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Physical activity during weight loss and weight loss maintenance in men: An experimental application of Social Cognitive Theory

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BPsych (Hons 1A)

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Thesis submitted in fulfilment of the requirements for the award of the degree of:

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Statement of Originality

This thesis contains no material which has been accepted 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 in the text. 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.

Signed: --

Name: Myles David Young

Date: 04/09/2014

Thesis by Publication

I hereby certify that this thesis is in the form of a series of published papers of which I am a joint author. I have included as part of the thesis a written statement from each co-author, endorsed by the Faculty Assistant Dean (Research Training), attesting to my contribution to the joint publications.

Signed: --

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Finally, I feel it is important to mention that when I was accepted into the PhD program, I sent a text message to a girl in the hope that the news might somehow impress her. Fast-forward four years and now we are planning our wedding and living in our own house. I guess it worked! To my wonderful Alyce, I could never put into words how much your kindness, love and support have meant to me through this experience. I love you dearly and am so proud of the life we have created together.

Publications and Presentations Arising from this Thesis

This thesis is presented as a series of seven papers. At the time of submission, five of these papers were published and two were under review.

Manuscripts in peer-reviewed journals: Published

1. **Young, M.D.,** Morgan, P.J., Plotnikoff, R.C., Callister, R., & Collins, C.E. (2012). Effectiveness of male-only weight loss and weight loss maintenance interventions: A systematic review with meta-analysis. *Obesity Reviews*, 13, 393-408. 2013 Impact Factor: 7.9. 2013 ISI Journal Citation Reports © Ranking: 7/123 (Endocrinology & Metabolism).

2. **Young, M.D.,** Collins, C.E., Callister, R., Plotnikoff, R.C., Doran, C.M., & Morgan, P.J. (2014). The SHED-IT weight loss maintenance trial protocol: A randomised controlled trial of a weight loss maintenance program for overweight and obese men. *Contemporary Clinical Trials*, 37, 84-97. 2013 Impact Factor: 2.0. 2013 ISI Journal Citation Reports © Ranking: 150/254 (Pharmacology and Pharmacy).

3. **Young, M.D.,** Plotnikoff, R.C., Collins, C.E., Callister, R., & Morgan, P.J. (2014). Social Cognitive Theory and physical activity: A systematic review and meta-analysis. *Obesity Reviews*, 15, 983-995. 2013 Impact Factor: 7.9. 2013 ISI Journal Citation Reports © Ranking: 7/123 (Endocrinology & Metabolism).

4. **Young, M.D.,** Lubans, D.R., Collins, C.E., Callister, R., Plotnikoff, R.C., & Morgan, P.J. (2015). Behavioural mediators of weight loss in the SHED-IT community randomized controlled trial for overweight and obese men. *Annals of Behavioural Medicine*, 49, 286-292. 2013 Impact factor: 3.6. 2013 ISI Journal Citation Reports © Ranking: 15/127 (Psychology, Multidisciplinary).

5. **Young, M.D.,** Plotnikoff, R.C., Callister, R., Collins, C.E., & Morgan, P.J. (in press). Impact of a male-only weight loss maintenance program on social-cognitive determinants of physical activity and healthy eating: A randomised controlled trial. *British Journal of Health Psychology*. Accepted 20th February 2015. 2013 Impact factor: 2.0. 2013 ISI Journal Citation Reports © Ranking: 44/111 (Psychology Clinical).

Manuscripts in peer-reviewed journals: Under review

1. **Young, M.D.,** Morgan, P.J., Collins, C.E., Callister, R., & Plotnikoff, R.C. (under review). A test of Social Cognitive Theory to explain physical activity changes in a weight loss program for men. *American Journal of Men's Health*.

2. Morgan, P.J., **Young, M.D.,** Collins, C.E., Plotnikoff, R.C., & Callister, R. (under review). Effectiveness of a scalable, gender-tailored intervention to prevent weight regain in men: The SHED-IT Weight Loss Maintenance randomised controlled trial. *International Journal of Obesity*.

Conference abstracts: Published in peer-reviewed journals

1. **Young, M.D.,** Morgan, P.J., Plotnikoff, R.C., Callister, R. & Collins, C.E. (2011). Development of a male-only weight loss maintenance program: Evaluating the SHED-IT Weight Loss Maintenance Program materials for quality, suitability and theoretical merit. *Obesity Research & Clinical Practice*, 5(Supplement 1): S66-S67. (Poster presentation). Australian & New Zealand Obesity Society (ANZOS) Annual Scientific Meeting, Adelaide, Australia, October 20-22, 2011.

2. **Young, M.D.,** Morgan, P.J., Plotnikoff, R.C., Callister, R., & Collins, C.E. (2012). Effectiveness of male-only weight loss and weight loss maintenance interventions: A systematic review with meta-analysis. *Obesity Research & Clinical Practice*, 6(Supplement 1): S84. (Poster presentation). Australian & New Zealand Obesity Society (ANZOS) Annual Scientific Meeting, Auckland, New Zealand, October 18-20, 2012.

Conference abstracts: Published in peer-reviewed conference proceedings

1. **Young, M.D.,** Morgan, P.J., Plotnikoff, R.C. Collins, C.E., & Callister, R. (2011). The SHED-IT Weight Loss Maintenance Study: Development of a theory based weight loss maintenance intervention exclusively targeting men. (Poster presentation). International Society for Behavioural Nutrition and Physical Activity (ISBNPA) Meeting, Melbourne, Australia, June 15-18, 2011.

2. **Young, M.D.,** Plotnikoff, R.C., Callister, R., Collins, C.E., & Morgan, P.J. (2015). A test of Social Cognitive Theory to explain physical activity changes in a weight loss program for men. (Oral presentation). International Society for Behavioural Nutrition and Physical Activity (ISBNPA) Meeting, Edinburgh, United Kingdom, June 3-6, 2015.

Additional Publications Co-authored During Candidature

Prior to commencing my PhD, I worked as a full-time research assistant at the University of Newcastle's Priority Research Centre in Physical Activity and Nutrition. The two major projects I worked on were the SHED-IT Community Weight Loss Randomised Controlled Trial (RCT) and the Healthy Dads Healthy Kids Community RCT. As a result of my practical and intellectual contributions to these projects, I was invited to contribute as a co-author on a several additional publications during my candidature. Further, during my PhD I learnt how to perform a number of advanced statistical procedures (e.g., linear mixed models, meta-analyses, structural equation modelling, and mediation analyses). As I remained employed by the centre for one day each week, I was able to use these skills to mentor other students and conduct novel analyses on existing datasets for other researchers. These contributions also led to co-authorship opportunities. Details of the additional papers I co-authored during my candidature are provided below.

Additional manuscripts in peer-reviewed journals: Published/Accepted for publication

1. Riley, N., Lubans, D.R., **Young, M.D.,** & Morgan, P.J. (in press). Outcomes and process evaluation of a program integrating physical activity into the primary school mathematics curriculum: The E.A.S.Y. (Encouraging Activity to Stimulate Young) Minds pilot randomized controlled trial. *Journal of Science and Medicine in Sport*. Accepted 1st September 2014. 2013 Impact Factor: 3.1. ISI Journal Citation Reports © Ranking: 2013: 9/81 (Sports Sciences).

2. Blomfield, R.L., Collins, C.E., Hutchesson, M.J., **Young, M.D.,** Jensen, M.E., Callister, R., Morgan, P.J. (2014). Impact of self-help weight loss resources with or without online support on the dietary intake of overweight and obese men: The SHED-IT randomised controlled trial. *Obesity Research & Clinical Practice*, 8, e476-e487. 2013 Impact Factor: 0.7. ISI Journal Citation Reports © Ranking: 2013: 68/78 (Nutrition & Dietetics).

3. Aguiar, E.A., Morgan, P.J., Collins, C.E., **Young, M.D.,** Plotnikoff, R.C., & Callister, R. (2014). The PULSE (Prevention Using Lifestyle Education) trial protocol: A randomised controlled trial of a diabetes prevention program for overweight and obese men. *Contemporary Clinical Trials*, 39, 132-144. 2013 Impact Factor: 2.0. ISI Journal Citation Reports © Ranking: 2013: 150/254 (Pharmacology and Pharmacy).

4. Hollis, J.L., Williams, L.T., **Young, M.D.,** Pollard, K.T., Collins, C.E., & Morgan, P.J. (2014). Compliance to step count and vegetable serve recommendations mediates 24-month weight loss in mid-age premenopausal women. *Appetite*, 83, 33-41. 2013 Impact Factor: 2.5. ISI Journal Citation Reports © Ranking: 2013: 78/338 (Neuroscience & Behaviour).

5. Morgan, P.J., Scott, H.A., **Young, M.D.,** Plotnikoff, R.C., Collins, C.E., Callister, R. (2014). Associations between program outcomes and adherence to Social Cognitive Theory tasks: Process evaluation of the SHED-IT community weight loss trial for men. *International Journal of Behavioural Nutrition and Physical Activity*, 11:89. 2013 Impact Factor: 3.7. ISI Journal Citation Reports © Ranking: 2013: 16/81 (Physiology).

6. Morgan, P.J., Collins, C.E., Plotnikoff, R.C., Callister, R., Burrows, T., Fletcher, R., Okely, A.D., **Young, M.D.,** Miller, A., Lloyd, A.B., Cook, A.T., Cruickshank, J., Saunders, K.L., & Lubans, D.R. (2014). The 'Healthy Dads, Healthy Kids' community randomized controlled trial: A community-based healthy lifestyle program for fathers and their children. *Preventive Medicine*, 61, 90-99. 2013 Impact Factor: 2.9. ISI Journal Citation Reports © Ranking: 2013: 25/150 (Medicine, General & Internal).

7. Collins, C.E., Jensen, M., **Young, M.D.,** Callister, R., Plotnikoff, R.C., & Morgan, P.J. (2014). Improvement in erectile function following weight loss in obese men: The SHED-IT randomized controlled trial. *Obesity Research &*

Clinical Practice, 7(6), e450-454. 2013 Impact Factor: 0.7. ISI Journal Citation Reports © Ranking: 2013: 68/78 (Nutrition & Dietetics).

