during replication of interventions.[32] Safety is particularly compromised when specific training is necessary, such as in the delivery of lifestyle interventions for people with psychosis.[32]

Since treatment effects in nonpharmacologic interventions are largely influenced by skill, training and motivation of care providers, independence of outcomes for participants receiving an intervention from the same care provider should not be assumed.[16,67] Adjustments to the sample size and statistical analyses need to control for this effect.[12,16,68,69] Where this effect is not controlled as seen in many studies in this review, results on treatment effects are difficult to generalise to other settings.[12,16,68,69]

Outcomes were generally specified in most lifestyle interventions, but details on potential changes to trial outcomes and procedures for outcome measurement were limited. Unreported changes to trial outcomes have been detected up to 60% of the time in other research fields, which in turn affects validity of results.[16] Validity of results is also affected by the outcome measurement procedure.[12,16] Weight, an outcome of interest in this review, is prone to measurement error.[28–58,70] Suitability of procedures used to measure this outcome was, however, difficult to evaluate because corresponding information was largely unspecified.[28–58,70] Poor reporting on trial outcomes may negate the usefulness of the other research sections because it becomes unclear whether results are a direct effect of the research methods and interventions.[12,16]

Accurate descriptions of trial design enable study replication, evaluation of sample size suitability and interpretation of results.[16] Although only RCTs were included, further information on the type of trial (such as parallel, crossover), study allocation ratio and care provider allocation procedure was lacking. The main types of trials referenced among lifestyle interventions were parallel and cluster trials.[30,32,39,44] Despite incomplete justification as why certain types of trials were selected rather than others, study setting emerged as an influencing factor.[30,32,39,44] This was seen in the case of cluster RCTs which were applied where participants resided in group homes.[39] Provision of an intervention or control condition to all group home residents minimised risk of contamination.[39] Further to this, application of other trial designs such as crossover trials may benefit prospective lifestyle intervention research; this is because participants would act as their own controls, between participants variation would be eliminated and fewer participants are required.[71] Inclusion of all information pertaining to the type of trial, study allocation ratio and care provider allocation allows appropriation and improvement to previous trial designs, especially in cases of more complex interventions that compare multiple behavioural treatments.[12,34]

Blinding was often not described in lifestyle interventions which may have been a result of treatment concealment difficulties and oversight by authors.[72] Admittedly, blinding is difficult to achieve during the administration of any type of nonpharmacologic intervention due to the significant involvement of care providers.[73] However, it is important that authors indicate whether blinding was applied or not, to whom blinding was applied

TABLE 3 Risk of bias assessment for lifestyle intervention studies among people with psychosis using the Cochrane risk of bias tool

	Cochrane risk of bias items					
Studies/Author information	Q1	Q2	Q3	Q4	Q5	Q6
Milano et al (2007)[28]	U	U	U	Y	U	N
Khazaal et al (2007)[31]	Y	Y	U	N	N	Y
Ratliff et al (2015)[34]	U	U	Y	Y	Y	Y
Greil et al (2010)[37]	Y	Y	Y	Y	U	N
McKibbin et al (2006) and McKibbin et al (2010)[40,55]	U	U	U	U	U	Y
Goldberg et al (2013)[41]	U	U	Y	Y	N	Y
Forsberg et al (2008)[44]	Y	Y	U	U	N	Y
Attux et al (2013)[79]	Y	Y	Y	N	Y	Y
Brar et al (2005)[38]	Y	Y	Y	N	Y	Y
Weber and Wyne (2006)[33]	U	U	U	U	Y	Y
Erickson et al (2016)[29]	N	N	U	U	Y	Y
Daumit et al (2013)[32]	Y	Y	Y	U	Y	Y
Speyer et al (2013)[30]	U	U	U	U	U	Y
Frank et al (2015)[54]	Y	Y	U	U	U	Y
Mauri et al (2008)[45]	U	U	U	N	U	Y
Kwon et al (2006)[51]	Y	Y	N	Y	U	N
Green et al (2015)[49]	Y	Y	U	U	U	N
Erickson et al (2017)[56]	U	U	U	N	N	N
Scocco et al (2006)[50]	U	U	U	N	Y	N
Jean-Baptiste et al (2007)[53]	Y	Y	Y	U	Y	Y
Evans et al (2005)[42]	Y	Y	Y	U	Y	Y
Masa-Font et al (2015)[80]	U	U	U	N	Y	N
Verhaeghe et al (2013)[39]	U	U	U	N	Y	Y
Methapatara and Srisurapanont (2011)[43]	Y	Y	Y	Y	Y	Y
Usher et al (2013)[46]	U	U	U	U	U	N
Skrinar et al (2005)[47]	Y	Y	Y	U	Y	Y
Scheewe et al (2013)[35]	U	U	Y	Y	Y	Y
Battaglia et al (2013)[48]	Y	U	Y	Y	U	N
Gaughran et al (2017)[57]	U	U	Y	Y	Y	N
Kilbourne et al (2017)[58]	U	U	Y	U	Y	Y
Total Y	14 (47%)	13 (43%)	14 (47%)	9 (30%)	16 (53%)	20 (67%)
Total N	1 (3%)	1 (3%)	1 (3%)	8 (27%)	4 (13%)	10 (33%)
Total U	15 (50%)	16 (53%)	15 (50%)	13 (43%)	10 (33%)	–

Note: Y = Yes, N = No, U = Unclear; Cochrane Risk of Bias Tool Questions: Q1 = Was the allocation sequence adequately generated?; Q2 = Was allocation adequately concealed?; Q3 = Was knowledge of the allocated interventions adequately prevented during the study?; Q4 = Were incomplete outcome data adequately addressed?; Q5 = Are reports of the study free of suggestion of selective outcome reporting?; Q6 = Was the study apparently free of other problems that could put it at a risk of bias?

(participants, care providers, or outcome assessors) and provide valid explanations where appropriate.[73] Furthermore, bias minimisation strategies, including concealment of treatment assignments and study hypothesis, and using external personnel in intervention delivery, can be used in nonpharmacologic interventions; these are applicable to lifestyle interventions delivered to people with psychosis.[16,28–58,74]

Exaggerated treatment effects are common where randomisation procedures are unclear, indicating possible hidden bias in sequence generation, allocation concealment or the personnel involved.[12,75,76] Randomisation techniques were described in less than 50% of lifestyle interventions, inhibiting study validity evaluations because it was not clear how participants and care providers were allocated to treatment groups.[12] Internal validity evaluations determine the strength of study

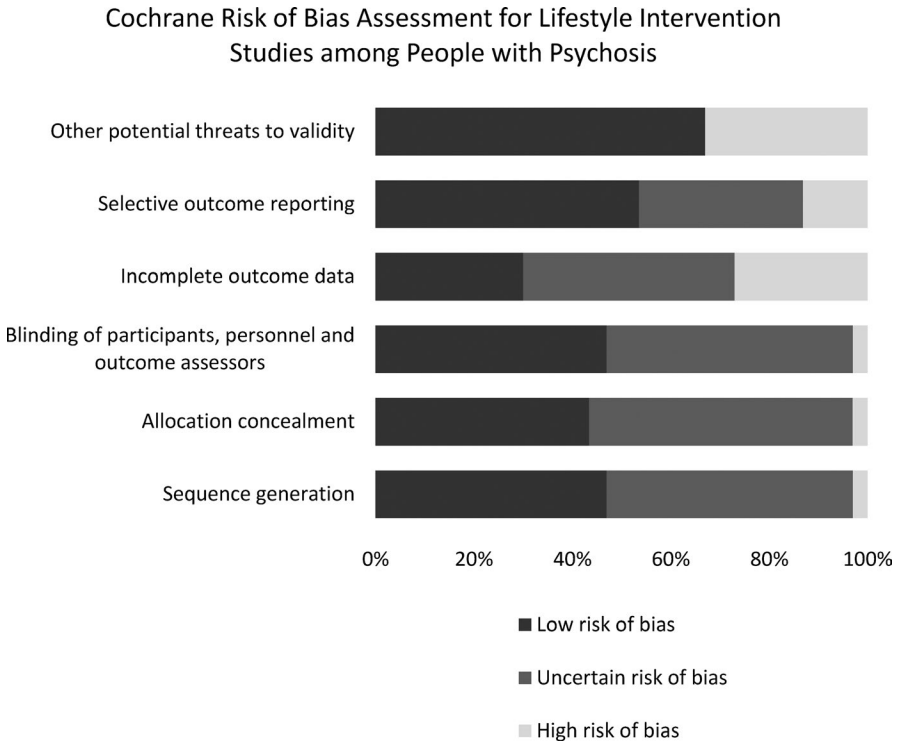

FIGURE 3 A horizontal bar chart showing results from the Cochrane risk of bias assessment for lifestyle intervention studies among people with psychosis

conclusions, while evaluations of external validity assessments reveal whether procedures are applicable to different settings.[77] Future lifestyle interventions for people with psychosis should provide details on randomisation and employ separate personnel for this process to enhance the validity of all subsequent phases of research.[16,76]

Many lifestyle interventions showed an uncertain risk of bias based on the Cochrane Risk of Bias Tool because corresponding information was often lacking.[28–58] This decreases confidence in study results and affects the strength of research conclusions.[1–3,7,63,78] Poor research communication, rather than inferiority in research, is the likely cause of evidence gaps in lifestyle interventions for people with psychosis.[1–3,7,63]

The main limitation from this review was that discrepancies could exist between what authors reported in lifestyle interventions, and how this was interpreted in the current review, further supporting employment of the CONSORT statement or similar guidelines for consistent reporting.[12] Errors of this kind are nonetheless unlikely to alter main findings which show that a large breadth of information was absent from research papers.[12] Adoption of the CONSORT statement or similar guidelines when reporting on lifestyle interventions for people with psychosis is likely to improve the quality of published reports, which will allow comprehensive appraisal of research, enabling the creation of strong guidelines and better-informed translation of best-practice research.[1–3,7,12,63]

5 | CONCLUSIONS

Lifestyle intervention studies targeting weight outcomes among people with psychosis are poorly reported.[1–3,7] These interventions utilise varied intervention components (education, tailored advice, goal setting, food and activity records, supervised exercise, motivational interviewing, cognitive behaviour therapy and psychoeducation) have specialised eligibility criteria for intervention providers and implementation settings, and are faced with unique challenges during blinding; specific information on these components, plus accounts of how participant, care provider and setting bias were controlled is necessary for comprehensive reporting.[12,28–58] Inadequate reporting has affected the quality of evidence in the field, hampering the creation of guidelines, leading to evidence gaps which limit research translation.[1–3,7] Consequently, those who experience psychosis might not benefit from current research in the field.[1–3,7] We recommend using the CONSORT statement for randomised trials of nonpharmacologic treatments or similar guidelines when designing and reporting lifestyle interventions for people with psychosis.[1–3,7] This could improve the quality of evidence in the field and enhance study replication which may lead to improved physical health outcomes in people with psychosis.[1–3,7]

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

ORCID

Doreen Mucheru https://orcid.org/0000-0001-7305-1245

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Chapter 6: Factors to Consider During the Implementation of Nutrition and Physical Activity Trials for People with Psychosis into an Australian Community Setting

6.1 Study Overview

This chapter describes a study that was inspired by the absence of information on effective translation of evidence-based lifestyle interventions trials for Australians with psychosis into the community setting (214, 222-224). Synthesis of evidence on efficacious lifestyle interventions strategies for people with psychosis is useful for guiding practice, and is crucial for knowledge translation (227). However, the evidence-base on lifestyle intervention strategies for people with psychosis is not yet comprehensive enough to guide practice (233). This is due to limitations associated with inadequate reporting in primary studies, and the need for further research to confirm existing findings (233).

Moreover, existing lifestyle interventions were not adopted into local settings following completion of the research (190, 194, 214, 221). This has resulted in a scarcity of data on the processes, enablers and barriers for translation of lifestyle interventions into practice settings (190, 194, 214, 221). Consideration of issues that affect end users of existing lifestyle interventions during research, may reduce the time taken to achieve knowledge translation in practice settings (235). It typically takes 17 years to achieve application of research into practice contexts (235). This is due to inadequate alignment between the priorities of researchers and practitioners, thus research findings are difficult to embed into contexts where they would generally be applied (235). Generation of specific information on the factors that should be considered during implementation of lifestyle interventions for people with psychosis (in particular contexts) is crucial for completion of the knowledge translation process (227, 235).

The “Integrated Promoting Action on Research Implementation in Health Systems” (i-PARIHS) knowledge translation framework was identified as a suitable framework to guide research which centred on distinguishing factors that are likely to affect implementation of a lifestyle intervention in a local community managed organisation (CMO) (227, 228). Concepts from the framework were used to guide formulation of research aims and interview questions, and the identification of suitable participant groups (227). The study aimed to identify the factors that affect program access in a local CMO from the perspectives of both consumers and staff. The secondary aim was to describe the elements that impact on program delivery from the perspective of staff. It is important to note that a lifestyle intervention was not being run at the CMO at the time of the study, however other programs were already in place. This was an original study designed by the PhD candidate (Miss Doreen Mucheru) and supervisory team (Assoc. Prof Lesley MacDonald-Wicks, Dr Mary-Claire Hanlon and

Assoc. Prof Mark McEvoy). The CMO was enthusiastic about hosting the study, however, the identity of the organisation will remain concealed for ethical purposes.