8. Morgan, P.J., Callister, R., Collins, C.E., Plotnikoff, R.C., **Young, M.D.,** Berry, N., McElduff, P., Burrows, T., Aguiar, E., & Saunders, K.L. (2013). The SHED-IT community trial: a randomised controlled trial of Internet- and paper-based weight loss programs tailored for overweight and obese men. *Annals of Behavioural Medicine*, 45, 139-152. 2013 Impact Factor: 3.6. ISI Journal Citation Reports © Ranking: 2013: 15/127 (Psychology, Multidisciplinary).

9. Collins, C.E., Neve, M., Morgan, P.J., Fletcher, K., Williams, R., **Young, M.D.,** & Callister, R. (2013). Effectiveness of interventions with a dietary component on weight loss maintenance. *The JBI Database of Systematic Reviews and Implementation Reports,* 11(8), 317-414. Impact factor: N/A.

10. Collins, C.E., Burrows, T.L., Bray, J., Asher, R., **Young, M.D.,** Morgan, P.J. (2013). Effectiveness of parent-centred interventions for the prevention and treatment of childhood overweight and obesity in community settings: a systematic review. *The JBI Database of Systematic Reviews and Implementation Reports,* 11(9), 180-257. Impact factor: N/A.

11. Morgan, P.J., Lubans, D.R., Plotnikoff, R.C., Callister, R.., Burrows, T., Fletcher, R., Okely, A.D., **Young, M.D.,** Miller, A., Clay, V., Lloyd, A., & Collins, C.E. (2011). The 'Healthy Dads Healthy Kids' community effectiveness trial: study protocol of a community-based lifestyle program for fathers and their children. *BMC Public Health*, 11, 876. 2013 Impact Factor: 2.3. ISI Journal Citation Reports © Ranking: 2013: 51/160 (Public, Environmental & Occupational Health).

12. Morgan, P.J., Collins, C.E., Plotnikoff, R.C., McElduff, P., Burrows, T., Warren, J.M., **Young, M.D.,** Berry, N., Saunders, K.L., Aguiar, E., & Callister, R. (2010). The SHED-IT community trial study protocol: a randomised controlled

trial of weight loss programs for overweight and obese men. *BMC Public Health*, 10, 701. Impact factor: 2.3. ISI Journal Citation Reports © Ranking: 2013: 51/160 (Public, Environmental & Occupational Health).

Additional manuscripts in peer-reviewed journals: Under review

1. Morgan, P.J., Hollis, J.L., **Young, M.D.,** Collins, C.E., Teixeira, P.J. (under review). Pre-treatment predictors of weight loss, behaviour change, and attrition in overweight and obese men: Results from a randomized controlled trial, *American Journal of Men's Health*.

2. Aguiar, E.A., Morgan, P.J., Collins, C.E., Plotnikoff, R.C., **Young, M.D.,** & Callister, R. (under review). Reductions in weight and HbA1C following a 6-month self-administered, gender-tailored lifestyle intervention for men: The type 2 diabetes mellitus PULSE Program randomized controlled trial. *American Journal of Preventive Medicine.*

3. Ashton, L.M., Morgan, P.J., Hutchesson, M.J., Rollo, M.E., **Young, M.D.,** & Collins, C.E. (under review). A systematic review of SNAPO (Smoking, Nutrition, Alcohol, Physical activity, and Obesity) randomized controlled trials in young adult men. *American Journal of Public Health*.

Additional conference abstracts: Published in peer-reviewed journals

1. Miller, A., Morgan, P.J., Lubans, D.R., Plotnikoff, R., Callister, R. Okely, A.D., Burrows, T.L., Fletcher, R., Collins, C.E., Lloyd, A., Cook, A., Clay, V., & **Young, M.D.** (2011). Effective strategies for the recruitment of overweight men and their children into a community trial: The Healthy Dads, Healthy Kids recruitment story. *Obesity Research & Clinical Practice*, 5(Supplement 1): S68. (Poster presentation). Australian & New Zealand Obesity Society (ANZOS) Annual Scientific Meeting, Adelaide, Australia, October 20-22, 2011.

2. Morgan, P.J., Callister, R., Collins, C.E., Plotnikoff, R.C., **Young, M.D.,** Berry, N., McElduff, P., Burrows, T., Aguiar, E., & Saunders, K.L. (2012). Physical

activity outcomes from the SHED-IT RCT: An evaluation of theoretically-based, gender-sensitised weight loss programs for men. *Journal of Science and Medicine in Sport*, 15, (Supplement 1): S367. (Oral presentation). Be Active Conference, Sydney, Australia, October 31 – November 3, 2012.

3. Saunders, K., Morgan, P.J., Callister, R., Collins, C.E., Plotnikoff, R.C., **Young, M.D.,** Berry, N., McElduff, P., Burrows, T., & Aguiar, E. (2012). Insights into engaging men in weight loss: Process evaluation of the SHED-IT RCT of gender-sensitised weight loss programs for overweight and obese men. *Journal of Science and Medicine in Sport*, 15, (Supplement 1): S348. (Poster presentation). Be Active Conference, Sydney, Australia, October 31 – November 3, 2012.

4. **Young, M.D.,** Morgan, P.J., Plotnikoff, R.C., Collins, C.E., & Callister, R. (2012). Relationship between physical activity outcomes and adherence to paper-based social cognitive tasks in a weight loss program for men. *Journal of Science and Medicine in Sport,* 15(Supplement 1): S351. (Poster presentation). Be Active Conference, Sydney, Australia, October 31 – November 3, 2012.

5. Morgan, P.J., Callister, R., Collins, C.E., Plotnikoff, R.C., **Young, M.D.,** Berry, N., McElduff, P., Burrows, T., Aguiar, E., & Saunders, K. (2012). The SHED-IT Community Trial: A randomised controlled trial of Internet- and paper-based weight loss programs tailored for overweight and obese men. *Obesity Research & Clinical Practice*, 6(Supplement 1): S30-S31. (Oral presentation). Australian & New Zealand Obesity Society (ANZOS) Annual Scientific Meeting, Auckland, New Zealand, October 18-20, 2012.

6. Ashton, L., Rollo, M., Hutchesson, M., **Young, M.D.,** Morgan, P., Callister, R., Plotnikoff, R.C., & Collins, C. (2013). A comparison of outcomes of young and old adult males in the SHED-IT weight loss program for men. *Obesity Research & Clinical Practice*, 7(Supplement 2): e96-97. (Poster presentation). Australian

& New Zealand Obesity Society (ANZOS) Annual Scientific Meeting, Melbourne, Australia, October 17-19, 2013.

7. Collins, C.E., Jensen, M.J., **Young, M.D.,** Callister, R., Plotnikoff, R.C., & Morgan, P.J. (2013). Erectile function improves in obese men following weight loss during the SHED-IT randomised controlled trial. Obesity Research & Clinical Practice, 7 (Supplement 2): E71. (Poster presentation). Australian & New Zealand Obesity Society (ANZOS) Annual Scientific Meeting, Melbourne, Australia, October 17-19, 2013.

8. Morgan, P.J., Scott, H., **Young, M.D.,** Callister, R., Collins, C.E., & Plotnikoff, R.C. (2014). Process evaluation of the SHED-IT community weight loss program for men: program engagement and its association with changes to weight, physical activity, and dietary intake. Obesity Reviews, 15(Supplement 2): 149. (Poster presentation). International Congress on Obesity, Kuala Lumpur, Malaysia, March 17-20, 2014.

9. **Young, M.D.,** Morgan, P.J., Hollis, J.L., Collins, C.E., & Teixeira, P.J. (2014). Sitting time at work and marital status: novel pre-treatment predictors of weight loss success in overweight and obese men. Obesity Reviews, 15(Supplement 2): 149. (Poster presentation). International Congress on Obesity, Kuala Lumpur, Malaysia, March 17-20, 2014.

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List of Abbreviations

BMI	Body-Mass Index
CONSORT	Consolidated Standards of Reporting Trials
HMRI	Hunter Medical Research Institute
kJ	Kilojoule
MVPA	Moderate-to-Vigorous Physical Activity
NWCR	National Weight Control Registry
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-analyses
RCT	Randomised Controlled Trial
SCT	Social Cognitive Theory
SD	Standard Deviation
SHED-IT	Self-Help, Exercise and Diet using Information Technology
TPB	Theory of Planned Behaviour
95% CI	95% Confidence Intervals

Note. This list represents the abbreviations used in the main text of the thesis. Additional abbreviations in tables are defined in the bottom row.

Thesis Abstract

Background

Australian men are a high-risk group for weight-related disease. Although behavioural weight loss programs have well-documented short-term efficacy, longer term results are poor, most programs are too intensive for realistic dissemination, few are based in theory, and the vast majority have failed to engage men. Although additional 'weight loss maintenance' interventions have shown initial promise to reduce the rate of weight regain, the evidence base for these programs is limited by many of the same concerns. Further, while successful weight loss maintenance requires a clear and sustained increase in physical activity, little is known about which cognitive, behavioural, or social factors are most important to target in interventions to increase physical activity in men. Currently, an evidence gap exists for effective, theory-based weight loss and weight loss maintenance programs for men that could be realistically rolled-out at the population level.

Objectives

This thesis-by-publication presents a series of studies that were conducted to address this gap in the evidence. Overall, these studies relate to: i) the utility of Bandura's Social Cognitive Theory (SCT) to explain physical activity behaviour, and/or ii) the development and evaluation of the SCT-based *SHED-IT (Self-help, Exercise and Diet using Information Technology) Weight Loss Maintenance Program* for men. This program was designed to follow on from the previously established and evaluated *SHED-IT Weight Loss Program,* to provide men with new knowledge and skills to maintain their weight loss over time.

Given the well-established importance of sustained increases in moderate-to-vigorous physical activity (MVPA) for weight loss maintenance, the primary aim of this thesis was to evaluate the effects of the *SHED-IT Weight Loss Maintenance Program* on men's MVPA cognitions and MVPA behaviour, 12 months after successfully completing the *SHED-IT Weight Loss Program*. The thesis also presents a series of studies investigating five key secondary aims, which are briefly described below. As

these studies provide important context for the primary analysis, the secondary aims are presented first in this thesis, in the following order:

Secondary Aim 1: To synthesise the current evidence base regarding the effectiveness of male-only weight loss and weight loss maintenance interventions.

To investigate this aim, a systematic literature search with no date restrictions was conducted across eight databases. In total, 24 articles describing 23 studies met the eligibility criteria. A fixed effects meta-analysis revealed a significant difference in weight change favouring weight loss interventions over no-intervention controls (weighted mean difference -5.66kg [-6.35,-4.97]), but study quality was mostly poor. Characteristics common to intervention effectiveness were: younger sample, increased contact, group face-to-face contact, and prescribed energy restrictions.

Secondary Aim 2: To systematically review the evidence for the utility of Social Cognitive Theory as a framework to explain physical activity

Ten electronic databases were systematically searched. Overall, 44 studies were retrieved containing 55 SCT models of physical activity. A random-effects meta-analysis revealed that SCT accounted for 31% of the variance in physical activity, but overall quality was poor. Methodological quality and sample age moderated the effect size for physical activity, with better quality and a higher mean age associated with greater variance explained. While self-efficacy and goals were consistently associated with physical activity, outcome expectations and socio-structural factors were not.

Secondary Aim 3: To identify behavioural mediators of sustained weight loss in a previous male-only weight loss study

In a secondary analysis of data from the SHED-IT Weight Loss Community Trial, an intention-to-treat, multiple-mediator model revealed the significant effect of the *SHED-IT Weight Loss Program* on weight at 6 months was mediated by increases in physical activity (steps/day) and decreases in take-away meals (kilojoules/day) and portion size at 3 months. The largest mediation effect was for physical activity (-0.6 kg; 95% CI -1.4,-0.1). Overall, the mediators accounted for 47% of the intervention's effect on weight.

Secondary Aim 4: To examine the utility of SCT as a theoretical framework to explain the physical activity changes of men during weight loss

Using data from Phase I of the *SHED-IT Weight Loss Maintenance Trial*, this study examined the utility of SCT to explain the physical activity changes of 204 men during weight loss. A longitudinal structural equation model revealed that SCT explained 61% of the variance in physical activity. All hypothesised pathways from cognitions to behaviour were supported with significant effects, except for the direct effect from outcome expectations. The strongest effects on physical activity were observed through changes in self-efficacy and intention.

Secondary Aim 5: To evaluate the effect of the SHED-IT Weight Loss Maintenance Program on men's weight and other health outcomes, 12 months after successfully completing the SHED-IT Weight Loss Program

In a two-phase, parallel-group, assessor-blinded, RCT, 92 overweight/obese men, who had lost at least 4kg following the 3-month *SHED-IT Weight Loss Program* (Phase I), were randomised (Phase II) to either the (i) *SHED-IT Weight Loss Maintenance Program* or (ii) a self-directed control group, who received no additional resources. The 6-month *SHED-IT Weight Loss Maintenance Program* included written materials (handbook, logbook), bi-weekly text messages, emails (including video messages) and resources (website, pedometer, gymstick).

Following Phase I, mean (SD) weight loss was 7.3 (2.5) kg (range 4.1-18.3 kg). At 12 months, the intervention group had regained 0.6 kg (95% CI -0.9. 2.2) (8% of Phase I weight loss) and the control group had regained 2.1 kg (95% CI 0.5, 3.7) (28% of Phase I weight loss), with no significant difference between groups (-1.5 kg, 95% CI, -3.7, 0.7, p=0.19). Significant treatment effects were found for fruit and vegetable intake (serves/day) and frequency of breakfast consumption at 12-months. While no between-group effect was found for weight, both groups demonstrated comparable maintenance to other, far more intensive, weight loss maintenance programs in the literature.

Primary Aim: The primary aim of this thesis was to evaluate the effects of the SHED-IT Weight Loss Maintenance Program on men's MVPA cognitions and MVPA behaviour, 12 months after successfully completing the SHED-IT Weight Loss Program

Using data from the SHED-IT Weight Loss Maintenance RCT, the primary aim of this thesis investigated whether men randomised to receive the *SHED-IT Weight Loss Maintenance Program* reported greater improvements in MVPA cognitions and MVPA behaviour in the 12 months after initial weight loss, compared to men who did not receive any maintenance-specific advice. Although significant improvements were noted for most SCT cognitions and for MVPA behaviour during Phase I, no significant differences were observed between the groups during the weight loss maintenance RCT (Phase II). However, as observed for weight, initial improvements in behaviours and cognitions were largely maintained by both groups at the end of the study.

Discussion

To date, men have been greatly under-represented in weight control and physical activity research. As such, there is a lack of knowledge concerning which theoretical and behavioural factors are most important to target in programs for men. This thesis determined that Bandura's SCT provides a useful framework to understand the physical activity behaviour of men, particularly during weight loss. In addition, the thesis revealed that a male-only approach may be an effective way to engage men in weight loss efforts. Although the primary hypothesis of this thesis was not supported, men who received the SCT-based *SHED-IT Weight Loss Program* reported significant increases in MVPA and clinically meaningful reductions in weight, which were largely maintained at 12 months in both RCT study arms. Additional research studies with longer durations and adequate power for behavioural outcomes are needed to build on the current findings with additional insights into the utility of targeting theoretical constructs for physical activity during weight loss maintenance in men.

Contribution Statement

This thesis includes several papers which pertain to the *SHED-IT Weight Loss Maintenance RCT*. As noted previously, although the primary aim of this trial was to test the effectiveness of a weight loss maintenance intervention for men, the primary aim of this thesis was to investigate the effect of the program on men's MVPA cognitions and MVPA behaviour. I was the sole PhD student and project manager of this study and was intricately involved in all aspects of the study conceptualisation, design, implementation, and evaluation. A summary of the contribution that I made to this study is provided below.

Acquisition of funding

I was a chief investigator on the three grants that funded this study:

Healthy Lifestyle Research Grant 2012: Hunter Medical Research Institute (HMRI)

Morgan, P.J., Callister, R., Collins, C.E., Plotnikoff, R.C., Doran, C.E., & **Young, M.D.** Engaging men to maintain weight loss using innovative and cost-effective interventions: The SHED-IT Weight Loss Maintenance RCT. **$19,800**

Seed Funding Grant 2011: Priority Research Centre in Physical Activity and Nutrition

Young, M.D., Morgan, P.J., Plotnikoff, R.C., Collins, C.E., & Callister, R. Development of theoretically grounded resources for a weight loss maintenance program for men. **$5,900**

Seed Funding Grant 2012: Priority Research Centre in Physical Activity and Nutrition

Young, M.D., Morgan, P.J., Plotnikoff, R.C., Collins, C.E., & Callister, R. Measuring men's dietary profiles and incorporating resistance training to strengthen the SHED-IT Weight Loss Maintenance RCT. **$6,000**

Program development

With guidance from my supervisors, I led the development of the *SHED-IT Weight Loss Maintenance Program*, which required the creation of a completely new set of resources. The program included: (i) the '*SHED-IT Weight Loss Maintenance Handbook for Men*', (ii) the '*SHED-IT Weight Loss Maintenance Logbook for Men*', (iii) weekly '*SHED-IT Weight Loss Maintenance Video Emails'* (which I delivered with my primary supervisor, Prof. Philip Morgan), and (iv) bi-weekly motivational text messages. Participants also received equipment including a Digiwalker SW200 pedometer and a Gymstick^{TM}. Prior to this PhD, I was a research assistant on the SHED-IT Community Weight Loss RCT. As such, I was closely involved in the development and refinement of the *SHED-IT Weight Loss Program* resources, which were provided to participants in the weight loss phase of the current study.

Ethics approval and clinical trial registry

I was responsible for gaining ethics approval from the University of Newcastle's *Human Research Ethics Committee* (H-2011-0361) and for registering the trial with the *Australian New Zealand Clinical Trials Registry* (ACTRN12612000749808). This involved developing a study proposal and justification, completing all ethics forms, designing the program recruitment material and developing the information statements, consent forms and participant screening procedures.

Study measures

In consultation with my supervisors, I selected all of the anthropometric and questionnaire-based assessments for this study. In addition, I conducted a pilot test of the social-cognitive measures used in this study with an independent sample (n = 22) to ensure the scales had adequate construct validity, content validity and test-retest reliability when used with overweight and obese Australian men.

Participant recruitment

I was responsible for liaising with the University of Newcastle's media department to draft the study recruitment media release. Following the publication of this release I engaged in six local and national radio interviews for recruitment purposes or general promotion of the program. As the project manager, I fielded enquiries from over 400 men in the first two weeks of recruitment.

Data collection, entry, and management

I was responsible for planning and coordinating the comprehensive study assessments for the 209 men who were eligible and agreed to participate. The participants attended four assessment sessions over 15 months at the University of Newcastle's Human Performance Laboratory (August 2012 – November 2013). With a fellow PhD student

(Mr. Elroy Aguiar), I created a series of protocols for completing anthropometric assessments (e.g., measuring height and weight) and for administering questionnaires. We also conducted comprehensive training sessions for all study assessors. Although I did not conduct any assessments (for blinding purposes), I was present at all study assessments to greet participants, address any concerns, randomise participants in the RCT phase, and familiarise each participant with their program resources. Following data collection I was responsible for cleaning, de-identifying and entering all data, including double-entry of primary outcome data to ensure accuracy.

Program implementation

With support from my supervisors, I successfully implemented both the *SHED-IT Weight Loss Program* (Phase I) and the *SHED-IT Weight Loss Maintenance Program* (Phase II), as described above. I was also the contact person for participants during the study and was responsible for managing all enquiries.

Data analysis

I completed all of the statistical analysis in this thesis. In order to complete the higher-level analyses, I attended several professional development courses. This included two advanced one-week courses in latent variable structural equation modelling at the University of Queensland (2012) and the University of Melbourne (2013).

Presentation of study results

During my candidature, I presented results from my thesis at three international and one national conference. In 2011 I was awarded first place in the '3-minute Thesis' public speaking competition at both the School of Education and Faculty of Education and Arts levels. I also competed in the university-wide grand final of the competition.