Results from this study are under review at BMC Health Services Research. Mucheru D, Ashby S, Hanlon MC, McEvoy M, and MacDonald-Wicks L. *Factors to Consider during the Implementation of Nutrition and Physical Activity Trials for People with Psychosis into an Australian Community Setting.* BMC Health Services Research (under review). 2019.

Factors to Consider During the Implementation of Nutrition and Physical Activity Trials for People with Psychosis into an Australian Community Setting

Abstract

Background: Research in lifestyle interventions focusing on nutrition and physical activity in people living with psychosis, highlights anthropometric and metabolic benefits of these interventions. However, little is known about potential factors to consider during implementation into real-world contexts. Community-managed organisations (CMOs) that provide services for people with mental illness, offer an ideal implementation context for lifestyle interventions. Successful translation of lifestyle interventions into CMOs may be achieved though considering the factors associated with program access and delivery in these settings. This study primarily aimed to identify the factors that affect program access in a local CMO from the perspective of consumers and staff. The secondary aim was to describe the elements that impact on program delivery from the perspective of staff.

Methods: Thirteen semi-structured interviews were conducted with 6 consumers and 7 staff in a CMO in regional Australia. Topics explored in interviews were based on implementation concepts identified in the "Integrated Promoting Action on Research Implementation in Health Systems" (i-PARIHS) knowledge translation framework. Thematic data analysis was conducted using Nvivo software.

Results: Emergent themes on issues that influenced program access were (1) consumer financial status, domestic responsibilities, and health; (2) the design and delivery of programs; (3) structure and practices of the organisation; (4) attitude, skills and effort of staff involved in program delivery; and (5) social connections and stigma experienced by consumers during program access. Moreover, staff perceptions on elements that impacted program delivery highlighted themes on consumer attendance and interest in prospective programs, availability and restrictions to the use of funding, as well as the organisational structure and practices.

Conclusions: The factors affecting program access and delivery can generally be managed or planned for during the design of lifestyle interventions and subsequent translation into the CMO context. However, resolution of issues related to consumer financial status and health requires the collaboration of various government sectors for system-wide solutions.

Keywords: Lifestyle interventions, psychosis, mental health, knowledge translation, community managed organisations.

Background

Lifestyle interventions that focus on nutrition and physical activity in people with psychosis, show significant efficacy in the research setting [1]. Meta-analytic comparisons of randomised controlled trials (RCTs) for these interventions, display mean improvements in weight (-4.1kg; 95% CI -7.77, -2.76, p<0.000), body mass index ([BMI] -2.9 points; 95% CI -1.78, -0.36, p=0.003), waist circumference (-2.2cm; 95% CI -6.9, -0.46, p=0.025), total cholesterol (-20.98 mg/dL; 95% CI -33.78, -8.19, p=0.001), triglycerides (-61.68 mg/dL; 95% CI -92.77, -30.59, p=0.0001) and fasting blood glucose (-5.79 mg/dL; 95% CI-9.73, -1.86, p=0.004), when compared to control conditions [1, 2]. Despite established efficacy, evidence-based lifestyle interventions in Australians with psychosis are primarily conducted for research, then discontinued after the trial period [2-4]. Moreover, a systematic review on the possible incentives and barriers of participating in lifestyle interventions among people with severe mental illness did not identify any relevant publications [5]. Some lifestyle interventions with a focus on efficacy, however, noted that illness symptoms, medication effects, transport provision, financial challenges, staff attributes, intervention characteristics, stigma and inclusion of staff in interventions, affected research participation [5]. Successful implementation of lifestyle interventions for people with psychosis requires broader information on the factors that could influence external validity of research [3]. Furthermore, knowledge is limited to existing trials because longitudinal work is lacking [1-3].

Existing lifestyle intervention research not only focuses on quantifying impact but also identifying efficacious strategies [1-4]. A recent network meta-analysis shows that combined use of education, personalised goals or plans, and progress review in the dietary and physical activity intervention components lead to the greatest mean decreases in weight (−4.1kg) and BMI (−2.9 points) [1]. Nonetheless, evidence on implementation of these RCTs following research is unavailable [1-4]. Knowledge translation frameworks can guide implementation by identifying factors that require consideration when translating evidence into practice [6]. These frameworks recognise that successful implementation requires consideration of priorities at the proposed setting; the feelings, attitudes, motivation, goals, knowledge, skills and resources of those who influence or receive the proposed change; and the role of the internal and external context in the knowledge translation process [6]. Investigation of these considerations, as they relate to the implementation of lifestyle interventions for people with psychosis, could provide rich detail on features that promote external validity [3, 6].

Community managed organisations (CMOs) offer feasible knowledge translation contexts for lifestyle interventions because they provide community-based services for Australians experiencing

mental illness.[7] Community-based support gained prominence following deinstitutionalisation of Australian mental health care, shifting treatment from long-stay psychiatric hospitals to community contexts [8]. CMOs offer psychosocial support, along with other services that target prevention, rehabilitation and early intervention for mental illness [7, 9]. Psychosocial services promote community engagement though employment, health promotion, social interaction and housing [7, 9].

CMOs, formerly known as non-government organisations were primarily funded by the Commonwealth or State Governments, with supplementary contributions made by philanthropic trusts and foundations [10, 11]. In 2013, the funding of disability support services (including psychiatric disability) commenced a transition to the National Disability Insurance Scheme (NDIS), which provides individualised plans and funding through the National Disability Insurance Agency (NDIA) [12, 13]. The shift presents various concerns for consumers with psychiatric disability including underestimation of persons eligible; flexibility of the scheme to support fluctuating needs of consumers; and boundaries of services accessed via the NDIS versus the rest of the health system [12]. Despite this, NDIS consumers now purchase services directly from CMOs, which gives them control over the funding [12, 13].

Identifying the various factors that affect program access and delivery in the CMO setting, allows for consideration of these issues during translation of evidence-based lifestyle interventions [6]. The aim of this study was to identify the factors that affect program access in a local CMO from the perspectives of both consumers and staff. Secondary to this, was to describe the elements that impact on program delivery from the perspective of staff.

Methods

Study Design

The “Integrated Promoting Action on Research Implementation in Health Systems” (i-PARIHS) knowledge translation framework aided the identification of suitable participant groups, and the construction of interview questions that were pertinent to evidence-based translation of programs [6]. The i-PARiHS framework highlights the importance of identifying local circumstances and priorities during evidence-based knowledge translation [6]. Additionally, the feelings, attitudes, motivation, goals, knowledge, skills and resources of those who influence or are affected by the implementation, ought to be sought [6]. Finally, contextual information on the local and external implementation setting supports evidence-based knowledge translation [6]. These implementation concepts were also used in the development of study aims [6].

Topics explored in consumer interviews focused on the programs already accessed at the CMO, and enablers and barriers that affected their attendance. In contrast, interviews for staff involved in program delivery assessed how the programs were developed, factors that affected consumer attendance of programs, and considerations prior to the introduction of new programs. Moreover, interviews for staff that oversaw program delivery delved into how existing programs were initially developed, selected, evaluated, and introduced into the setting. These topics endeavoured to provide an appreciation of the circumstances at the CMO, considerations that influenced program access, and contextual factors likely to impact on program delivery.

Setting and Participant Recruitment

This study was conducted at a CMO that provides programs and services to people with mental illness, in a regional city in New South Wales, Australia. Approximately 25 consumers were accessing programs at the organisation in 2019.

Initial permission to conduct the study was obtained by M-CH from the CMO manager. DM then sought written and informed consent to recruit from the CMO. DM volunteered at the CMO to gain familiarity with the context, form rapport with staff and consumers, and determine suitable recruitment methods. Staff and consumers at the CMO were aware of the intent to carry out research in the setting. Inclusion criteria for staff were, direct involvement with delivery of consumer programs, or overseeing delivery of consumer programs. Staff were verbally invited into the study by DM. Staff who expressed interest were provided with a study information statement.

Consumers who were interested in the study were referred by staff. Referrals were made if participants were 18 years and over, had access to CMO programs, and could consent to and participate in interviews with minimal risk of distress. Staff requested eligible and willing consumers to fill out a consent form, approving phone or email contact from DM for further study information. Those expressing interest were provided with a study information statement.

Data Collection and Consent

Interviews were completed following written and informed consent, when convenient to participants, and conducted on CMO premises. One-on-one, semi-structured interviews were conducted, with none of the interviews repeated. All interviews were audio-recorded, and the interview durations ranged between 15 and 40 minutes. As part of the member-checking process, participants were provided the option of reviewing interview transcripts.

Six consumer interviews were completed, with all those referred agreeing to participate. Staff interviews for those involved in program delivery yielded five participants, which excluded two staff

who did not show an interest in participating. Two CMO managers were interviewed, based on their oversight of program delivery. A transition in CMO leadership during the research period allowed for two interviews instead of one.

Analysis

Interviews were transcribed verbatim. Transcripts were assessed for accuracy by DM via comparison with audio data. Thematic data analysis as prescribed by J Saldaña [14] was completed by DM using NVivo12—a computer assisted data analysis package. Data were coded and similar codes clustered into themes and subthemes. Support for this process was provided by SA.

Results

Sample Characteristics

Thirteen participants took part in the present study: six were consumers experiencing a mental illness and seven were staff at the CMO. Of the seven staff, five were support workers and two were managers.

1. Staff and consumer perceptions of the factors that affect program access

Perceptions of the factors that affect program access yielded five themes, which are discussed in subsequent sections.

1.1 Consumer financial status, domestic responsibilities and health

This theme describes the various aspects of consumers' personal lives that impacted program access.

An issue raised by both groups was the impact of consumers' health status on program attendance. Poor health was a consequence of physical or mental illness, and was often a deciding factor for program attendance. Staff 4 stated:

> *"The thing is, often they might get sick. Or they don't come in one week, and then that just sets ... They won't come in the next week, and then the next week. Or some of the clients have had to go to hospital, cause they'll have a lapse* [*sic*]*."*

In addition, consumers and staff participants recognised that medication side effects contributed to fatigue, which limited the capacity to attend programs. Consumer 4 summarised this:

"Because I take medication at night, in the morning I'm pretty groggy and it's hard to wake up, and hard to get going. That's probably what it is, mainly."

Commencement and continuation with programs was limited by lack of NDIS financial support and by additional program costs that were non-reimbursable under the NDIS, as reported by consumers and staff. Additionally, consumers were often on a budget as illustrated by Consumer 1:

> *"I'm paying a lot of things, I'm only on the pension so I only have a couple of days of work a week so, it all adds up."*

Consumers, but not staff, reported that domestic responsibilities and chores were an important overall determinant of attendance. Consumer 5 expressed how family responsibilities affected her capacity to attend programs:

> *"And apart from the children's problems, my husband has a terminal illness. So, if he is not well, or if he needs to go to the hospital, or stuff like that, that will stop me from attending groups as well."*

One staff participant added that consumer motivation could positively, or negatively, affect program attendance. Staff 4 described this in the statement:

> *"But the ones that have come, they've wanted to come. But they haven't had the transport, and no* [*sic*] *support worker."*

However, consumer and staff reports indicated that consumer motivation could be altered through positive encouragement from staff. Staff 5 described this by stating:

> *"So sometimes, it's really pushing them out of their comfort zone. But I say, I always encourage. I say, 'It's just a little step. It's a little step. Think about the future. It's another step."*

1.2 Program design and delivery

This theme related to the different aspects of programs that affected attendance.

Consumers and staff agreed that activities offered in programs influenced whether consumers enjoyed the programs, which affected continued program attendance. Consumer 2's response to why she continued to attend one of the available programs was:

> *"I like doing things with the people in the group and* [states name] *makes up interesting things for us to do each month, so that's really good."*

Inconvenient program location was cited as a potential barrier to attending existing programs by consumers and staff. Convenience was based on proximity of program activities to consumer

residence (as programs were not always within CMO premises), or difficulties associated with accessing program meeting spaces within the CMO. Staff 4 highlighted this in the comment:

> *"Some people find it daunting coming in here, because it's up the stairs. It's a physical barrier to the space itself."*

Providing consumers with transport to the venue was described by consumers and staff as a way of facilitating program attendance because consumers experienced transport difficulties associated with the inability to drive, or catch public transport. Staff 2 reported:

> *"All of our clients don't travel [*sic*], so travel training and being able to pick them up and things, so unless they can get into centre, a lot of them can't get here and a lot of them just won't take public transport."*

Consumers and staff stated that the timing of programs affected the consumer's capacity to attend. This was primarily due to medication side effects (which included feelings of lethargy early in the morning). Staff 7 summarised this by stating:

> *"We talked to the guys, they don't like groups early morning. They all struggle to get up and get motivated, and out the door, and that's a lot around their* [*sic*] *medication that they take."*

One staff participant mentioned that seasonal timing of programs affected attendance because interruption of programs by holidays resulted in consumers failing to return. This is how Staff 4 explained her experience regarding consumers' initial response to a program:

> *"Initially very good. We had about six people, which I think is quite big for here. They thought it was really good. Just …….. I think there was a holiday that happened."*

Staff added the importance of considering individual consumer needs when planning program sessions, and involving consumers in planning and executing programs. This provided a sense of ownership, and contributed to enjoyment, participation in program activities, and attendance. Staff 6 expressed this in a response on consumer incentives for attending existing programs:

> *"If they feel that their voices is* [*sic*] *being heard and if they feel that they're going to get something out of it—everybody would be different……. You know, so it's gonna* [*sic*] *be different for everyone who comes and I think what you gotta* [*sic*] *do, you've got to be flexible to be able to cater for everybody's needs."*

Finally, two staff participants noted the importance of ensuring consumers had the right perceptions about what programs entailed, to prevent anxiety pertaining to the unknown which could influence

their attendance. When asked why consumers cancelled participation in certain programs, Staff 5 said:

> *"Some of it is to do with their perception of what it's going to be."*

1.3 Organisational structure and practices

This theme comprised determinants of program access that relate to the CMO and how it was run.