Awards received during candidature

In 2012, I was awarded the HMRI Barker Scholarship, which is a two-year top up scholarship awarded to one PhD student from the Hunter Region in a health-related field. I also won two awards at the Priority Research Centre in Physical Activity and Nutrition for 'best published paper' in the Obesity theme (2013) and Population Health theme (2014), and one University award for best paper in the Faculty of Education and Arts (2013). In 2015, I was awarded the HMRI Jennie Thomas Travel Grant.

CHAPTER 1

THESIS INTRODUCTION

1.1 Overview

This chapter begins with a brief overview of the increasing prevalence of overweight and obesity in Australia and globally. A summary of the negative physical, psychological and economic consequences of these conditions is then presented, followed by a discussion of why overweight and obesity in men is a unique challenge for public health. The introduction then moves to a discussion of the key limitations of the current evidence base for behavioural weight control programs, leading to the conclusion that a clear evidence gap exists for effective, theory-based and scalable interventions that can assist men to achieve sustainable increases in physical activity and long-term weight loss maintenance. To place this thesis in context, a short history of the research regarding the male-only *SHED-IT (Self-help, Exercise and Diet using Information Technology) Weight Loss Program* is then presented. This section details how this previous research has led to the development, implementation, and evaluation of the *SHED-IT Weight Loss Maintenance Program*, which is a central component of this thesis. Finally, the chapter concludes by outlining the primary and secondary aims of this thesis and providing a short description of the six investigations that were conducted to address these aims.

1.2 Background and Context

1.2.1 Prevalence of overweight and obesity

Overweight and obesity are chronic, relapsing health conditions that are associated with a host of physical and psychological co-morbidities (1). Of concern, body-mass index (BMI) data, which standardise weight for height, indicate that the international prevalence of overweight (BMI $\geq$ 25 kg/m^2) and obesity (BMI $\geq$ 30 kg/m^2) has been increasing for the past 30 years (2, 3). As these conditions are associated with substantial negative health consequences (1), and have affected every country with available data (n = 188) (2), researchers have suggested the world is in the grip of an ‘obesity pandemic’ (4).

Internationally, between 1980 and 2010, the mean BMI of adults increased by 0.4 kg/m^2 per decade in men and 0.5 kg/m^2 per decade in women (3). Consequently, during this period, the global prevalence of overweight and obesity also increased from 29% to 37% in men, and from 30% to 38% in women (2). This is concerning, as 3.4 million deaths worldwide were attributed to overweight and obesity in 2010 (5), representing a 170% increase from 1990. Notably, these figures are conservative as they do not include the deaths from other risk factors associated with obesity, such as hypertension, high cholesterol, poor diet, or physical inactivity (5). As such, rising obesity levels are clearly an international health concern.

In Australia, 63% of adults are currently overweight or obese (6). This represents an increase from 56% in 1995 (6). Notably, this increase is completely attributed to increases in obesity prevalence, which rose from 19% in 1995 to 28% in 2011-2012 (6). These increases are largely attributed to Australia's 'obesogenic environment' (7), where the need to perform physical activity is decreasing and the availability of cheap kilojoule (kJ)-dense, nutrient-poor foods has increased (8). According to the most recent data (2011-2012), only 19% of Australian adults are meeting the physical activity recommendation of 10,000 steps per day (9). Conversely, adults are sitting for approximately 39 hours per week, including an average of 10 hours at work and 13 hours watching television (9). Australian adults are also eating poorly, with kJs from discretionary foods (e.g., chocolate, pizza, potato chips, sugar-sweetened soft-drinks) representing 35% of the average daily energy intake (10). Of concern, these foods are often high in sugar, salt and saturated fat. Further, 94% of adults are not meeting the recommendation of eating at least two servings of fruit and five servings of vegetables per day (6). Given the large numbers of Australians who are currently overweight or obese, identifying effective methods to improve dietary and physical activity behaviours and assist people with weight loss, is a current national health priority (8, 11).

1.2.2 Consequences of overweight and obesity

1.2.2.1 Health consequences

Being overweight or obese significantly increases the risk of cardiovascular disease, hypertension, elevated lipids and type II diabetes (1, 8). Increased BMI is also significantly associated with increased risk of several cancers (12, 13). According to the *World Cancer Research Fund* (13), each 5 kg/m^2 increase in BMI is associated with an increased relative risk (RR) for cancer of the kidney (RR = 1.31, 95% CI 1.24-1.39), gallbladder (RR = 1.23, 95% CI 1.15, 1.32) and pancreas (RR = 1.10, 95% CI 1.07, 1.14). For colorectal cancer, each 1 kg/m^2 increase in BMI is associated with an increased relative risk of 1.02 (95% CI 1.02, 1.03). Overweight and obesity are also linked to a rapidly expanding list of non-fatal co-morbidities such as osteoarthritis, asthma, sleep apnoea, and chronic back pain (1).

In addition to the physical consequences, people who are overweight and obese also face considerable weight-related stigma (14) and discrimination (15). Further, overweight and obesity have been associated with a range of deleterious mental health consequences including depression (16), poor quality of life (17), anxiety (18), and disordered eating (19). Notably, these psychological consequences may become more prevalent as weight status increases. In a recent analysis of 41,654 adults, Petry and colleagues (20) determined that, while overweight adults were at a greater risk of some anxiety and substance abuse disorders compared to healthy weight adults, obese adults were at a significantly increased risk of *any* mood, anxiety, personality, or alcohol-use disorder (with Odds Ratios ranging from 1.21 to 2.08).

1.2.2.2 Economic consequences

The most recent economic data from the *Australian Diabetes, Obesity and Lifestyle* (AusDiab) study indicate the annual direct cost of overweight and obesity to Australia in 2005 was $21 billion (21). The majority of these costs were attributed to prescription medication, hospitalisation, and ambulatory services (21). Of note, this estimate does not include indirect costs, such as lost productivity and wellbeing, which are substantial. For example, in 2008, obesity alone cost Australia an estimated $3.6 billion in productivity costs and $1.9 billion in carer costs (22). However, when the net cost of lost wellbeing was considered, the estimated cost inflated to $58.2 billion.

1.2.3 Overweight and obesity in men

Although increases in overweight and obesity have been observed for both sexes, obesity in Australian men (and internationally) is a significant public health concern for many reasons. First, 70% of Australian men are currently overweight/obese compared to 56% of women and men are more likely than women to be obese in every age group (6). Second, in the past 30 years, the average BMI of Australian men has increased by 0.9 kg/m^2 per decade, which is more than double the international average (0.4 kg/m^2) (3). Third, men may be exposed to greater health risks from their obesity due to sex-differences in body fat distribution (23). For example, men are significantly more likely than pre-menopausal women to store fat abdominally, which greatly heightens the risk of type 2 diabetes, cardiovascular disease, and the metabolic syndrome (24, 25). Fourth, men are significantly less likely than women to perceive themselves as being overweight, consider their weight a problem (26), or attempt weight loss (26, 27). Fifth, when men do try to lose weight, population-based evidence suggests they are significantly less likely than women to achieve long-term weight loss maintenance (28).

1.2.4 Behavioural weight loss interventions

Behavioural weight loss programs make an important contribution to reducing the burden of disease associated with overweight and obesity. Although long-term, population-targeted approaches may have the largest impact on overweight and obesity prevalence (e.g., taxes and advertising restrictions) (29), effective behavioural weight loss interventions targeting individuals are needed by those currently seeking help. Behavioural obesity treatment involves the modification of physical activity, eating, sitting time, and cognitions that contribute to weight gain (30). These programs often include behaviour change techniques such as self-monitoring, goal setting, and stimulus control, which are applied to increase physical activity, improve diet quality, and/or decrease overall energy intake to facilitate weight loss (31). To date, these programs have well-documented efficacy for assisting overweight and obese participants to achieve weight losses of approximately 5% to 10% of their initial body weight (32-34), which is sufficient to confer clinically meaningful health benefits (35, 36) and improve quality of life (37). Despite these advantages, however, the evidence base for behavioural weight loss programs is currently limited by:

(i) An under-representation of men,
(ii) A lack of pragmatic and scalable interventions, and
(iii) Poor long-term effectiveness.

Each of these limitations is addressed in additional detail below.

1.2.4.1 Under-representation of men

A major limitation of weight loss research to date is the distinct lack of male participants. In 2012, Pagoto and researchers (2012) investigated the proportion of males included in 244 behavioural weight loss randomised controlled trials (RCTs) published between 1999 and 2011. Overall, the study samples were 27% male. Further, 32% of trials were exclusively female, but only 5% were exclusively male (38).

A major barrier to men participating in weight loss research is the general notion among men that dieting and weight loss are feminine pursuits (26). Further to this, if men are interested in participating, they may feel uncomfortable signing up to programs where they know that the majority of participants will be women (39). In addition, as research suggests that men prefer programs they can complete independently (40), they may perceive the standard model of face-to-face contact or group sessions to be unappealing. Indeed, self-guided weight loss interventions (e.g., mail, e-mail, and online programs) have typically had the highest representation of men, compared to group-based interventions, which have had the lowest (38). Of interest, however, while men appear more reluctant to participate in group-based research, research shows that this can be an effective intervention component in male-only studies (26). As a result of these factors, women have significantly outnumbered men in the vast majority of weight loss research to date. Consequently, the evidence for the effectiveness of many weight loss programs may not apply to men.

1.2.4.2 Lack of pragmatic and scalable interventions

A second limitation of the evidence base for behavioural weight loss programs is the lack of scalable programs that could be realistically implemented within strained healthcare budgets. To generate meaningful decreases in overweight and obesity rates, efficacious behavioural weight management interventions need to be scaled up for widespread implementation (41). However, this is not a realistic goal for many programs, given that the standard model for behavioural weight loss treatments includes weekly sessions of 60-90 minute duration for 16-26 weeks (42). These sessions, which are either individual or group-based, are often delivered by health professionals such as behavioural psychologists, exercise physiologists or registered dietitians (42, 43). Although this approach is generally sufficient to help people lose weight (44), the inclusion of these intensive intervention components increases costs and greatly reduces the potential for scalability on a population level (41).

1.2.4.3 Poor long-term effectiveness

In addition to the shortage of male participants and scalable interventions, the third major limitation of weight loss programs to date is the lack of long-term effectiveness. Assisting participants with long-term weight loss maintenance is a substantial challenge for weight loss programs, as people must resist returning to previous habits in addition to overcoming powerful physiological responses that encourage weight regain (8). Consequently, the long-term success rate of behavioural weight loss programs has been poor (32). Importantly, the first year after treatment appears critical, with multiple systematic reviews indicating that approximately 50% of weight is regained during this time (45-47). As weight regain effectively negates the health benefits of initial weight loss, it is imperative to identify strategies that facilitate long-term weight loss maintenance (48).

1.2.5 Behavioural weight loss maintenance interventions

To address the problem of weight regain after weight loss, researchers are now developing additional weight loss maintenance interventions, which are designed to teach participants new behaviours and skills to halt the weight regain trajectory (49). These interventions were initially informed by studies such as the *U.S. National Weight Control Registry (NWCR)* (50), which has collected data on over 10,000 men and women who have lost at least 13.6 kg (30 lbs) and maintained the loss for at least one year (51). This research found long-term success may be associated with maintenance-specific skills and behaviours. For example, successful weight loss maintenance is significantly associated with: (i) eating a low-kJ diet (52-54), (ii) increasing intake of fruits and vegetables (52, 54, 55), (iii) maintaining a consistent eating pattern (52, 56-58), (iv) minimising time spent watching television (59-61), and (v) taking action to prevent small weight increases from becoming large regains (50, 52, 55, 62, 63).

Of note, substantial research indicates long-term weight loss maintenance requires a clear and sustained increase in physical activity (44, 50, 52, 64). Data from the NWCR registry indicate successful weight loss maintainers are extremely active (65, 66). In a recent sub-study (65), the objective physical activity patterns of NWCR members (n = 26) were compared to two control groups who matched the NWCR members' current mean BMI (i.e., healthy weight control; n = 30) and self-reported 'pre-weight loss' BMI (i.e., overweight control; n = 34). After one week of accelerometry, the NWCR members had spent a significantly greater mean (SD) time in structured moderate-to-vigorous physical activity (MVPA) compared to the overweight control group (41.5 min/day (35.1) vs. 19.2 min/day (18.6), p<0.01). The difference in mean (SD) MVPA between NWCR members and the never-overweight control group also approached significance (41.5 min/day (35.1) vs. 25.8 min/day (23.4), p=0.08). In total, NWCR members performed approximately 290 minutes of MVPA per week (65). This aligns with the *American College of Sports Medicine's* recommendations for the amount of physical activity required to prevent regain after weight loss (i.e., 250-300 minutes of moderate physical activity per week) (64). However, it is important to note the NWCR is approximately 80% female (50), and the sub-study sample was 90% female (65). As such, more research is required to determine the optimal amount of physical activity to sustain weight loss in men.

As previously noted, researchers are currently testing the utility of these insights in experimental research by providing participants with additional weight loss maintenance interventions that target these key 'maintenance' behaviours. This approach has shown initial promise, with a recent meta-analytic review of 25 behavioural weight loss maintenance RCTs reporting participants who received an additional maintenance intervention regained significantly less weight over 12 months compared to controls (weighted mean difference: -1.6 kg; 95% CI -2.3, -0.9) (49). Although this result was a modest difference, research shows that each additional kg of weight lost is associated with a 1.0 to 2.4 mm Hg decrease in systolic blood pressure (67) and a 16% reduction in incident diabetes (68). Therefore, behavioural weight loss maintenance interventions may be an effective strategy to increase the longevity of initial treatment effects on weight and assist participants to maintain clinically meaningful health improvements.

Despite these benefits, Dombrowski and colleagues reported most weight loss maintenance programs to date have been compromised by many of the same problems as weight loss programs. For example, the authors noted that the average proportion of men in the included weight loss maintenance trials was only 27%. Further, 7% of studies used male-only samples compared to 29% with female only samples (49). As such, the majority of insights gleaned from this research may not apply to men. Further, most maintenance programs included in the review required considerable contact with health professionals (e.g., in-person counselling, supervised exercise sessions, or regular phone consultations) (49), which would likely increase costs and decrease scalability. As such, Dombrowski et al. strongly encouraged researchers to develop novel weight loss maintenance interventions that are effective and scalable for widespread use.

1.2.6 The role of psychological theory

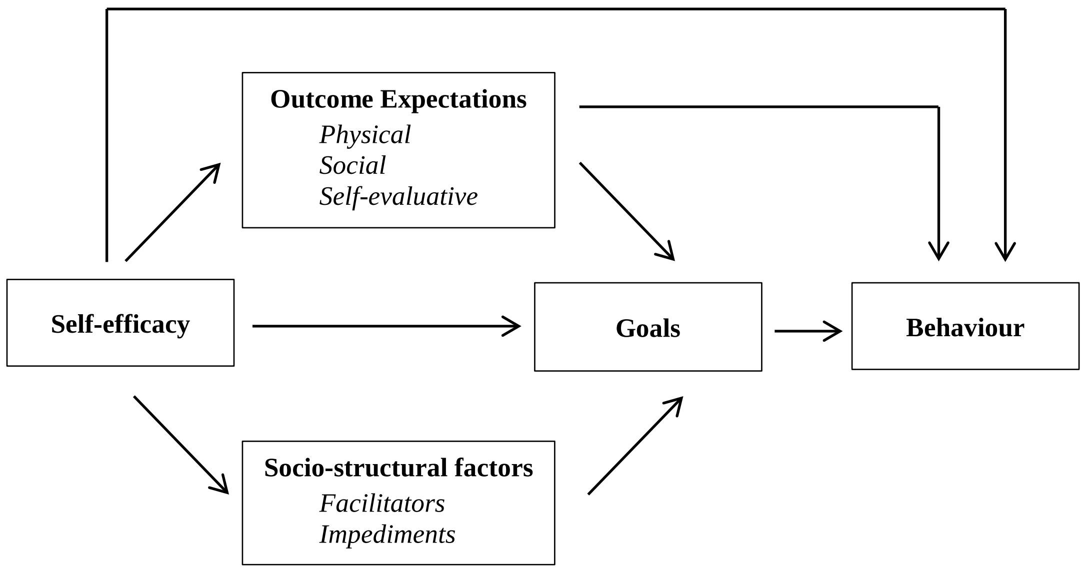
The aim of health psychology is to further the understanding of the psychological determinants of health behaviour and the processes of behaviour change. Given that a substantial proportion of the mortality and burden of disease from obesity is due to maladaptive behaviour patterns, health psychology can make an important contribution to the development of effective weight management interventions (31).

As previously described, achieving long-term weight loss maintenance requires significant behaviour changes that are sustained in the face of a series of physical, psychological, social and environmental barriers. As such, an advanced understanding of behaviour change has particular relevance for weight loss maintenance interventions. However, the majority of behavioural maintenance interventions to date have not been explicitly informed by psychological theory (49). To progress the field, Sniehotta and colleagues recently recommended that experimental research is needed to: (i) test the assumptions of behaviour change theories during weight loss maintenance, and (ii) determine which social and cognitive determinants can be effectively targeted to increase the longevity of participants' weight loss and associated health outcomes (48). A prominent behaviour change theory that may have particular utility in weight loss maintenance research is Bandura's Social Cognitive Theory (SCT), which is briefly described below.

1.2.6.1 Social Cognitive Theory

SCT is centred on a premise called ‘reciprocal determinism’, which suggests that behaviour is the result of complex and ongoing interactions between personal, environmental, and behavioural factors (69). As seen in Figure 1.1, the primary construct in SCT is *self-efficacy*, which is defined as the self-belief one has regarding their ability to perform a behaviour to bring about a desired outcome (70). In a health context, Bandura has referred to self-efficacy as the belief that one can exercise control over one’s health habits (71). Self-efficacy is seen as the pivotal construct within SCT as it is hypothesised to exhibit a direct influence on behaviour and an indirect influence through all other variables in the model (Figure 1.1).

Figure 1.1. Bandura’s Social Cognitive Theory model of health behaviour, including direct and indirect paths of influence (71).



The second construct in SCT is *outcome expectations*, which represent one’s judgements about the potential costs and benefits of particular actions. Bandura specifies three major types of outcome expectations: (i) physical (i.e., bodily sensations), (ii) social (i.e., responses from others), and (iii) self-evaluative (i.e., feelings about oneself) (72). The third construct is *socio-structural factors*, which represent the various facilitators (e.g., social support) and impediments (i.e., barriers) that could encourage or hinder behaviour change (71). As noted in Figure 1.1, self-efficacy, outcome expectations, and socio-structural factors operate in combination to influence one's goals (i.e., intentions) to perform, or not perform, a particular behaviour. Using physical activity as an example, SCT suggests that people who have high physical activity self-efficacy will: (i) be more physically active (direct influence on behaviour), (ii) have more positive views about the outcomes of physical activity (direct influence on outcome expectations), perceive more opportunities for physical activity in their environment and less potential barriers (direct influence on socio-structural factors), and (iv) will set more ambitious physical activity goals, compared to someone with low physical activity self-efficacy (71, 73).

Although SCT clearly represents a network of inter-related constructs, it is important to note that most SCT research in the physical activity domain has focused solely on self-efficacy, or has examined self-efficacy in combination with only one or two other variables (74). This has perpetuated the misguided notion that SCT is a 'one factor theory' (72). To advance the understanding of SCT and its utility for explaining physical activity, researchers have called for more research examining the role of self-efficacy in the context of the full SCT model, rather than in isolation (75, 76).