One consumer reported that a lack of equipment for those with mobility disabilities hindered program attendance; however, this was later rectified. Consumer 2 reported this by saying:

> *"I couldn't come for such a long time to things because they're all up here and they didn't have a chair lift …….. And there are other people who are older, who won't use the stairs either because they're very steep."*

Staff indicated that dissemination of program information to CMO consumers was poor as it was not always clear whose responsibility it was, or how it was to be done. When asked whose responsibility it was to distribute fliers with information on consumer programs, Staff 2 stated:

> *"That's the problem. Not every support worker comes into the office and not every support worker would print them at home and hand them to their "clients".*

1.4 Staff attitude, skills and effort

This theme described the effect of staff involved with program delivery on attendance.

Consumers and staff admitted that the attitude and professional skills of staff affected rapport with consumers, which was a motivator for continuing with programs. Important staff characteristics included friendliness, empathy, showing interest in the lives of consumers, providing step-by-step guidance, and well-planned program sessions. Consumer 5 described the effect staff can have in her decision to attend programs by explaining:

> *"Depending on the support worker that I have, cause, I get along with some better than others. Some of them, if they came to my house and talked to me for a while, they can probably twist my arm to come."*

In addition, follow-up provision was regarded as essential by consumers and staff. Follow-up included checking why consumers could not attend program sessions, or providing attendance reminders. Consumer 4 commented:

"I think I get enough support. Like [states name] *rings me and says, each second Wednesday morning, 'Am I coming?'"*

1.5 Social connections and stigma

The effect of social factors on program access was presented in this theme.

Attaining strong social connections with those attending programs motivated program attendance as per consumer and staff reports; one manager recognized that staff could facilitate and foster a social environment during program delivery. Consumer 6 described his objective for attending one of the available programs:

"I was very, very shy and very shell-shocked for the first 10 years of the group. It's only in the last couple of years that I've started to spread my wings, you might say. So, people will remember me as being particularly shy. But I get social connections out of it."

In contrast, stigma associated with mental illness was considered a possible deterrent of attendance by staff. They perceived that consumers had a fear of being recognised as having a mental illness or associating with those with mental illness. When asked why some consumers failed to attend programs, Staff 3 responded:

"Some don't want to identify with other people with mental health problems and we only have mental health clients."

Furthermore, one consumer expressed satisfaction with a service delivery name change that no longer reflected a focus on mental illness, due to the associated stigma. Consumer 2 stated:

"Every time somebody gets killed or something happens, it's always someone with schizophrenia. So, I was really glad when [states the service name] *changed its name."*

2. Staff perceptions on the elements that impact on program delivery

Three themes emerged from staff perceptions on elements that impacted on program delivery (introducing or running programs).

2.1 Consumer attendance and interest

This theme was on consumer-related factors that affected program delivery.

Staff indicated that adequate consumer attendance determined whether programs were introduced or continued running. When asked about possible deterrents to a new program, Staff 2 said;

"I think again, it's trying to get a way of engaging clients to come into the centre."

Additionally, staff reported that consumer attendance was the primary indicator of program success. This was because consumers did not typically express their feedback verbally due to various impairments.

Consumer interest in prospective programs also determined which programs were introduced in the setting because consumer feedback and ideas were sought prior to implementation. Staff 7 stated this in the interview:

> *"Ultimately I have all say about what groups would or wouldn't be delivered. But, at this point in time, because I'm reasonably new, we talk to our participants and ask them what they want."*

2.2 Availability and restrictions to the use of funding

The availability of funding or the stipulated uses of financial resources, was the second theme on program delivery.

One manager reported that the NDIS was the primary and only way consumer programs were funded, and thus program cost-effectiveness had to be ensured through a staff-to-consumer ratio that was financially justifiable. Staff 7 summarised this by saying:

> *"Because of the way NDIS funds, you've got to have a viable number of people in the group against your staffing ratios to make it financially viable."*

In addition, both managers acknowledged that lack of funding was a challenge because service availability was wholly dependent on funding allocated to individual NDIS plans. This funding was generally not allocated to specialised services, such as those offered by allied health, despite the possibility for this under the NDIS. Staff 6 expressed some of these challenges in her statement:

> *"If we had had a lot of money, like* [names another centre] *coming in every year, to be able to employ staff and not have to worry about having someone coming, a client coming to be able to pay that staff member, then we could have done a lot more."*

Finally, NDIS funding covered staff wages and organisational maintenance costs, but not program activity costs, which limited the programs that could be run without charging consumers additional fees for program activities. Staff 7 stated:

"It [funding] *covers the support workers and it covers the centre. So anything above that comes out of our bottom line. But NDIS, which is how our customers are funded, are very clear about [sic], they don't pay for food. They don't pay for activity costs themselves."*

306 *2.3 Organisational structure and practices*

307 The third theme on the issues that affect program delivery was on matters pertaining to the CMO
308 and how it was run.

309 Facility availability was highlighted as determinant of what programs could be delivered: two staff
310 participants mentioned the importance of having indoor gym equipment at the CMO, as this could
311 promote engagement with physical activity programs and activities. Staff 5 explained it this way:

312 "*There's no exercise machines here [*sic*]. It would be good if we had one in here. Someone*
313 *might get on a treadmill, you know. Yeah. And there's not a reason why. I suppose it depends*
314 *on budget.*"

315 Additionally, policies and procedures sometimes limited availability of some program activities at the
316 CMO. One manager noted that policies and procedures stipulated that onsite access to gym
317 equipment had to be supervised by specialised staff, who were otherwise unavailable at the CMO.
318 This restricted physical activity program activities. Staff 6 discussed the potential barriers to a new
319 nutrition and physical activity program by saying:

320 "*Policy and procedures play a big part, like we had the offer of donation of gym equipment,*
321 *but we got told from Sydney that if you have a gym equipment here* [*sic*] *you've got to have*
322 *someone qualified on site. So that went out the door*."

323 Staff input determined which programs were delivered. Support worker input was requested
324 regarding ideas for prospective programs; however, managers ultimately decided which programs
325 were delivered. Staff 7 explained the process of introducing new programs in the statement:

326 "*I will usually talk to a staff member and say, "Would you like to be a part of this?" Then we*
327 *work through the process of what that might look like, what resources they will need, and*
328 *then we talk through each week, "How did it go," until they're really confident to run the*
329 *group on their own*."

330 Finally, limitations in staff roles and training determined which programs were delivered. One
331 manager mentioned that support workers generally delivered programs, however, they were not
332 trained to provide specialised services. Staff 7 described it thus:

333 *"You could go to* [states name] *Park and there's all this equipment ……. but a general*
334 *support worker isn't trained to do that, so you actually need a specialist. But there's no*
335 *funding available for that to work. So that disconnect is quite significant, I think."*

336

Discussion

This study is the first to identify the factors which affect program access and attendance from consumers and staff in a regional CMO. Program access, or attendance was shaped by five themes: consumer financial status, domestic responsibilities and health; program design and delivery; organisational structure and practices; staff attitude, skills and effort; and social connections and stigma experienced by consumers. Furthermore, staff accounts on the elements that impacted program delivery highlighted consumer attendance and interest, availability and restrictions to the use of funding, and organisational structure and practices. An important step to improving the translation of evidence-based lifestyle interventions for people with psychosis into CMOs, is the consideration of factors that affect program access and delivery during the process of intervention design and implementation [1, 5, 6, 15]. This greater understanding can enhance efficiency of knowledge translation and promote success of lifestyle interventions [6, 15].

Consumer program access was affected by poor health status, negative medication side-effects, NDIS financial support, domestic responsibilities and motivation levels. Despite lack of comparable research from other CMOs, these challenges commonly occur in people with psychosis and other severe mental illness [16]. Previous research identified that illness symptoms can be a barrier to participating in short-term lifestyle intervention research for those with severe mental illness, with antipsychotic treatment further limiting engagement due to side effects [5, 17]. Loss of motivation is a persistent health problem in those with psychosis and other severe mental illness that can also be a program access barrier [5, 16]. The overall impact of these health issues can negatively affect financial status, although Australians experiencing psychiatric disability are eligible for service access funding though the NDIS [18]. This funding can be used to purchase services that help maintain independence, health and wellbeing—including assistance for domestic duties [18]. CMO consumers however noted that they had to prioritise family and domestic duties over attendance. It is difficult to address all these consumer-related concerns within the context of a CMO because government collaboration is necessary to manage health and financial issues [19]. However, anticipating and considering these factors during implementation could result in more user-friendly programs for CMO consumers [6, 13].

Consumer engagement with the CMO programs was also influenced by program design and delivery, which comprised the activities offered, convenience of meeting location, transport provision, time of year and time of day that programs were held, consideration of individual needs during delivery, and consumer perceptions about programs. Primary health care research for people with severe mental illness shows that organised transport provision promotes attendance of appointments, hence

should be utilised by CMOs [20]. Other program-related issues pertaining to timing, individual consumer needs, and consumer perceptions, can generally be addressed during implementation without altering fidelity of intervention content [1, 15]. Moreover, program activities in prospective lifestyle interventions can be adapted to suit consumers, if components that lead to efficacy are known [15]. Comprehensive knowledge on elements that contribute to program efficacy is essential for successful design alteration, to ensure efficacious elements are retained during integration of consumer suggestions [15].

Equipment availability and dissemination of information about programs, were the only organisational structure and practices that impacted program access. Translation of lifestyle intervention research into the community could be hampered by equipment discrepancies, if specialised equipment and trained personnel are required [6]. Considering the needs of both the scientific community and real-world practice settings in research and implementation, would enhance intervention usability [6, 15]. Further, adequate dissemination of information regarding CMO programs would minimize any associated service access challenges [21].

The potential effect of staff attitude towards consumers, and relevance of their professional skills during program delivery, were important considerations for consumer program attendance. This was in addition to provision of follow-up by staff, affirming literature that highlights the key role of mental health staff in facilitating or hampering health service attendance [5, 21, 22]. Addressing legitimate consumer concerns, concerning program or service providers, is of great importance in people with psychosis and other severe mental illness, because they face additional societal barriers to access [22]. Stigma associated with mental illness was one of the societal barriers in this study, while value of program social connections was a motivator. Internalised stigma and discrimination inhibit primary health care access and community participation in people with severe mental illness [21, 23]. Moreover, adequate social participation is an integral part of improving quality of life for those experiencing psychosis and other severe mental illness, hence should be promoted in programs [5, 23]. In contrast, societal stigma or discrimination is harder to control when delivering programs because public education is necessary [21, 23]. Nevertheless, consulting with consumers and conducting programs in spaces they perceive as non-stigmatizing may alleviate this [23].

Consumer attendance and interest in prospective services were parameters used to determine which programs could be delivered in the CMO, indicating the application of person-centred approach [24]. Clinical research shows that person-centred care enhances consumer empowerment and treatment outcomes [24]. The implication for implementing lifestyle interventions is the involvement of consumers in decision-making within target intervention settings [24].

Program delivery in the CMO was limited by lack of funds to cover program activity costs or employ specialised staff, with the NDIS allotments. Additionally, program cost-effectiveness had to be ensured through a financially justifiable consumer-to-staff ratio, to ensure NDIS funding was sufficient to cover running costs. Programs and services funded under the NDIS are required to minimize impairments that inhibit consumers from performing activities of daily living or engaging in the community [12, 18, 25]. The implication for lifestyle interventions seeking delivery through this avenue is that outcomes ought to demonstrate impact on these parameters [18]. Alternatives to NDIS funding for lifestyle intervention delivery in CMOs, are grants and funding from charitable organisations that support non-for-profits [26]. Literature does not indicate that this has been done previously, but it could be trialled in future to create a case for continued funding.

Organisational structure and practices that influenced program delivery, including the availability of facilities, policies and procedures, staff input and ideas, and the role limitations of staff, generally require consideration prior to lifestyle intervention implementation [6]. Facilities at a CMO may limit lifestyle intervention delivery, if specialised equipment or spaces are required [27]. In addition, all proposed programs would need to demonstrate adherence to policies and procedures especially with regard to work health and safety, as breaches can lead to harm of persons and costly fines [28]. Finally, incorporating ideas from CMO staff into the design of simple lifestyle interventions that can be delivered by a range of professionals, may promote program success in this context [6]. This will ensure that programs have the intended impact on consumers [6, 15].

Study strengths and limitations

Although the present study was characterised by a relatively small sample size (n=13), information provided on the factors which affect program access, mirrors some previously reported challenges in people with psychosis and other severe mental illness [5, 16, 23]. Findings may therefore provide a template for issues which can be evaluated by other CMOs when delivering programs for this population [5, 6, 16, 23]. However, information on elements to consider during program delivery may differ depending on context, and caution should be observed prior to application of current findings [6]. In light of the resource and time limitations confronted, adoption of semi-structured interviews rather than unstructured interviews promoted research efficiency; nonetheless, unstructured interviews may have produced richer data [29].

Conclusion

This study identified the factors that affect program access and delivery in a CMO delivering services to people with mental illness. Consideration of the issues cited by consumers and staff led to the

notion that various strategies could be applied to address challenges associated with the programs delivered, the organisation structure, staff involved, consumer social issues and funding available for programs [5, 15]. Although factors pertinent to the personal lives of consumers' presented as problematic to address, anticipating and planning for these complexities may alleviate some of the associated effects [30]. Translation of evidence-based lifestyle interventions for people with psychosis into CMOs, necessitates the consideration of issues that affect program access and delivery during the process of intervention design and implementation [1, 5, 6, 15]. This will enhance efficiency of knowledge translation and promote success of the lifestyle interventions [6, 15].

List of abbreviations

Body mass index (BMI)

Community managed organisations (CMOs)

National Disability Insurance Scheme (NDIS)

National Disability Insurance Agency (NDIA)

Integrated Promoting Action on Research Implementation in Health Systems" (i-PARIHS)

Declarations

Ethics approval and consent to participate

Ethics approval was obtained from University of Newcastle Human Ethics Research Committee (reference number H-2018-0237). Written and informed consent was obtained from the study site and individual study participants.

Consent for publication

Consent for data publication was obtained from the study site and individual study participants.

Availability of data and materials

The data generated and analysed in the current study are not publicly available, in order to protect the confidentiality of the study site and participants; however, further data to support the current findings can be provided by the corresponding author upon reasonable request.

Competing interests

The authors declare that they have no competing interests

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Authors' contributions

DM, MC-H, MM and LM-W designed the study. Data collection was completed by DM and the analysis conducted by DM and SA. All authors participated in the preparation of the manuscript and approved the final version.

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Chapter 7: Discussion, Recommendations for Future Research and Concluding Thoughts

Overview

Findings from the studies in this thesis are reviewed in this chapter, with specific reference to methodological strengths and weaknesses. Research conclusions are provided and future directions suggested. The "Integrated Promoting Action on Research Implementation in Health Systems" (i-PARIHS) knowledge translation framework is used to summarise the conclusions from each separate study, to support future translation of present findings (227). The i-PARIHS knowledge translation framework comprises four constructs: innovation, recipients, context and facilitation (227).

Innovation relates to available evidence in a particular field of interest, which can include research results, anecdotal evidence from local practice and any necessary alterations of evidence that allow for usability in different situations or by different practitioners (227). This thesis details evidence on lifestyle risk factors and lifestyle interventions for people with psychosis, therefore provides information pertinent to this construct.

Recipients are the target group(s) to whom a particular body of evidence directly applies, and those likely to support or resist knowledge translation (227). They include end-users of the innovation and those involved in delivering the innovation (227). Recipient characteristics are crucial for successful translation (227). I-PARIHS highlights the importance of issues like motivation, values, goals, skills and resources of groups involved, but important recipient descriptors are likely to be broader than this (227). This thesis primarily describes characteristics of people with psychosis, but acknowledges the importance of service providers (individuals and teams) within the various delivery contexts.

Importantly, i-PARIHS recognises that evidence is tied to the contextual conditions for which it is relevant (227). This includes the immediate local setting where evidence is applied and the wider environment that indirectly affects outcomes (227). Majority of the research in this thesis is pertinent to the Australian mental health service delivery setting including government and non-government sectors, which provide inpatient, outpatient and community services. The National Disability Insurance Scheme (NDIS) is also discussed due to its relevance to service delivery. In contrast, the systematic review component of this thesis is applicable to a variety of community settings within different countries.

Facilitation activates implementation by responding to circumstances or conditions outlined in the other constructs (227). Various strategies are applied during facilitation; the quality of these strategies is dependent on information outlined in the other three constructs (227). A facilitator oversees the facilitation process (227). Where applicable, strategies that could be considered during prospective

implementation of evidence are presented in this thesis discussion (227). I-PARIHS terminology (innovation, recipients, context and facilitation) is used in subsequent section of the thesis, to aid discussion of findings in view of the framework (227).

7.1: Discussion

7.1.1: Cardiovascular Disease Lifestyle Risk Factors in People with Psychosis: A Cross-sectional Study (Chapter 3)

Cardiovascular disease (CVD) is the consequence of non-modifiable risk factors (family history, increasing age, ethnicity and gender), modifiable risk factors (dyslipidaemia, hypertension, hyperglycaemia, central obesity, overweight and obesity) and lifestyle risk factors (poor nutrition, smoking and inadequate physical activity) (10, 43, 50, 51, 236, 237). Lifestyle risk factors are the main down-stream risk factors that contribute to the development of modifiable risk (51). In people with psychosis, impact of potential risk moderators requires further investigation because of the disproportionally high rate of CVD and the associated modifiable risk factors (10, 43, 50, 51, 236, 237).

To further understand CVD risk factors in people with psychosis, chapter 3 described the relationship between CVD lifestyle risk factors and dyslipidaemia, hypertension and hyperglycaemia, while controlling for potential confounding factors in all 1,825 participants from Survey of High Impact Psychosis (SHIP) (84). Associations between CVD lifestyle risk factors with dyslipidaemia, hypertension and hyperglycaemia showed some variation when compared to research from the general population, even after adjusting for confounders (84). The only relationships that were consistent with general population data were between smoking status with dyslipidaemia and hypertension; and nutrition (vegetable intake) with hypertension (84). Moreover, confounding effects were marginal, as the adjusted estimates did not differ substantially from the unadjusted estimates (84).

Although study bias was minimised because assessors were trained, participant blood samples collected, and valid and reliable tools used to assess lifestyle risk factors; discrepancies with previous research may have been affected by the use of self-report tools in the assessment of lifestyle risk factors and medications (84). Memory impairments sometimes experienced in psychosis can diminish quality of self-reports (238). Additionally, the tools may have lacked the sensitivity to obtain comprehensive research data (84, 238) This can be rectified during prospective facilitation of similar research by supplementing self-reports with direct sources information; fruit and vegetable intake could also be assessed using retrospective food diaries which record photographic data of intake on mobile devices (239, 240). Accelerometers could be used to record the duration and intensity of physical activity while smoking may be measured using monitors which measure levels of expired carbon monoxide, which is correlated to plasma nicotine and tobacco use (241-244). Finally, medication information may be obtained directly from treating physicians and pharmacists (245).

Aggregation of current findings highlights that innovation evidence on the relationship between CVD lifestyle risk factors, confounders and modifiable risk factors is inconclusive; SHIP was designed to provide a snapshot of people with psychosis in 2010, therefore, longitudinal research is necessary to address many of the existing research limitations (43, 84). This may provide a better understanding of factors that contribute to excess or early CVD in people with psychosis in the Australian context (43, 84).

Chapter 3 also aimed to identify the clustering patterns of lifestyle risk factors from the same participants and describe the demographic characteristics associated with different clusters of lifestyle risk factors (84, 146). Prior to this research, evidence on the co-occurrence of lifestyle risk factors was primarily from the general population (146). The results provided greater understanding of patterns of lifestyle risk factor occurrence among participants (227). Persons showing the most risk for all three lifestyle risk factors (poor nutrition, smoking and inadequate physical activity) were younger; males; those lacking tertiary qualifications; and people relying on pensions for income ($p<0.05$) (84). Therefore it is important that lifestyle risk factor programs focus on this recipient group (84). In contrast, the cluster that primarily required support with nutrition and physical activity did not display any distinct demographic characteristics for age, gender, and education (84). Moreover, being female, possessing tertiary qualifications, receiving an income (not from a government pension) and older age may buffer against lifestyle risk; these recipient characteristics were associated with meeting fruit and vegetable recommendations, non-smoking behaviour and the highest levels of moderate and vigorous physical activity ($p<0.05$) (84). Certain sociodemographic factors may therefore influence engagement with healthy lifestyle behaviours (84, 246, 247). Prospective facilitation of current findings should thus involve tailoring lifestyle interventions to characteristics that define recipients, such as their economic situation, to enhance accessibility and usefulness of the strategies provided (84, 246-248).

7.1.2: Self-Reported Nutrition and Physical Activity Program Utilisation among Australians with Psychosis: A Cross-sectional Analysis of Data (Chapter 4)

As noted previously, poor nutrition and inadequate physical activity are points of concern in people with psychosis, because they compound the risk of CVD and associated complications (2, 114, 237). The prevalence of CVD and metabolic syndrome in SHIP were 26.8% and 53.5% respectively, in contrast to 22% and 31% in the general population (2, 249, 250). Disparities between these populations could actually be greater, due to undiagnosed physical illness in those with psychosis (21, 237). Services that target the underlying lifestyle risk factors are thus an important resource for this group (164).

The utilisation of community nutrition and physical activity programs for people with psychosis in Australia was unknown, and it was unclear whether there were any benefits associated with these

programs (2, 219). Chapter 4 described the self-reported attendance of community nutrition and physical activity programs in the government and non-government sectors among SHIP participants, and identified demographics associated with overall self-reported program attendance (251). The chapter also assessed whether there was an association between improved nutrition and physical activity outcomes and program attendance (251). Since data analysed in Chapters 3 and 4 were both from SHIP, limitations discussion in section 7.1 apply here (251).

Innovation evidence for this field showed that participation in community nutrition and physical activity programs was low (5.3% in the government sector and 8.7% in the non-government sector), and was marked by long program durations (≥19 weeks) in the Australian context (2, 227). Overall program attendance differed by diagnosis (χ^2=14.824, p = 0.022), and education qualifications attained (χ^2=17.394, p = 0.004) in recipients or the people with psychosis (227, 251). Reasons for service utilisation discrepancies across diagnostic groups were unclear and require further investigation (10). However, facilitation of these findings should involve application of Royal Australian and New Zealand College of Psychiatrists (RANZCP) guidelines for physical health management in people with psychosis, which may lead to consistent and increased service referral for these recipients (227, 251, 252). Moreover, advocacy on the importance of community nutrition and physical activity programs by general practitioners (GPs) and case managers, and the design of programs with flexible commitment options may also promote service use (26, 29, 227, 251, 253). The positive association between education qualifications and program attendance shows that skills obtained through education may equip people with psychosis to access services; thus, prospective facilitation of evidence should involve service access support for those with low education attainment or capacity (227, 251, 254).

Finally, the impact of community nutrition and physical activity programs for people with psychosis in the Australian context, requires local monitoring and evaluation to ensure anticipated benefits are attained and sustained (255). This is because outcome comparisons between attenders and non-attenders only showed increased consumption of low fat milk (39.2% vs 25%, χ2= 11.366, p = 0.010) and decreased food insecurity (20.1% vs 31.6%, χ2= 7.232, p = 0.007) (251). While results may suggest improved dietary intake among program attenders, positive outcomes were not reflected across the other nutrition and physical activity variables of meal events per day, breakfast consumption, fruit and vegetable intake, and time spent in physical activity (251). Consequently, conclusions on overall impact of community nutrition and physical activity programs for people with psychosis in Australia cannot be made; generation and publication of these data will provide broader innovation evidence relevant to this field (227, 251).

7.1.3: Comparative Efficacy of Lifestyle Intervention Strategies that Target Weight Outcomes in People with Psychosis: A Systematic Review and Network Meta-analysis (Chapter 5.1)

Chapter 5 focused on existing lifestyle intervention trials for community-dwelling people with psychosis. Lifestyle intervention trials differ from community nutrition and physical activity programs because trials are conducted for the purpose of establishing evidence for practice (172, 224). At the time of research commencement in 2016, various lifestyle interventions trials had been conducted in people with psychosis (207). These trials proved efficacious at reducing anthropometric and metabolic measures (207). Meta-analyses also found that the lifestyle interventions delivered using an individual or one-on-one approach produced greater weight loss (Effect size [ES]=-0.67, 95% CI -1.04 to -0.30, p =0.0004) than those delivered in a group setting (ES=-0.36, 95% CI -0.60 to -0.13, p =0.002); however, interventions that utilised both individual and group delivery were superior to both (ES=-0.99, 95% CI -1.61 to -0.37, p =0.002) (172). Lack of further information on the strategies that contributed to the efficacy of these studies highlighted an evidence gap in the field (172).