There are two key reasons why SCT may be an effective behaviour change theory to apply in weight loss maintenance research. First, rather than simply explaining behaviour, SCT provides clear principles on how to help people change their thinking patterns, environments, and behaviours (71). For example, Bandura (1997) suggested that self-efficacy can be increased by targeting key sources of information including: (i) setting participants graded tasks to ensure they experience repeated successes (mastery), (ii) providing consistent encouragement (verbal persuasion), and (iii) using relatable role models to provide personal recommendations on how they have overcome common barriers (vicarious experience) (73). Second, Bandura (2004, p. 144-145) proposed that the constructs in SCT are sufficient to explain individual's initiation of health behaviours and also their motivation to persist in the face of potential barriers (71). In this sense, SCT appears to be an ideal framework to choose when designing weight loss maintenance interventions, which are administered during the post-weight loss phase when initial motivations have typically waned and unique challenges are faced (52).

1.2.7 Summary

Overweight and obesity in men is a significant public health concern. Although behavioural weight loss programs have well-documented short-term efficacy, longer term results are modest, recidivism is common, most programs are too intensive for realistic dissemination, and typical programs have failed to engage men. Studies of people who have successfully maintained long-term weight loss have identified a number of key behaviours that are associated with success including substantial increases in MVPA and various improvements in diet quality and eating patterns. Although weight loss maintenance interventions that target these behaviours have been modestly successful at preventing weight regain, these programs: i) remain too intensive for scalability, and ii) have also failed to engage men. As long-term success requires sustainable behaviour change, the application of behaviour change theory to these interventions may improve intervention effectiveness without substantially increasing costs. Given the unique challenges associated with male obesity, effective and scalable weight loss and weight loss maintenance programs that engage men are urgently required.

1.3 The SHED-IT Weight Loss Studies

This thesis builds on an extensive body of previous research investigating the efficacy and effectiveness of the *SHED-IT Weight Loss Program*, which is a gender-tailored, scalable, theory-based weight loss program designed specifically to appeal to men (77-86). In order to put the current thesis into context, a brief summary of previous research regarding the *SHED-IT Weight Loss Program* is presented below.

1.3.1 The SHED-IT Pilot Weight Loss RCT

The first experimental trial of the *SHED-IT Weight Loss Program* was a pilot study in 2007 with a sample of staff and students from the University of Newcastle, Australia (83, 84). The aim of this study was to determine whether a weight loss program designed specifically for men would be an effective strategy to engage and assist men with weight loss. In this study, 65 overweight/obese men were randomly assigned to: i) an intervention group, who received a pilot version of the *SHED-IT Weight Loss Program* including access to a study website to self-monitor diet and activity (www.calorieking.com.au) and seven e-feedback sheets, or ii) a minimal intervention control group, who received the SHED-IT program resources but did not have access to the study website or e-feedback. Both groups also received a face-to-face information session delivered by the study chief investigator.

The pilot sample had a mean (SD) age of 35.9 (11.1) years and mean (SD) weight of 99.1 (12.8) kg. Overall, 48% of the men were overweight and 52% were obese. After 3 months, significant weight loss was achieved by both the intervention group (-4.8 kg, 95% CI -6.4, -3.3) and the minimal intervention group (-3.0 kg, 95% CI -4.5, -1.4), with no significant difference between groups. Notably, this weight loss was largely maintained at both 6 months (3-month follow-up) and 12 months (9-month follow-up) in both groups (83, 84). This pilot study revealed that simple, weight-loss interventions could be effective in achieving clinically important weight loss in a convenience sample of men from the University. Importantly, while men indicated high levels of satisfaction with the programs (84, 86), extensive evaluations suggested the program could be improved through targeted changes to the intervention content, delivery mode, and operationalisation of theoretical constructs.

1.3.2 The SHED-IT Community Weight Loss RCT

After establishing the SHED-IT program's preliminary efficacy, the SHED-IT weight loss community RCT (81, 82) was conducted in 2010 to investigate the program's effectiveness in a larger and more representative sample of men from the community. To increase the programs potential for widespread and practical dissemination, the information session was replaced with a DVD. In recognition of the effectiveness of the SHED-IT resources-only 'control' condition from the pilot, a paper-based version of the program was developed, which included a physical set of resources to self-monitor diet and physical activity. Finally, to strengthen the validity of the results, a wait list control arm was also included in the experimental design.

In total, the study recruited 159 overweight and obese men from the Hunter Region of NSW, Australia. The sample had a mean (SD) age of 47.5 (11.0) years and a mean (SD) weight of 103.4 (14.0) kg. At 6 months, significant weight loss was observed in both the Online group (-4.7 kg; 95% CI -6.1, -3.2) and Resources-only group (-3.7 kg; 95% CI -

4.9, -2.5) compared to the wait-list control (-0.5 kg; 95% CI -1.4, 0.4). This study demonstrated that scalable, gender-sensitised weight loss programs could assist community-dwelling men to lose weight and experience a range of clinically meaningful health benefits (77, 78, 81).

1.3.3 The SHED-IT Weight Loss Maintenance RCT

Several publications in this thesis pertain to the development and evaluation of the *SHED-IT Weight Loss Maintenance Program*. This program was designed to follow on from the *SHED-IT Weight Loss Program* to provide men with new knowledge and skills needed to maintain their weight loss over time. Although the maintenance of weight loss during the first two weight loss trials was promising, the *SHED-IT Weight Loss Maintenance* RCT was longer in duration (15 months) and men were only included if they achieved clinically significant weight loss after completing the *SHED-IT Weight Loss Program* (i.e., ≥ 4 kg). As such, the included sample had experienced greater initial weight loss and would have been more susceptible to a greater potential for weight regain.

In addition to recommending a series of evidence-based dietary and cognitive weight loss maintenance strategies, the program included a distinct focus on increasing MVPA, given its clear association with long-term success (64). In line with the original program, the *SHED-IT Weight Loss Maintenance Program* was gender-tailored to ensure that the messages were meaningful and memorable for men. Finally, to increase the likelihood of sustained behaviour changes, the program was explicitly informed by the behaviour change principles outlined in Bandura’s SCT.

1.4 Research Aims

1.4.1 Primary aim

1. The primary aim of this thesis was to evaluate the effects of the *SHED-IT Weight Loss Maintenance Program* on men's MVPA cognitions and MVPA behaviour, 12 months after successfully completing the *SHED-IT Weight Loss Program* (Chapters 5 and 8).

1.4.1.1 Thesis hypothesis

The primary hypothesis for this thesis is that men who receive the *SHED-IT Weight Loss Maintenance Program* will demonstrate significantly greater improvements in MVPA cognitions and MVPA behaviour, 12 months after successfully completing the *SHED-IT Weight Loss Program*, compared to a self-help control group who will receive no additional program.

1.4.2 Secondary aims

This thesis also examined the following secondary aims:

1. To synthesise the current evidence base regarding the effectiveness of male-only weight loss and weight loss maintenance interventions (Chapter 2)
2. To systematically review the evidence for the utility of SCT as a framework to explain physical activity (Chapter 3).
3. To identify behavioural mediators of sustained weight loss in a previous male-only weight loss study (Chapter 4).
4. To examine the utility of SCT as a theoretical framework to explain the physical activity changes of men during weight loss (Chapter 6).
5. To evaluate the effect of the *SHED-IT Weight Loss Maintenance Program* on men's weight and other health outcomes, 12 months after successfully completing the *SHED-IT Weight Loss Program* (Chapters 5 and 7).

1.5 Thesis Structure

This thesis is presented as a series of seven papers. To date, two of these papers have been published, two have been accepted for publication, one is under review, and two have been submitted to journals for consideration. For additional information on these publications, refer to page vii.

1.5.1 Introduction

This thesis began with a brief overview of the increasing prevalence of overweight and obesity, the specific health and economic consequences of obesity, and the unique problem of overweight and obesity in men. Following this, the limitations of the current evidence for behavioural weight control programs were discussed. It was concluded that an evidence gap exists for theory-based, scalable weight loss maintenance interventions that target men, despite the considerable benefit such interventions could have for public health. Finally, the introduction briefly covers the history of the *SHED-IT Weight Loss Program* body of research.

1.5.2 Male-only weight management interventions

Chapter 2 presents the results of a systematic review of all behavioural weight loss and weight loss maintenance interventions that recruited men only. This review searched eight databases with no date restrictions to determine the overall effect of these studies on weight and to identify intervention characteristics associated with effectiveness (*Secondary Aim 1*). Overall, 24 articles describing 23 studies met the eligibility criteria. Key study information was extracted in a standardised manner and risk of bias was independently determined for all studies. Results from RCTs with a true control group were pooled using *RevMan Meta-analysis* (87). The outcomes of this study have been published in *Obesity Reviews* (see Chapter 2).

1.5.3 Social Cognitive Theory models of physical activity

As long-term weight loss maintenance requires a significant and sustained increase in physical activity (64), and theoretical interventions may be more effective at changing behaviour than a-theoretical interventions (88), a systematic review was conducted to determine the utility of SCT as a framework to explain and predict physical activity

(*Secondary Aim 2*). Chapter 3 presents the results of this review, which searched 10 electronic databases using a standardised protocol. Forty-four articles were retrieved containing 55 SCT models of physical activity. Models were assessed for methodological quality using a standardised tool and a random-effects meta-analysis combined the variance explained in behaviour (R^2). The outcomes of this study have been published in *Obesity Reviews* (see Chapter 3).

1.5.4 Behavioural mediators of weight loss in men

Chapter 4 presents the results of a multiple-mediation analysis using data from the SHED-IT weight loss community RCT. This analysis examined which weight loss behaviours specifically targeted in the *SHED-IT Weight Loss Program* also served as significant mediators of the interventions effect on weight at follow-up (*Secondary Aim 3*). As mediation analysis can help identify which intervention recommendations are most effective, this secondary analysis was conducted for the purposes of refining and improving the *SHED-IT Weight Loss Program*, which all men in the current trial received during the weight loss phase. The outcomes of this study have been published in *Annals of Behavioural Medicine* (see Chapter 4).

1.5.5 SHED-IT Weight Loss Maintenance Trial protocol paper

After reporting the results of the formative systematic reviews and mediation analysis, the thesis moves to a detailed presentation of the rationale and methods of the current trial. Chapter 5 outlines the development of the *SHED-IT Weight Loss Maintenance Program*, which is a gender-tailored, theory-based program to prevent weight regain after weight loss in men. Specific detail is provided on the gender-tailoring process and how the behaviour change principles of SCT were integrated into the intervention. This chapter also provides a comprehensive description of the study design, outcome measures, and randomisation procedure. This protocol paper has been published in *Contemporary Clinical Trials* (see Chapter 5).