Chapter 5.2 provided a systematic review and network meta-analysis which ranked the efficacy of different types of lifestyle intervention strategies on weight outcomes (weight, body mass index [BMI], waist circumference and waist-to-hip ratio) in community-dwelling people with psychosis (233, 256). The advantage of network meta-analysis over previous meta-analyses was that a global estimate of efficacy was provided, based on direct effects (head-to-head comparisons available from trials) and indirect effects (comparisons via a common comparator) (172, 207, 257, 258). The systematic review included thirty-two randomised controlled trials (RCTs) that delivered lifestyle interventions (233). Lifestyle interventions were qualitatively summarised, to identify features that were used for subgroup categorisation for pooling of intervention effects (233). Characteristics that were most consistent across all RCTs were the basis for subgroup categorisation; these included the lifestyle intervention components utilised in each study, and mode of delivery in these components (233).

Lifestyle interventions with a structured diet and structured physical activity approach showed the greatest efficacy for decreasing weight (ES = -4.12, 95% CI=-7.772 to -2.760, p<0.000) and BMI (ES = -2.94, 95% CI=-1.78 to -0.357, p=0.003), being the only subgroup that attained statistical significance for these outcomes (233). Intervention components in structured diet and structured physical interventions contributed to innovation evidence on the design of efficacious lifestyle interventions for weight and BMI decrease in people with psychosis (227, 233). Important core components were education, tailored advice or goal setting, and use of progress review in both dietary and physical activity intervention components (233). Supplementary intervention components were food and physical activity records, and supervised group exercise (233). These strategies may have enhanced

interventions due to individual needs being catered to, and the availability of accountability and monitoring (259-264). Prospective facilitation of current findings should thus explore the effect of structured lifestyle intervention on other outcomes such as waist circumference and waist-to-hip ratio. Moreover, evidence generated from local practice settings on efficacy of lifestyle interventions in people with psychosis could indicate if the strategies work in non-research environments (227, 233).

A crucial step in the synthesis of evidence is the quality rating (226). The certainty of evidence ranged from low to very low for lifestyle intervention strategies effects on weight, BMI and waist circumference, based on GRADE (Grading of Recommendations Assessment, Development and Evaluation) criteria (226, 233). This was the consequence of risk of bias in primary studies; vague and insufficient reporting in the same studies; and funnel plot asymmetry which highlighted risk of reporting and publication bias (233). These are areas which can be rectified during future facilitation of similar research (233).

Overall, findings from the systematic review and network meta-analysis advanced the field because it was the most superior source of evidence on lifestyle intervention strategies for people with psychosis dwelling in various community contexts around the world (172, 207, 212, 233). The inner contexts for intervention delivery included outpatient mental health clinics, psychiatric rehabilitation programs, participant homes or supported accommodation, local sports facilities, and research offices (233). Moreover, recipients involved in intervention delivery were case managers, nurses, dietitians, lifestyle coaches, nutritionists, mental health support workers, psychomotor therapists, care-coordinators, health educators and health coaches (233).

The secondary segment of the review stratified lifestyle interventions that targeted the same weight outcomes in people with psychosis, according to their inclusion of dietary information that adheres to the Australian Dietary Guidelines (ADGs) (99). Assessments highlighted that most studies included dietary information which complied with some of the guidelines (233). Although none of the studies showed evidence for using dietary approaches that contradicted current public health guidelines, inadequate and vague information prevented studies from being rated as compliant with all the guidelines (99, 233, 265). This highlighted an innovation gap on dietary approaches used in previous lifestyle interventions for community dwelling people with psychosis, which can be rectified in future through adequate reporting (227, 233). Consequently, conclusions on efficacious nutrition or dietary advice for people with psychosis were not generated from the study (233, 256).

7.1.4: An Appraisal of Methodology Reporting in Lifestyle Interventions among People with Psychosis: A Systematic Review (Chapter 5.2)

The systematic review on efficacy of lifestyle intervention strategies in people with psychosis, highlighted shortcomings related to poor reporting (233). This prevented comprehensive appraisal and synthesis of knowledge pertinent to nutrition or dietary advice for people with psychosis (233). A formal appraisal of lifestyle intervention reporting was thus employed in Chapter 5.3 to highlight areas for improvement in the reporting of lifestyle interventions for people with psychosis (215, 216). Chapter 5.3 aimed to critically appraise lifestyle intervention studies that target weight outcomes for people with psychosis against the methods component of the Consolidated Standards of Reporting Trials (CONSORT) statement for randomised trials of nonpharmacologic treatments (215). Nonpharmacologic treatments involve the application of behavioural techniques to modify health outcomes (215).

Non-compliance in the reporting of treatments applied in lifestyle interventions was the most concerning result, which indicated inadequate innovation evidence on lifestyle intervention treatments (227, 266). Key issues included lack of comprehensive information on how efficacy of different treatment components was ensured, processes for tailoring treatments to individual participants, treatment standardisation procedures, and the treatment adherence procedures that ascertained weight loss (266). Moreover, studies tended to focus on the role of participants and generally overlooked information on care providers, limiting appraisal of evidence for recipients involved in intervention delivery (216). Relevant information for both participants and care providers includes their eligibility criteria, procedures implemented to ensure adherence to the protocol, measures taken to control for their effect on sample size and statistical analyses, and reports of whether or not they were blinded and how this was done (216). Finally, omission of eligibility criteria for data collection settings and or other community settings where lifestyle interventions were delivered, highlighted a potential lack of awareness on the impact these variables could have on outcomes (266). Inadequate information on these settings could limit translation to the appropriate contexts for lifestyle interventions (227, 266).

The resultant innovation evidence from the overall appraisal indicated inadequate description of lifestyle interventions in the existing literature (227, 266). Facilitation of research on lifestyle intervention trials for people with psychosis should therefore involve adherence to the CONSORT statement or similar guidelines, for consistent and comprehensive reporting in the field (227, 266). This will allow for effective appraisal, creation of stronger guidelines, and translation of best-practice research (266).

7.1.5: Factors to Consider During the Implementation of Nutrition and Physical Activity Trials for People with Psychosis into an Australian Community Setting (Chapter 6)

Despite ongoing research on lifestyle intervention trials in people with psychosis, information on factors that influenced external validity and translation of interventions was scarce (214). Community managed organisation (CMOs) play a significant role in maintaining the health of Australians with mental illness and complement the efforts in public and private mental health services; therefore, identifying issues that affect program access and delivery in this setting provided evidence on the recipient and context constructs for prospective facilitation of lifestyle interventions in CMOs (227, 267).

Considerations that affected program access primarily provided evidence pertinent to recipients, as the issues raised were generally applicable to consumers and staff (227). These factors included consumers' domestic responsibilities and health; the design and delivery of programs; staff attitude, skills and effort; as well as social connections and stigma experienced by consumers when accessing programs. Some of the issues affecting program access were however contextual (227). Availability of consumer finances for the access of programs was largely dependent on the receipt of funding from the NDIS—the government scheme responsible for funding disability support services in the Australian context (32). Moreover, organisational structure and practices provided evidence on the internal context of the CMO (227).

An important element impacting program delivery was the attendance and interest of consumers, highlighting the important role recipients play in this process (227). Further, internal and external contextual factors including the organisational structure and practices, and funding were also crucial for program delivery (227).

Although findings on program access and delivery represented a small group (n=13) of consumers and staff at the Australian CMO, results reflected some of the well-known challenges experienced by people with psychosis and other severe mental illness (2, 165, 224). It was apparent that strategies could be applied to address most of the program access and delivery concerns to alleviate barriers, except where matters raised were pertinent to the external context (e.g. NDIS funding) or the health status of consumers (32). Consequently, facilitation of research on lifestyle interventions for people with psychosis into CMOs should involve the consideration of elements that affect program access and delivery (227). This is likely to improve efficiency and success of the process, and reduce the gap between knowledge creation and translation of evidence (227, 235, 268).

7.2: Recommendations for Future Research

After reviewing knowledge in the fields covered in this thesis, progress in the different areas can be achieved through:

- Conducting longitudinal research among Australians with psychosis that focuses on the relationship between CVD lifestyle risk factors, modifiable risk factors and potential population-specific confounding variables, to uncover all the risk factors that lead to excess or early-onset CVD in people with psychosis. This will allow for creation of interventions that address the cause of excess CVD risk, through the implementation of strategies that are of direct proportional impact.
- Prospective research in people with psychosis which applies objective data collection methodology; nutrition could be assessed using food records which capture photographic data on intake, physical activity via accelerometers, and smoking behaviour using carbon monoxide monitors, to minimize likelihood of bias. Moreover, tools for measuring lifestyle risk should be identified and validated for people with psychosis and general population research should not be generalised to this group.
- Undertaking comprehensive evaluation of existing community nutrition and physical activity programs for people with psychosis (available in the Australian government and non-government sectors) using uniform criteria or standards, to ensure these programs are targeting measurable health outcomes and are applying evidence-based approaches in the process. Evaluations should also gather consumer feedback, to capture their view of existing services.
- Further research on the impact of education, tailored advice or goal setting, and progress review as core elements in both dietary and physical activity components of lifestyle interventions for people with psychosis. Research should assess whether improvements in weight, body mass index, waist circumference and waist-to-hip ratio can be attained, sustained and translated into real-world practice settings. Research should measure the effects associated with individual intervention strategies. Moreover, the impact of adding other strategies and tools including food and physical activity records, and supervised exercise as supplementary intervention elements should be quantified.
- The establishment of specific nutrition and physical activity advice which leads to efficacy of lifestyle interventions in people with psychosis. This advice would need to adhere to existing public health guidelines which include the Australian Dietary Guidelines, and Australia's Physical Activity and Sedentary Behaviour Guidelines.
- Comprehensive reporting in lifestyle intervention trials for people with psychosis, which can be realised through adherence to reporting guidelines for nonpharmacologic interventions.

Accessibility of supplementary study information should also be ensured, as it may not always be practical to include all the information that is relevant for replication in a published manuscript.

- Collaboration between researchers, those with psychosis and practitioners in real-world practice settings (like the Australian community managed sector) during translation of lifestyle interventions. Researchers should first identify the intervention components that produce anthropometric and metabolic health benefits, and liaise with staff and consumers in implementation settings about the other factors that could promote intervention success in these settings. Appropriate theoretical implementation and evaluation frameworks should be employed when translating these interventions into other contexts, for the effective translation of evidence.

7.3: Concluding Thoughts

Lifestyle risk factors (poor nutrition, smoking and inadequate physical activity) heighten the vulnerability of people with psychosis by increasing the risk of CVD and associated health problems, likely contributing to early mortality in this population. This research identified the anticipated patterns of lifestyle risk factor occurrence among Australian adults with psychosis, thus contributed evidence for the intervention design process. Government bodies and researchers can enhance the usefulness of this information by funding and investigating all the factors (i.e. confounders, mediators, and effect modifiers) that come into play in the relationship between CVD lifestyle risk factors, modifiable risk factors and excess or early-onset CVD among people with psychosis, so findings can be incorporated into the design of prospective intervention programs.

Moreover, community nutrition and physical activity programs for Australians with psychosis present an avenue with unrealised potential due to low utilisation, service access barriers and a lack of clear overarching advantages of service use. This demands a response from the government and other funding bodies who can foster standardised monitoring and evaluation practices to streamline some of the problems in this sector, so that available services meet consumer needs.

Existing research on lifestyle intervention trials in people with psychosis provides preliminary evidence that is marked by various shortcomings. Future consideration of these limitations and challenges will prevent a reoccurrence of the same, and will lead to creation of a firmer evidence base that can be translated into different contexts, meeting the needs of a variety of consumers. Superior lifestyle intervention outcomes are likely to be attained through application of knowledge translation frameworks during implementation into different settings.

Finally, the advancing service provision environment in the Australian community managed sector provides an ideal setting where researchers and consumers can merge efforts to provide co-designed and tailored lifestyle interventions for people with psychosis. This thesis contributes to the knowledge translation process by providing an understanding of the needs in real-world practice settings and the contextual factors that affect service access and delivery; this can be furthered during actual implementation as novel issues may be encountered.

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Appendices

Appendix 1: Statement of Contribution and Collaboration for Chapter 3

I attest that the Research Higher Degree candidate Doreen Mucheru contributed to the following paper:

Mucheru D, Hanlon MC, Campbell LE, McEvoy M, and MacDonald-Wicks L. *Cardiovascular disease lifestyle risk factors in people with psychosis: a cross-sectional study. BMC Public Health.* 2018; 18(1): 742.

Doreen Mucheru contributed to the research question, study design, data analysis and manuscript preparation as the primary author. Dr Mary-Claire Hanlon, A/Prof Mark McEvoy and A/Prof Lesley MacDonald-Wicks also contributed to the study design, data analysis and manuscript preparation within their capacity as PhD supervisors and/or co-authors. Dr Mary-Claire Hanlon and Dr Linda E. Campbell were involved in implementing and reporting data from the Survey of High Impact Psychosis which was analysed for this study.

By signing below, I confirm that this information is true.

Author Name	*Signature*	*Date*
Miss Doreen Mucheru		25/09/19
Dr Mary-Claire Hanlon		25/09/19
Dr Linda E. Campbell		25/09/19
A/Prof Mark McEvoy		19/09/19
A/Prof Lesley MacDonald-Wicks (Faculty Assistant Dean Research Training)		25/09/19

Appendix 2: Statement of Contribution and Collaboration for Chapter 4

I attest that the Research Higher Degree candidate Doreen Mucheru contributed to the following paper:

Mucheru D, Hanlon MC, Campbell LE, McEvoy M, MacDonald-Wicks L. *Self-Reported Nutrition and Physical Activity Program Utilisation among Australians with Psychosis: A Cross-Sectional Analysis of Data. J Community Med Public Health*. 2019; 3: 155.

Doreen Mucheru contributed to the research question, study design, data analysis and manuscript preparation as the primary author. Dr Mary-Claire Hanlon, A/Prof Mark McEvoy and A/Prof Lesley MacDonald-Wicks contributed to the research question, study design, data analysis and manuscript preparation within their capacity as PhD supervisors and/or co-authors. Dr Mary-Claire Hanlon and Dr Linda E. Campbell were involved in implementing and reporting data from the Survey of High Impact Psychosis which was analysed for this study.

By signing below, I confirm that this information is true.

Author Name	*Signature*	*Date*
Miss Doreen Mucheru		25/09/19
Dr Mary-Claire Hanlon		25/09/19
Dr Linda E. Campbell		25/09/19
A/Prof Mark McEvoy		19/09/19
A/Prof Lesley MacDonald-Wicks (Faculty Assistant Dean Research Training)		25/09/19

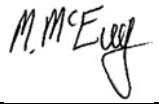
Appendix 3: Statement of Contribution and Collaboration for Chapter 5.1 Paper 1

I attest that the Research Higher Degree candidate Doreen Mucheru contributed to the following paper:

Mucheru DW, Hanlon MC, McEvoy M, and MacDonald-Wicks L. *Comparative efficacy of lifestyle intervention strategies on weight outcomes in people with psychosis: a systematic review and network meta-analysis protocol.* JBI Database System Rev Implement Rep. 2017; 15(6): 1593-601.3.

Doreen Mucheru contributed to the design of the research question, study methodology, literature review and manuscript preparation. Dr Mary-Claire Hanlon, A/Prof Mark McEvoy and A/Prof Lesley MacDonald-Wicks contributed to the design of the research question, study methodology, literature review and manuscript preparation within their capacity as PhD supervisors and/or co-authors.

By signing below, I confirm that this information is true.

Author Name	*Signature*	*Date*
Miss Doreen Mucheru		25/09/19
Dr Mary-Claire Hanlon		25/09/19
A/Prof Mark McEvoy		19/09/19
A/Prof Lesley MacDonald-Wicks (Faculty Assistant Dean Research Training)		25/09/19

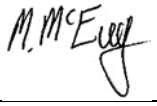
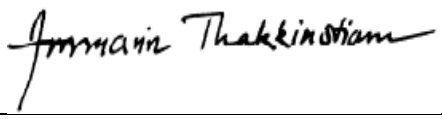
Appendix 4: Statement of Contribution and Collaboration for Chapter 5.1 Paper 2

I attest that the Research Higher Degree candidate Doreen Mucheru contributed to the following paper:

Mucheru D, Hanlon MC, McEvoy M, Thakkinstian A and MacDonald-Wicks L. *Comparative efficacy of lifestyle intervention strategies that target weight outcomes in people with psychosis: a systematic review and network meta-analysis.* JBI Database System Rev Implement Rep. 2019. doi: 10.11124/JBISRIR-2017-003943

Doreen Mucheru contributed to the design of the research question, study methodology, literature search, screening of studies, data extraction and analysis, meta-analysis and network meta-analysis, bias assessments, evaluation of findings using GRADE criteria and manuscript preparation. Dr Mary-Claire Hanlon, A/Prof Mark McEvoy and A/Prof Lesley MacDonald-Wicks contributed to the design of the research question, study methodology, literature search, screening of studies, data extraction and analysis, meta-analysis and network meta-analysis, bias assessments, evaluation of findings using GRADE criteria and manuscript preparation within their capacity as PhD supervisors and/or co-authors. Dr Ammarin Thakkinstian was consulted on the meta-analysis and network meta-analysis methods. Ms Debbie Booth, the Senior Research Librarian at the University of Newcastle assisted in the development of the literature search strategies.

By signing below, I confirm that this information is true.

Author Name	*Signature*	*Date*
Miss Doreen Mucheru		25/09/19
Dr Mary-Claire Hanlon		25/09/19
A/Prof Mark McEvoy		19/09/19
Dr Ammarin Thakkinstian		25/09/19
A/Prof Lesley MacDonald-Wicks (Faculty Assistant Dean Research Training)		25/09/19

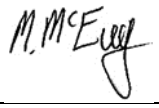
Appendix 5: Statement of Contribution and Collaboration for Chapter 5.2

I attest that the Research Higher Degree candidate Doreen Mucheru contributed to the following paper:

Mucheru D, Hanlon MC, McEvoy M, and MacDonald-Wicks L. *An Appraisal of Methodology Reporting in Lifestyle Interventions among People with Psychosis using the CONSORT Statement for Randomised Trials of Nonpharmacologic Treatments: A Systematic Review.* In Health Promot J Austr. 2019. doi 10.1002/hpja.293

Doreen Mucheru contributed to the design of the research question, study methodology, literature search, screening of studies, data extraction and analysis, bias assessments, and manuscript preparation. Dr Mary-Claire Hanlon, A/Prof Mark McEvoy and A/Prof Lesley MacDonald-Wicks contributed to the design of the research question, study methodology, literature search, screening of studies, data extraction and analysis, bias assessments, and manuscript preparation within their capacity as PhD supervisors and/or co-authors. Ms Debbie Booth, the Senior Research Librarian at the University of Newcastle assisted in the development of the literature search strategies.

By signing below, I confirm that this information is true.

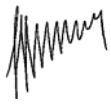
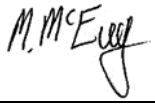
Author Name	*Signature*	*Date*
Miss Doreen Mucheru		25/09/19
Dr Mary-Claire Hanlon		25/09/19
A/Prof Mark McEvoy		19/09/19
A/Prof Lesley MacDonald-Wicks (Faculty Assistant Dean Research Training)		25/09/19

Appendix 6: Statement of Contribution and Collaboration for Chapter 6

I attest that the Research Higher Degree candidate Doreen Mucheru contributed to the following paper:

Mucheru D, Ashby S, Hanlon MC, McEvoy M, and MacDonald-Wicks L. *Factors to Consider during the Implementation of Nutrition and Physical Activity Trials for People with Psychosis into an Australian Community Setting.* BMC Health Services Research (under review). 2019.

Doreen Mucheru contributed to the research question, study design, human research ethics application, data collection and analysis, and manuscript preparation as the primary author. Dr Mary-Claire Hanlon, A/Prof Mark McEvoy and A/Prof Lesley MacDonald-Wicks contributed to the research question, study design, human research ethics application, data collection and analysis, and manuscript preparation within their capacity as PhD supervisors and/or co-authors. Dr Samantha Ashby was consulted on data analysis and also contributed to manuscript preparation.

Author Name	*Signature*	*Date*
Miss Doreen Mucheru		25/09/19
Dr Samantha Ashby		28/08/19
Dr Mary-Claire Hanlon		25/09/19
A/Prof Mark McEvoy		19/09/19
A/Prof Lesley MacDonald-Wicks (Faculty Assistant Dean Research Training)		25/09/19

Appendix 7: Organisational Consent Form for Chapter 6

Dr Lesley MacDonald-Wicks

Hunter Building room HE26

University Drive, Callaghan NSW 2308

Ph: (02) 4921 6646

Lesley.Wicks@newcastle.edu.au

Organisational Consent Form for the Research Project: Developing an Implementation Plan for "A Healthy Living Program" in People with Psychosis and Other Severe Mental Illness within a Community Managed Organisation

Version 3 (27/11/2018)

Chief Investigator: Dr Lesley MacDonald-Wicks

Investigators: Dr Mary-Claire Hanlon, Associate Professor Mark McEvoy and Miss Doreen Mucheru (student)

I ……. (Position/ Title) of (Centre Name Blocked for Confidentiality) agree for this research study to be conducted within my organisation. I understand that the project will be conducted as described in the Organisational Information Statement, a copy of which I have retained.

I understand that (Centre Name Blocked for Confidentiality) can withdraw from the study at any time and does not have to give a reason for this withdrawal.

I consent to:

- My organisation participating in this research project through the recruitment of staff and clients in the study
- The undertaking of study interviews within the premises of (Centre Name Blocked for Confidentiality)
- The recruitment of staff to screen and refer clients to the student researcher and monitor the signing of consent forms to ensure that participants have not been coerced into participating in research

I understand that all participation in the project is voluntary for all prospective participants.

I understand that my organisation's information will remain confidential to the researchers.

I have had the opportunity to have any questions answered to my satisfaction.

Print Name: _____

Contact Phone: _____

Contact Address: _____

Email: _____

Signature: _____ Date: _____

Please indicate (circle) whether you would like a summary of the study findings	Yes / No
If you indicate yes, please select the preferred method of contact	Email / Post

This project has been approved by the University's Human Research Ethics Committee, Approval No. H-2018-0237.

Appendix 7: Permission Form to Contact Consumers in Chapter 6

Consent for Contact and Release of Information for the Research Project:

Developing an Implementation Plan for "A Healthy Living Program" in People with Psychosis and Other Severe Mental Illness within a Community Managed Organisation:

Document Version [1]; dated [27/11/18]

I hereby freely give my consent to be contacted by Doreen Mucheru, a student researcher from the University of Newcastle in regard to the research project 'Developing an Implementation Plan for "A Healthy Living Program" in People with Psychosis and Other Severe Mental Illness within a Community Managed Organisation'.

This contact is only for the purpose of receiving further study information so that you are able to consider whether you would like to participate. This is not consent for your participation and should you decide to take part in the study, another consent form will need to be completed.

Print Name: _____

Contact Phone: _____

Email: _____

Signature: _____

Date: _____

This project has been approved by the University's Human Research Ethics Committee, Approval No. H-2018-0237.

Appendix 8: Consent Form for Consumers in Chapter 6

Dr. Lesley MacDonald-Wicks

Hunter Building room HE26

University Drive, Callaghan NSW 2308

Ph: (02) 4921 6646

Lesley.Wicks@newcastle.edu.au

Client Consent Form for the Research Project: Developing an Implementation Plan for "A Healthy Living Program" in People with Psychosis and Other Severe Mental Illness within a Community Managed Organisation

Version 3 (7/11/2018)

Chief Investigator: Dr Lesley MacDonald-Wicks

Investigators: Dr Mary-Claire Hanlon, Associate Professor Mark McEvoy and Miss Doreen Mucheru (student)

I agree to participate in the above research study and give my consent freely.

I understand that the project will be conducted as described in the Information Statement, a copy of which I have retained.

I understand I can withdraw from the study at any time and do not have to give a reason for my withdrawal.

I consent to:

- Completing an interview lasting approximately one and half hours at (Centre Name Blocked for Confidentiality) and being audio-recorded during the interview
- The disclosure of important information which can be acted on relating to my health and wellbeing that may arise from interviews, to a staff member of my choice from (Centre Name Blocked for Confidentiality).
- The contact of relevant emergency health or crisis services (such as an ambulance) if I become so unwell that the researcher or your nominated (Centre Name Blocked for Confidentiality) staff member believes I need emergency medical help. This information may be passed on to these services without further consent, other than that provided in this consent form.
- The publication or dissemination of anonymous information from interviews, which may include the use of direct interview quotes

I understand that my personal information will remain confidential to the researchers.

I have had the opportunity to have questions answered to my satisfaction.

What should the researchers do in case your mental health changes thus affecting your ability to give consent or participate in the study?

_____

_____

Which member of staff do you nominate to receive actionable important information, relating to your health and wellbeing that may arise from interviews? _____

Print Your Name: _____

Contact Phone: _____

Contact Address: _____

Email: _____

Signature: _____

Date: _____

Please indicate (circle) whether you would like to review your interview transcript prior to researchers using your data Yes / No

Please indicate (circle) whether you would like a summary of the study findings Yes / No

If you indicate yes, please select the preferred method of contact Email / Post

This project has been approved by the University's Human Research Ethics Committee, Approval No. H-2018-0237.

Appendix 9: Consent Form for Staff in Chapter 6

Dr Lesley MacDonald-Wicks

Hunter Building room HE26

University Drive, Callaghan NSW 2308

Ph: (02) 4921 6646

Lesley.Wicks@newcastle.edu.au

Staff Consent Form for the Research Project: Developing an Implementation Plan for "A Healthy Living Program" in People with Psychosis and Other Severe Mental Illness within a Community Managed Organisation

Version 3 (7/11/2018)

Chief Investigator: Dr Lesley MacDonald-Wicks

Investigators: Dr Mary-Claire Hanlon, Associate Professor Mark McEvoy and Miss Doreen Mucheru (student)

I agree to participate in the above research study and give my consent freely.