1.5.6 A Social Cognitive Theory model of physical activity in men

When examining the utility of SCT to explain physical activity (Chapter 3), the systematic review revealed that men were considerably under-represented in the models. Further, no models had tested SCT in a male-only sample. Thus, Chapter 6 presents the results of a longitudinal, structural equation model examining the associations between men's SCT cognitions and physical activity behaviour during the *SHED-IT Weight Loss Program* (*Secondary Aim 4*). The outcomes of this study are currently under review in the *American Journal of Men's Health* (see Chapter 6).

1.5.7 SHED-IT Weight Loss Maintenance Trial: Primary outcomes

Chapter 7 presents the primary outcomes of the SHED-IT Weight Loss Maintenance Trial (*Secondary Aim 5*). Using a rigorous, two-phase, assessor-blinded, parallel-group RCT design, this study was designed to test the effectiveness of the male-only, gender-tailored *SHED-IT Weight Loss Maintenance Program*, which was guided by the behaviour change principles outlined in SCT. Of note, the program included no face-to-face, email, or telephone contact or any individualised intervention components. In total, 92 men who lost at least 4 kg during Phase I (i.e., the weight loss phase) were randomly allocated to receive: i) the *SHED-IT Weight Loss Maintenance Program*, or ii) no addition resources (self-help control). Participants were re-assessed at 6 months (post-test) and 12 months (follow-up) after randomisation. The outcomes of this study are currently under review in the *International Journal of Obesity* (see Chapter 7).

1.5.8 SHED-IT Weight Loss Maintenance Trial: SCT outcomes

Although health psychology can play a key role in the development of effective weight loss maintenance interventions (48), little research has tested the assumptions of behaviour change theories in the context of a weight loss maintenance intervention (49). According to a recent review, no weight loss maintenance RCTs have test an intervention that explicitly operationalises SCT and reports on the study outcomes for all core SCT constructs (49). Thus, in line with the primary aim of this thesis, Chapter 8 presents the results of the *SHED-IT Weight Loss Maintenance Trial* for MVPA behaviour and SCT cognitions including self-efficacy, outcome expectations, behavioural goal, social support and self-regulation. This paper also reports on the program's effect on discretionary food cognitions and behaviour, but these outcomes were not a focus of this thesis. The outcomes of this study were published in the *British Journal of Health Psychology* (see Chapter 8).

CHAPTER 2

EFFECTIVENESS OF MALE-ONLY WEIGHT LOSS AND WEIGHT LOSS MAINTENANCE INTERVENTIONS: A SYSTEMATIC REVIEW WITH META-ANALYSIS

Preface:

This chapter presents the results of a meta-analytic review, which I conducted to investigate *Secondary Aim 1* of this thesis (i.e., to synthesise the current evidence base regarding the effectiveness of male-only weight loss and weight loss maintenance interventions).

The content presented in this chapter is not the final version of the article which is published in *Obesity Reviews.* Permission was granted by *John Wiley and Sons* to use the content presented here.

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Abstract

Objectives: The objectives of this systematic review were to investigate the effectiveness of male-only weight loss and weight loss maintenance interventions and to identify intervention characteristics associated with effectiveness.

Methods: In May 2011, a systematic literature search with no date restrictions was conducted across eight databases. Twenty-four articles describing 23 studies met the eligibility criteria.

Results: All studies included a weight loss intervention and four studies included an additional weight loss maintenance intervention. Study quality was mostly poor for weight loss studies (median = 3/10, range = 1-9) and weight loss maintenance studies (median = 3.5/10, range = 1-6). Twenty-three of 31 individual weight loss interventions (74%) from the eligible studies were considered effective. Meta-analysis revealed a significant difference in weight change favouring weight loss interventions over no-intervention controls at the last reported assessment (weighted mean difference -5.66kg [-6.35,-4.97] Z=16.04 [P<0.00001]). Characteristics common to effectiveness were: younger sample (mean age ≤ 42.8 years), increased frequency of contact (> 2.7 contacts/month), group face-to-face contact and inclusion of a prescribed energy restriction.

Conclusions: Male-only weight loss programs may effectively engage and assist men with weight loss. However, more high quality studies are urgently needed to improve the evidence base, particularly for maintenance studies.

2.1 Introduction

Men who are overweight or obese are widely recognised as a hard to engage, yet high-risk group for obesity-related chronic disease (22, 86). Despite estimated global prevalence rates of obesity almost doubling for both men (4.8% to 9.8%) and women (7.9% to 13.8%) over the past 30 years (3), males remain less likely to perceive themselves as overweight (27), attempt weight loss or participate in weight loss programs (23, 86, 89). Men are also more likely than pre-menopausal women to store excess fat abdominally (27), which independently increases the risk of many obesity-related diseases including type 2 diabetes, cardiovascular disease, dyslipidaemia, hypertension, the metabolic syndrome (25) and some cancers (13). To compound these problems, many people who lose weight are poor at sustaining weight loss long-term (52) and most men will return to their baseline weight within five years post treatment (42). This demonstrates a clear and urgent need to identify evidence-based approaches and program components that can effectively engage men in initial weight loss and successful long-term weight loss maintenance.

Providing evidence-based strategies to weight loss for males is difficult as men are consistently underrepresented in weight loss research. For example, in a systematic review of 80 weight loss trials of at least 12 months duration (published between 1997 and 2004), the average proportion of male participants per study was only 27% (90). Further, only three of the 80 studies (4%) had male-only groups compared to 19 (24%) that were female-only. Another recent systematic review of web-based weight loss interventions identified that at least 77% of 5700 included participants were female (33). A possible explanation for this difference is that men want weight loss programs with participants they can relate (86, 91) to and may feel uncomfortable signing up to programs where the majority of participants are women (39, 86). Regardless of the reasons, it is clear that treatments available to men are currently informed by weight management studies that have been largely conducted in females (23, 34, 92). Studies that are male only and/or include programs tailored specifically for men are needed to determine which treatment approaches and strategies are linked to successful weight loss and long-term weight loss maintenance in men.

The aim of this systematic review was to synthesise the current evidence of the effectiveness of weight loss and weight loss maintenance interventions that recruited men only, in order to encourage and inform future research into weight management treatments for men. A secondary aim of this review was to identify the characteristics of male-only interventions that were associated with successful outcomes.

2.2 Methods

The conduct and reporting of this review adhered to the guidelines outlined in the Preferred Reporting Items for Systematic Reviews and Meta-analyses (*PRISMA*) Statement (93).

2.2.1 Eligibility criteria

Types of participants: Males aged 18-65 years who were overweight or obese by either of the following recognised criteria at baseline: World Health Organization body-mass index (BMI) cut offs or a body weight that was ≥120% of ideal weight for height, according to the 1983 Metropolitan Height and Weight Tables (equates to a BMI >28).

1. *Types of intervention*: Weight loss or weight loss maintenance interventions with clear intent to change behaviour or lifestyle.
2. *Types of primary outcome measures*: Weight change or weight at baseline and a minimum of one post-intervention time point, reported in kilograms or pounds.
3. *Types of studies*: Experimental trials investigating the impact of weight loss or weight loss maintenance treatments.

Studies were excluded if they met any of the following criteria: (i) participants were targeted groups with diagnosed complications linked to obesity (e.g., type II diabetes) or were from special populations (e.g., people with severe mental illness, people with eating disorders); (ii) the study was published in a language other than English; or (iv) the intervention involved bariatric surgery, anti-obesity medication, or a supervised exercise or dietary regime employed primarily to investigate the effect of weight loss on other outcomes. The control arms of these studies were not considered in this review.