I understand that the project will be conducted as described in the Information Statement, a copy of which I have retained.

I understand I can withdraw from the study at any time and do not have to give a reason for my withdrawal.

I consent to:

- Completing an interview lasting approximately one and half hours at (Centre Name Blocked for Confidentiality) and being audio-recorded during the interview
- The publication or dissemination of anonymous information from interviews, which may include the use of direct interview quotes

I understand that my personal information will remain confidential to the researchers.

I have had the opportunity to have questions answered to my satisfaction.

Print Name: _____

Contact Phone: _____

Contact Address: _____

Email: _____

Signature: _____ Date: _____

Please indicate (circle) whether you would like to review your interview transcript prior to researchers using your data Yes / No

Please indicate (circle) whether you would like a summary of the study findings Yes / No

If you indicate yes, please select the preferred method of contact Email / Post

This project has been approved by the University's Human Research Ethics Committee, Approval No. H-2018-0237.

Appendix 10: Participant Information Statement for Chapter 6

Dr Lesley MacDonald-Wicks

Hunter Building room HE26

University Drive, Callaghan NSW 2308

Ph: (02) 4921 6646

Lesley.Wicks@newcastle.edu.au

Participant Information Statement for the Research Project:

Developing an Implementation Plan for "A Healthy Living Program" in People with Psychosis and Other Severe Mental Illness within a Community Managed Organisation

Document Version 3: Dated 7/11/18

Invitation

You are invited to participate in the research study identified above which is being undertaken by Miss Doreen Mucheru and is part of her PhD at the University of Newcastle, under the supervision of Dr Lesley MacDonald-Wicks from the School of Health Sciences, Dr Mary-Claire Hanlon and Associate Professor Mark McEvoy both from the School of Medicine and Public Health, all from the mentioned institution of study.

Why is the research being done?

We aim to find out the factors that would affect the implementation or introduction of a new "Healthy Living Program" for people with psychosis and other severe mental illness at (Centre Name Blocked for Confidentiality). The "Healthy Living Program" is however not being introduced as part of the study. The information will enhance understanding in this field and could also be applied in the future introduction of programs in this setting.

Who can participate in the research?

This study may be suitable for you if you are aged 18 to 64 years old and have been told by the doctor you have schizophrenia/ bipolar disorder/ schizoaffective disorder/ major depressive disorder or any other mental illness, and attend (Centre Name Blocked for Confidentiality) for programs and have been referred to the study by a support worker who will have already assessed your ability to consent and participate in the study is not affected by physical or mental illness.

This study may also be suitable for you if you are a support worker, primary recovery support worker, site coordinator or area leader at (Centre Name Blocked for Confidentiality) or volunteer in any of these roles.

What would you be asked to do?

If you do decide to participate in this study, the student researcher will organise a suitable day and time that you already plan to be attending (Centre Name Blocked for Confidentiality), for an interview.

You will be asked to sign a consent form on the interview day to confirm participation. The consent process will be monitored by a member of staff to ensure that no one has been coerced into participating in the research.

Interviews for clients attending (Centre Name Blocked for Confidentiality) for programs will focus on the current programs they attend, what they like about these programs, hindrances to attending programs, the perceived need for "A Healthy Living Program" which focuses on nutrition and physical activity and future expectations from such a program.

Participant wellbeing is important, therefore, we are seeking permission for the following from clients attending (Centre Name Blocked for Confidentiality) for programs:

- To disclose any important findings that could be acted on relating to health and wellbeing that may arise from interviews, to a (Centre Name Blocked for Confidentiality) staff member that you nominate in your consent form.
- The contact of relevant emergency health or crisis services (such as an ambulance) if you become so unwell that the researcher or your nominated (Centre Name Blocked for Confidentiality) staff member believes you need emergency medical help. The only consent required in this event, is consent you provide in the consent form with your signature.
- To obtain advice in case of changes to mental health which affects the ability to consent or participate in the study. This advice may entail the proper procedures for researchers to follow if participants show distress or symptom exacerbation. This advice will be adhered to except in cases where doing so would be contrary to the best interests of participants. In case initial participation is affected by changes to mental health, participation will be temporarily suspended, and you will be provided with another opportunity to participate in subsequent weeks when you are well enough to resume the study.

Interviews for staff or volunteers at (Centre Name Blocked for Confidentiality) will focus on the development, introduction and running of programs, motivators for involvement with programs, program evaluation, perceived need for "A Healthy Living Program" for clients which focuses on nutrition and physical activity, future expectations from such a program and considerations to the introduction of such a program.

At the conclusion of each interview, participants will have the option of revising their responses to any of the questions and will be able to renegotiate their consent to the information being used.

All interviews will be audio recorded hence those unwilling to have interviews recorded cannot participate in the study.

Typed interview transcripts will be provided to consenting participants (in person) to check for information accuracy, in confidence, at a convenient time. Participants will have the opportunity to make changes to the transcripts until satisfied where they will return them to the student researcher.

What choice do you have?

Participation in this research is entirely your choice. Only those people who give their informed consent will be included in the project. Whether or not you decide to participate, your decision will not disadvantage you, nor will it affect your engagement with services at (Centre Name Blocked for Confidentiality). If you do decide to participate, you may withdraw from the project at any time without giving a reason, and have the option of withdrawing any data which identifies you. It will, however, not be possible to withdraw from the study once results have been disseminated or published.

How much time will it take?

The interview will last approximately 1 hour 30 minutes, however, the time spent reviewing interview transcripts by participants who choose to do so will be highly dependent on how quickly they are able to complete this process. This is however not expected to take more than 2 hours. Staff interviews will take place outside their paid work hours, either before the commencement of their shift or after their shift. Staff wishing to take the interview during their work break will have the option of doing so and will have the opportunity of taking the interview in 2 or 3 sessions to ensure the interview duration does not exceed their allocated work break.

What are the risks and benefits of participating?

The risk associated with participating in interview-based research is minimal. Less frequently, some individuals have reported experiencing feelings of anxiety when answering particular questions.

If you experience anxiety, you can ask for the interview to stop, refuse to answer a particular question or stop to have a rest. If the student researcher notes or suspects anxiety, then she will stop the interview and ask whether you would like to discontinue with the interview or with a particular question or stop to have a rest. You will be provided the opportunity to postpone the interview should you discontinue with the interview due to anxiety.

The is no personal benefit for participation in this study, however, findings will provide an understanding of the factors that need to be considered when implementing programs at (Centre Name Blocked for Confidentiality) and more generally, the community managed organisation setting.

How will your privacy be protected?

Identifying information such as data containing participant names will strictly be confidential to the student researcher and will be stored separately in password protected computer systems. Audio-recording devices, field notes and consent forms will be stored in lockable cupboards when not in use. Data from audio-recording devices and field notes will be transferred to password protected computer systems, which only the research team will access. Reports or any publications from the research will not contain any identifying information and the identity of (Centre Name Blocked for Confidentiality) will also remain concealed. This may, however, not guarantee complete anonymity as information provided may still be traceable by those who know interviewees therefore, researchers request that participants withhold information that may be detrimental to them, their employment or relationships when participating in interviews.

Research data will be preserved for 5 years after completion of the study, which is in accordance with the study institution's data management guidelines and destroyed thereafter.

How will the information collected be used?

Results from this study will be submitted as part of Doreen Mucheru's PhD thesis and presented at conferences and in scientific journals. Direct quotes from interviews will also be included in the thesis, conference presentations and journal publications.

Participants will not be identified in any of these research outputs. Consenting participants will receive a copy of study results after all data is compiled and written into a report.

What do you need to do to participate?

Please read this Information Statement carefully and ensure you understand the content before giving your consent for participation. If there is anything you do not understand, or you have questions, contact the student researcher prior to completing the consent form.

If you wish to participate, please complete the consent form when it is provided to you.

Further information

For further information, please contact:

Doreen Mucheru: Ph. 042061918 email: Doreen.Mucheru@uon.edu.au

Lesley MacDonald-Wicks: Ph. 492 16646 email: Lesley.Wicks@newcastle.edu.au

Thank you for considering this research invitation

Dr Lesley MacDonald-Wicks
School of Health Sciences, Faculty of Health and Medicine

Doreen Mucheru

School of Health Sciences, Faculty of Health and Medicine

On behalf of the research team

Complaints about this research

This project has been approved by the University's Human Research Ethics Committee, Approval No. H-2018-0237.

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 Human-Ethics@newcastle.edu.au.

Appendix 11: Interview Protocol for Consumers in Chapter 6

Interview Questions for the Research Project: Developing an Implementation Plan for "A Healthy Living Program" in People with Psychosis and Other Severe Mental Illness within a Community Managed Organisation

Version 3 (7/11/2018)

Interview Questions for Adults (18-64 years) with Psychosis or Other Severe Mental Illness

Participants

Interviewer: Doreen Mucheru (Student Researcher)

Interviewee: An adult with psychosis or other severe mental illness attending (Centre Name Blocked for Confidentiality)

Welcome/ Orientation

Interviewer: Hello _____ (use the name of the interviewee). How are you?

(Pause to provide the interviewee an opportunity respond)

Interviewer: Thank you for agreeing to meet with me today. I would like to ask you some questions about your experiences participating here at (Centre Name Blocked for Confidentiality). I would like to discuss the sorts of programs you attend here, how you are finding them and perhaps any thoughts on a new program called "A Healthy Living Program" that could be made available in the future.

(Pause to provide the interviewee an opportunity to comment if they would like to)

Interviewer: The interview is expected to take a maximum of 1 hour 30 minutes, with a 15-minute break. You can choose to stop the interview at any time to have another break, or if you no longer wish to participate. You are not required to give a reason for changing your mind about participating.

(Pause to provide the interviewee an opportunity to comment if they would like to)

Interviewer: If you seem uncomfortable during the interview, then I will offer you the opportunity to take a break, postpone the interview or altogether withdraw from the study.

(Pause to provide the interviewee an opportunity to comment if they would like to)

Interviewer: I understand that sometimes changes to your mental health can affect participation in day-to-day activities and I would appreciate your thoughts on what I should do if this happens during the interview. If you cannot continue with the study because of changes to your mental health, then we will provide you with other opportunities in the future.

(Pause to provide the interviewee an opportunity to comment if they would like to)

Interviewer: I would also like to get your permission to disclose information that may be important to maintaining your health and wellbeing to appropriate support staff at (Centre Name Blocked for Confidentiality). I will do this in a respectful manner, by ensuring that I inform you first, and I will only provide this information to the staff member that you nominate. I will do this if you decide continue with the interview.

(Pause to provide the interviewee an opportunity to comment if they would like to)

Interviewer: As part of the consent process, we are also seeking permission to pass on information that may negatively affect your health and wellbeing to relevant emergency health or crisis services. This information may be passed on to these services without further consent from you, other than that provided in the consent form.

(Pause to provide the interviewee an opportunity to comment if they would like to)

Interviewer: All the information that you provide during the interview will be confidential to me and I will conceal your identity and that of (Centre Name Blocked for Confidentiality) in any results. I will provide you with the opportunity to request a summary of the results when filling out the consent form.

(Pause to provide the interviewee an opportunity to comment if they would like to)

Interviewer: That was a lot of information, do you have any questions about what I have said or do you need anything clarified?

(Pause to provide the interviewee an opportunity to comment if they would like to)

Interviewer: If you would like to go ahead with the interview, then I will give you a consent form to sign which you will do with a staff member present, if that is okay with you. We invite someone else to make this process transparent and also to ensure that you have not been coerced into participating.

Interviewer: If you would no longer like to participate in the study, this is the end for now but I would like to thank you for the time you have given to this study.

(Pause to provide the interviewee an opportunity to comment)

(Excuse yourself to call the member of staff)

Interviewer: Please sign the consent form if you agree to take part in the interview.

(Allow the participant time to complete the consent form and release the staff member once this process is complete)

Interviewer: Thank you for providing written consent to participate in this study. We will now start the interview.

1. What programs do you attend at (Centre Name Blocked for Confidentiality)?
    a. Do you choose these programs? * *If applicable* How do you choose these programs? *(Prompt if necessary for information related to cost, content and duration of programs, program days and time)*
    b. How do you find out about programs?
    c. What do you enjoy about the programs that you attend?
    d. What do you not enjoy about the programs you attend?
    e. Why do you continue attending certain programs?
    f. Why do you discontinue certain programs?
2. What do you like about how staff run programs?
3. What do you not like about how staff run programs?
4. Are there things that make it difficult to attend programs?

a. What are these things? * *If applicable*

b. Does your health affect participation or your attendance of programs? **if not mentioned*

c. If so how?

d. Would you like to be supported by staff if it's harder to attend or participate in programs because of your health? * *If applicable*

e. If so how?

5. Do you think you need a new healthy living program at (Centre Name Blocked for Confidentiality) which promotes good nutrition and adequate physical activity to help you maintain your health? **Prompt*
    a. Can you please explain some of the reasons behind your answer?

If participants do not see the need for a healthy living program, then end the interview here with the phrase 'Thank you for your participation. That is the end of the interview.'

If they, however, see the need for a healthy living program, proceed with the phrase 'We will now have our mid-way 15 minute break. If you do not want to take a break, we will continue with the interview'

6. Would you like to receive education as part of the healthy living program? * *If applicable* a. What are some of the topics you would like covered?

7. How often would you consider attending the healthy living program? **Prompt*
    a. What are some of the reasons behind your answer?
8. Who would you like to see deliver the healthy living program? **Prompt*
    a. What are the reasons behind your answer?
9. Do you have some personal goals you would like to achieve if you attended the healthy living program? * *If applicable*
    a. What are these personal goals?
10. Would program cost influence your decision to attend the healthy living program? **Prompt*
    a. Please give me some reasons behind your answer
11. How would you feel about attending the healthy living program with a friend or family member if you chose to attend this program? **If applicable*
    a. Please give me some reasons behind your answer

Thank you for your participation. That is the end of the interview.

Appendix 12: Interview Protocol for Staff in Chapter 6

Interview Questions for the Research Project: Developing an Implementation Plan for "A Healthy Living Program" in People with Psychosis and Other Severe Mental Illness within a Community Managed Organisation

Version 3 (7/11/2018)

Interview Questions for Support Workers, Primary Recovery Support Worker and Site Coordinator

Participants

Interviewer: Doreen Mucheru (Student Researcher)

Interviewee: Support Workers/ Primary Recovery Support Worker/ Site Coordinator at (Centre Name Blocked for Confidentiality)

Welcome/ Orientation

Interviewer: Hello _____ (use the name of the interviewee). How are you?

(Pause to provide the interviewee an opportunity respond)

Interviewer: Thank you for agreeing to meet with me today. I wanted to meet with you so I could know more about the things that need to be considered when one is involved with delivering or running programs at (Centre Name Blocked for Confidentiality).

(Pause to provide the interviewee an opportunity to comment if they would like to)

Interviewer: The interview is expected to take a maximum of 1 hour 30 minutes, with a 15-minute break. You can choose to stop the interview at any time to have another break, or if you no longer wish to participate. You are not required to give a reason for changing your mind about participating.

(Pause to provide the interviewee an opportunity to comment if they would like to)

Interviewer: If you seem uncomfortable during the interview, then I will offer you the opportunity to take a break, postpone the interview or altogether withdraw from the study.

(Pause to provide the interviewee an opportunity to comment if they would like to)

Interviewer: All the information that you provide during the interview will be confidential to me and I will conceal your identity and that of (Centre Name Blocked for Confidentiality) in any results. I will provide you with the opportunity to request a summary of the results when filling out the consent form.

(Pause to provide the interviewee an opportunity to comment if they would like to)

Interviewer: That was a lot of information, do you have any questions about what I have said or do you need anything clarified?

(Pause to provide the interviewee an opportunity to comment if they would like to)

Interviewer: If you would like to go ahead with the interview, then I will give you a consent form to sign which you will do with another staff member present, if that is okay with you. We invite

someone else to make this process transparent and also to ensure that you have not been coerced into participating.

Interviewer: If you would no longer like to participate in the study, this is the end for now but I would like to thank you for the time you have given to this study.

(Pause to provide the interviewee an opportunity to comment)

(Excuse yourself to call the other member of staff)

Interviewer: Please sign the consent form if you agree to take part in the interview.

(Allow the participant time to complete the consent form and release the witness once this process is complete)

Interviewer: Thank you for providing written consent to participate in this study. We will now commence with the interview.

1. Are you involved in running or developing programs delivered at (Centre Name Blocked for Confidentiality)? **If applicable*
    a. What role/s do you play in the programs?

2. Do you know how the programs you are involved with were developed? **If applicable*
    a. Please tell me how?
    b. Do you receive support prior to running new programs?
    c. What kind of support do you find helpful?

    d. What kind of support do you not find helpful?

3. How would you define evidence-based practice? **If no answer, the following definition will be provided.*

    Evidence-based practice is the diligent and judicious application of the best evidence from research, the clinical environment and patient values to guide healthcare in patients (269).
    a. Is evidence-based practice applied when delivering programs? **If applicable*
    b. How is this done? ** Prompt – Is there a process or guideline that (Centre Name Blocked for Confidentiality) follows when implementing a program?*

4. What affects your motivation in your involvement with client programs?
5. Can you usually gauge if clients are enjoying programs? **If applicable*

    a. How do you do this?

We will now have our mid-way 15 minute break. If you do not wish to take a break, we will continue with the interview

6. Are there factors that are associated with the clients' continued participation or engagement with programs? **If applicable*
    a. Please explain some of these factors?

7. How do you define program success?
    a. What features in a program make it successful?

8. Do you see the need for a new healthy living program focusing on good nutrition and adequate physical activity at (Centre Name Blocked for Confidentiality)? ** Prompt*

a. Please give me the reasons behind your answer? **If applicable*

If participants do not see the need for a healthy living program, then end the interview here with the phrase 'Thank you for your participation. That is the end of the interview.'

9. What would you like to see the healthy living program achieve?

10. How do you think clients would benefit from the healthy living program?
11. Are there some things in the workplace that would make it difficult to have the healthy living program? **If applicable*

    a. Please tell me about these things
    b. Tell me about any workplace changes that might be needed to make it possible to have the healthy living program?
12. Would you need any support in the workplace if you were to be involved with the healthy living program? **If applicable*
    a. What kind of support do you anticipate that you would need?

Thank you for your participation. That is the end of the interview.

Appendix 13: Interview Protocol for Manager in Chapter 6

Interview Questions for the Research Project: Developing an Implementation Plan for "A Healthy Living Program" in People with Psychosis and Other Severe Mental Illness within a Community Managed Organisation

Version 3 (7/11/2018)

Interview Questions for the Area Leader

Participants

Interviewer: Doreen Mucheru (Student Researcher)

Interviewee: Area Leader

Welcome/ Orientation

Interviewer: Hello _____ (use the name of the interviewee). How are you?

(Pause to provide the interviewee an opportunity respond)

Interviewer: Thank you for agreeing to meet with me today. I wanted to meet with you so we could discuss the factors that require consideration when running programs at (Centre Name Blocked for Confidentiality).

(Pause to provide the interviewee an opportunity to comment if they would like to)

Interviewer: The interview is expected to take a maximum of 1 hour 30 minutes, with a 15-minute break. You can choose to stop the interview at any time if you desire a break, or if you no longer wish to participate. You are not required to give reasons for withdrawing from the study.

(Pause to provide the interviewee an opportunity to comment if they would like to)

Interviewer: If you seem uncomfortable during the interview, then I will offer you the opportunity to take a break, postpone the interview or altogether withdraw from the study.

(Pause to provide the interviewee an opportunity to comment if they would like to)

Interviewer: All the information that you provide during the interview will be confidential to me and I will conceal your identity and that of (Centre Name Blocked for Confidentiality) in any results. I will provide you with the opportunity to request a summary of the results when filling out the consent form.

(Pause to provide the interviewee an opportunity to comment if they would like to)

Interviewer: That was a lot of information, do you need anything clarified?

(Pause to provide the interviewee an opportunity to comment if they would like to)

Interviewer: If you would like to proceed with the interview, then I will give you a consent form to sign which we will do with a witness present.

Interviewer: If you would no longer like to participate in the study, this is the end for now but I would like to thank you for the time you have given to this study.

(Pause to provide the interviewee an opportunity to comment)

(Excuse yourself to call the witness)

Interviewer: Please sign the consent form if you agree to take part in the interview.

(Allow the participant time to complete the consent form and release the witness once this process is complete)

Interviewer: Thank you for providing written consent to participate in this study. We will now commence with the interview.

1. What are some of the services and programs offered to clients at this branch of (Centre Name Blocked for Confidentiality)?
2. What is the process of selecting programs that are delivered to clients?
3. Do you have a system in place that assesses the relevance of current programs to client needs? **If applicable*
    a. How do you do this?
4. Do you evaluate the success of programs? **If applicable*
    a. How do you do this?
5. Are there factors that make a program sustainable over time? **If applicable*
    a. What are these factors?
    b. What kind of programs have been discontinued?
6. Are there regulations that new programs have to abide by?
    a. What are these regulations?
7. How are programs funded?
    a. Are there challenges associated with obtaining this funding? **If applicable*
    b. What are these challenges?
    c. What is the process of navigating through these challenges?

We will now have our mid-way 15 minute break. If you do not wish to take a break, we will continue with the interview

8. Are there organisational resources that are available for programs?
    a. What are these resources?
9. How do you initiate new programs?
10. Are staff trained to deliver new programs? **If applicable*
    a. How is this done?
11. Do you think there is a current need for an evidence-based healthy living program which focuses on good nutrition and adequate physical activity? **Prompt*
    a. What are some of the reasons behind your answer?

If participant does not see the need for a healthy living program, then end the interview here with the phrase 'Thank you for your participation. That is the end of the interview.'

12. What are the barriers to the implementation of the healthy living program?
    a. What are the enablers to the implementation of the healthy living program?
13. Which individuals should be involved in the implementation of the healthy living program?

14. Are there some incentives that can be put in place to promote interest and engagement with the healthy living program by staff/ clients?
a. What are these incentives?

Thank you for your participation. That is the end of the interview.

Appendix 14: CONSORT Statement for Randomized Trials of Nonpharmacologic Treatments: A 2017 Update and a CONSORT Extension for Nonpharmacologic Trial Abstracts

From: Ann Intern Med. 2017;167(1):40-47. doi:10.7326/M17-0046

Table 1. 2017 CONSORT Checklist of Information to Include When Reporting Randomized Trials Assessing NPTs*

Checklist Item Number, by Section/Topic Item	CONSORT Item	Extension for NPT Trials
Title and abstract		
1a	Identification as a randomized trial in the title	–
1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	Refer to CONSORT extension for abstracts for NPT trials
Introduction		
Background and objectives		
2a	Scientific background and explanation of rationale	–
2b	Specific objectives or hypotheses	–
Methods		
Trial design		
3a	Description of trial design (such as parallel, factorial) including allocation ratio	When applicable, how care providers were allocated to each trial group
3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	–
Participants		
4a	Eligibility criteria for participants	When applicable, eligibility criteria for centers and for care providers
4b	Settings and locations where the data were collected	–

Interventions†		
5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Precise details of both the experimental treatment and comparator
5a		Description of the different components of the interventions and, when applicable, description of the procedure for tailoring the interventions to individual participants.
5b		Details of whether and how the interventions were standardized.
5c		Details of whether and how adherence of care providers to the protocol was assessed or enhanced
5d		Details of whether and how adherence of participants to interventions was assessed or enhanced
Outcomes		
6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	-
6b	Any changes to trial outcomes after the trial commenced, with reasons	-

Sample size		
7a	How sample size was determined	When applicable, details of whether and how the clustering by care providers or centers was addressed
7b	When applicable, explanation of any interim analyses and stopping guidelines	-
Randomization		
Sequence generation		
8a	Method used to generate the random allocation sequence	-
8b	Type of randomization; details of any restriction (such as blocking and block size)	-
Allocation concealment mechanism		
9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	-

Implementation		
10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	-
Blinding		
11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	If done, who was blinded after assignment to interventions (e.g., participants, care providers, those administering co-interventions, those assessing outcomes) and how
11b	If relevant, description of the similarity of interventions	
11c		If blinding was not possible, description of any attempts to limit bias

Statistical methods		
12a	Statistical methods used to compare groups for primary and secondary outcomes	When applicable, details of whether and how the clustering by care providers or centers was addressed
12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	-
Results		
Participant flow (a diagram is strongly recommended)		
13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analyzed for the primary outcome	The number of care providers or centers performing the intervention in each group and the number of patients treated by each care provider or in each center
13b	For each group, losses and exclusions after randomization, together with reasons	-
13c		For each group, the delay between randomization and the initiation of the intervention
New		Details of the experimental treatment and comparator as they were implemented

Recruitment		
14a	Dates defining the periods of recruitment and follow-up	-
14b	Why the trial ended or was stopped	-
Baseline data		
15	A table showing baseline demographic and clinical characteristics for each group	When applicable, a description of care providers (case volume, qualification, expertise, etc.) and centers (volume) in each group
Numbers analyzed		
16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	-
Outcomes and estimation		
17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	-
17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	-
Ancillary analyses		
18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	-
Harms		
19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	-

Discussion		
Limitations		
20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	In addition, take into account the choice of the comparator, lack of or partial blinding, and unequal expertise of care providers or centers in each group
Generalizability		
21	Generalizability (external validity, applicability) of the trial findings	Generalizability (external validity) of the trial findings according to the intervention, comparators, patients, and care providers and centers involved in the trial
Interpretation		
22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	-
Other information		
Registration		
23	Registration number and name of trial registry	-
Protocol		
24	Where the full trial protocol can be accessed, if available	-
Funding		
25	Sources of funding and other support (such as supply of drugs), role of funders	-

CONSORT = Consolidated Standards of Reporting Trials; NPT = nonpharmacologic treatment.
* Additions or modifications to the 2010 CONSORT checklist. Modifications of the extension are in boldface.
† These items are consistent with the Template for Intervention Description and Replication (TIDieR) checklist.