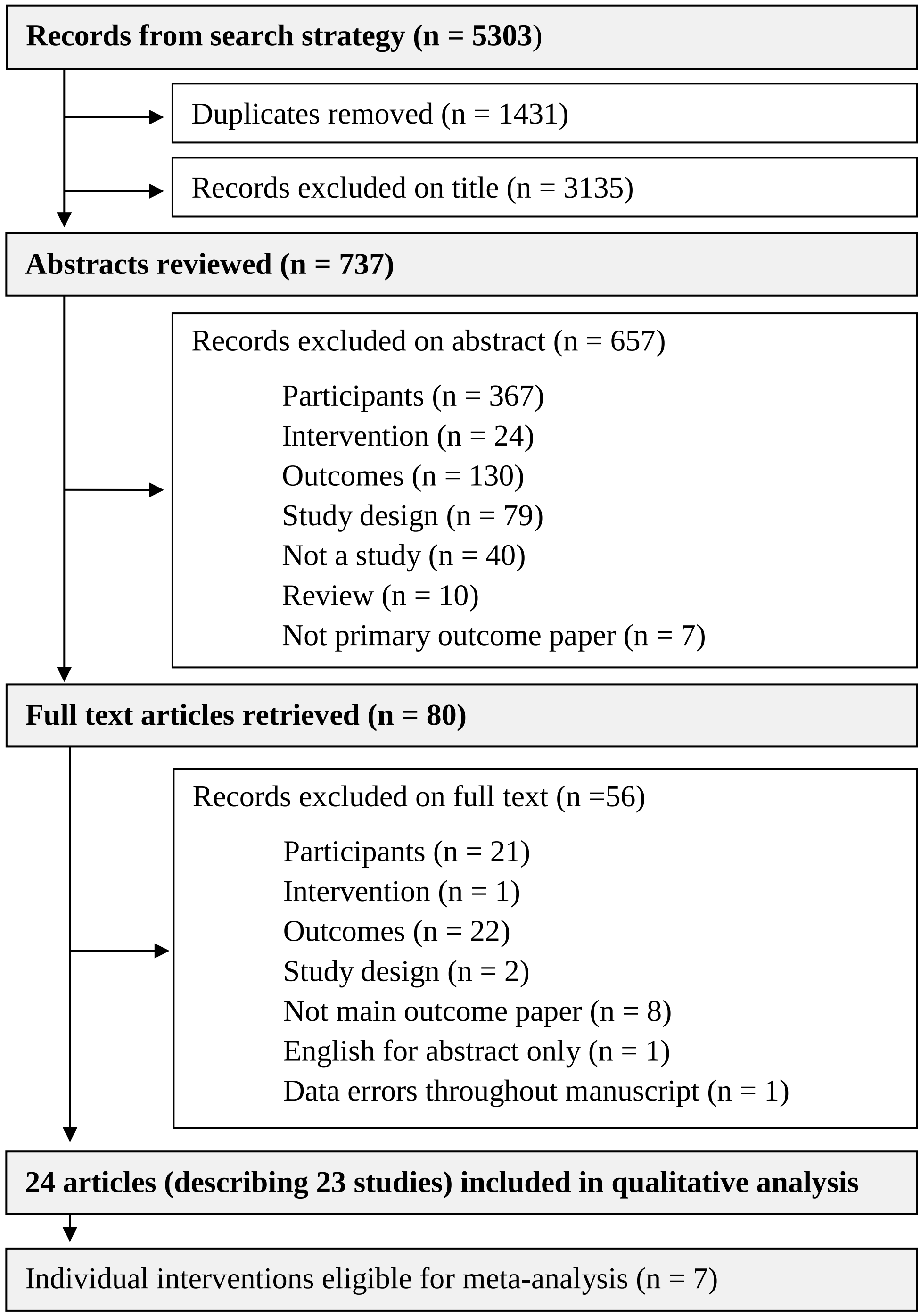
2.2.2 Information sources and search

Studies were identified by searching electronic databases and scanning reference lists of included articles. The search was applied to CINAHL, EMBASE, MEDLINE, PsycINFO, and PubMed and was adapted for SportDiscus, SCOPUS and Web of Science. No publication date restrictions were imposed in any database and the last search was completed in May 2011. Search terms were divided into three groups: (i) population (e.g., overweight OR obes*); (ii) study design (e.g., intervention OR random*) and (iii) intervention type (e.g., weight loss OR obesity treat*). The Boolean phrase 'AND' was used between groups and the phrase 'OR' was used within groups. Articles with the terms 'women' or 'female*' in the subject heading were excluded. Limits used were English language, male, journal article or review, human and adult (18-65 years of age).

2.2.3 Study selection

Following the search, the lead author (MDY) removed all duplicates and screened the titles and abstracts of remaining records for relevance in a non-blinded, standardised manner. A second author (PJM) checked all decisions and any disagreements were resolved by discussion. Full text articles were retrieved for all remaining records. Both authors (MDY and PJM) independently screened these articles for inclusion and exclusion with both reviewers conferring on differences to reach full consensus on all articles. Reference lists of included studies were searched for additional eligible studies although none were identified. Figure 2.1 displays this selection process in more detail.

Figure 2.1. PRISMA flowchart of studies through the review process.



2.2.4 Data collection process

One reviewer (MDY) extracted data relating to methodology (e.g., design, sample size, treatment length), participant characteristics (e.g., mean age, mean BMI), intervention description (e.g., focus, mode of delivery, treatment intensity and frequency) and the intervention effect on weight. (i.e., mean weight or mean weight change, standard deviations and the number of participants included in the analysis). In a small number of cases the required statistics were not reported. If available, and if possible, other statistics (e.g., 95% CIs) were converted to the required form according to the calculations outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (94).

2.2.5 Risk of bias in individual studies

Risk of bias was independently assessed by two reviewers (MDY and PJM) using a tool adapted from the Consolidated Standards of Reporting Trials (CONSORT) statement (95) and previously used quality criteria for methodology and reporting (96). Each item was scored as 'present' (✓), 'absent' (×) or 'unclear or inadequately described' (?). Disagreements were resolved by discussion. Following this, inter-rater reliability was calculated on a dichotomous scale (✓ vs. × or ?) using percentage agreement and Cohen's κ. Depending on the study design, some items were not applicable. These were scored as such (n/a) prior to assessment. Unweighted sum totals were calculated for each study using a pre-defined scoring system (✓ = 1 | × = 0 | ? = 0 | n/a = 0). Each study was then assigned a risk of bias category based on the following cut-offs: high risk (0-3), medium risk (4-7) or low risk (8-10).

2.2.6 Synthesis of results

The first aim was to investigate the effectiveness of male-only weight loss and weight loss maintenance interventions. To address this, data were first collated and described in a narrative summary with emphasis given to results from randomised controlled trials (RCTs). In addition, results from weight loss interventions in RCTs with true controls (n = 7) were pooled in a meta-analysis using RevMan Analyses 5.1.2 (87). When a study compared multiple treatment groups to a single control (n = 2), the sample size of the shared control was split to avoid double counting (94). All results were continuous and reported on the same scale (kg) so the aggregate result was calculated as the weighted mean difference (WMD) between interventions and controls. Meta-analysis was not possible for weight loss maintenance treatments due to the small number of RCTs (n = 2).

The second aim was to determine which characteristics in male-only studies were commonly associated with effectiveness. Interventions were considered effective if participants achieved a mean weight loss of at least 5% by the final assessment, prior to any additional weight loss maintenance intervention. This represents clinically important weight loss and is linked to a reduction in weight-related morbidity (36, 97). Interventions were dichotomised a number of times according to whether or not they featured a particular characteristic (e.g., a prescribed energy restriction) and proportions of effective interventions in each group were compared. A particular characteristic was regarded as more (or less) related to effectiveness if the difference in proportions was at least 20%. Recently, Fjeldsoe and colleagues (98) used this approach in a systematic review of physical activity and dietary interventions. However, this analysis used a more conservative cut-off, as some interventions being compared were from the same study and may have shared some additional factors in common. Continuous characteristics (e.g., mean age of participants) were investigated by dichotomising interventions that were greater than or less than or equal to the median of all interventions.

2.3 Results

2.3.1 Study selection

The search provided a total of 3872 unique citations. From this, a total of 24 articles describing 23 studies were identified for inclusion. Figure 2.1 presents a flow diagram detailing the selection process.

2.3.2 Study characteristics

Table 2.1 displays selected characteristics of all eligible studies, representing 1869 participants. All studies tested a male-only weight loss intervention (83, 84, 99-120). Participants in four studies also received a weight loss maintenance intervention (103, 112, 116, 120). For this review, all weight loss interventions are reported together, but the four maintenance interventions are reported separately. Each maintenance intervention received an individual risk of bias assessment, unrelated to the preceding weight loss intervention.

Five weight loss studies were published between 2010-2011 (84, 104, 105, 109, 110), nine between 2000-2009 (83, 101, 103, 106, 112-114, 117-119), eight between 1990-1999 (99, 100, 102, 108, 111, 115, 116, 120), and one in 1985 (107). The majority of studies were conducted in Australia (83, 104-106, 108, 115), the United States of America (99-102, 107, 116) and Japan (109, 110, 117-119). Remaining studies were tested in the United Kingdom (103, 114), Canada (113), Finland (112), Sweden (111) and the Netherlands (120).

Weight loss interventions were investigated using a number of designs. Twelve studies were RCTs (83, 99-109); ten studies were pre-test/post-test trials (where a single group of participants were measured before and after the intervention) (111-120) and one study was a non-randomised experimental trial (where participant preferences were considered during allocation to one of two interventions or a control) (110). The active intervention periods ranged from 3 weeks to 24 months. Eleven interventions ranged from 3-4 months (83, 99, 102-106, 110, 114, 117, 120), five ranged from three weeks to 2 months (101, 107, 109, 112, 115, 116), five ranged from 11.5-12 months (100, 108, 113, 118, 119) and one was 24 months (111). Participant follow-up, defined as the length of time after post-test assessment, was included in four weight loss studies (83, 105, 109, 115) and ranged from 3 months (105) to 21 months (115) (median length of follow-up: 7.5 months).

Table 2.1 also displays the characteristics of the weight loss maintenance interventions, which followed four previously described weight loss interventions (103, 112, 116, 120). Two interventions used a pre-test/post-test design and two were RCTs where participants were randomised to either weight loss maintenance or to no intervention groups after the conclusion of a weight loss phase (112, 120).

Table 2.1. Intervention characteristics of male-only weight loss and weight loss maintenance interventions.

Study	Length (months)	Mode	Treatment Intensity (contacts)					Freq [a]	Description
			Total	M	PA	E	Ph		
Weight Loss*: *RCTs									
Dennis *et al.* (1999) (99)	4	(a) F2F (Group) + resources	80	*16*	*64*	-	-	20	(a) **Diet**: RED (500 kcal daily deficit; 50-55% carbohydrate, <20% protein, <30% fat) + **Cognitive-behavioural (CB):** Dietary advice, non-descript behaviour modification & cognitive control techniques, weight & diet self-monitoring + **Physical Activity (PA)**: Aerobic exercise sessions.
		(b) F2F (group)	64	-	*64*	-	-	16	(b) *Usual care control*: **PA**: as in (a) [usual navy training routine]
Frey-Hewitt *et al.* (1990) [b] (100)	11.5	(a) F2F (group) + F2F (ind)	20	*20*	-	-	-	1.7	(a) **Diet:** RED (300-500 kcal daily deficit; macronutrient composition maintained) + **CB:** Dietary advice, goal setting, weight & dietary self-monitoring.
		(b) n/a (control)	-	-	-	-	-	-	(b) *No intervention control.*
Hannum *et al.* (2006) (101)	2	(a) F2F (group)	8	*8*	-	-	-	4	(a) **Diet:** LED (approx. 1700 kcal/day; 55% carbohydrate, 25% protein, fat 20%) based on the *Food Group Pyramid* + **CB:** Straightforward instruction & information. Weight self-monitoring.
		(b) F2F (group)	8	*8*	-	-	-	4	(b) **Diet:** as in (a), however pre-packaged meals provided for lunch & dinner + **CB:** As in (a).
Kraemer *et al.* (1999) (102)	3	(a) F2F (group)	12	*12*	-	-	-	4	(a) **Diet:** LED (1600 kcal/day) with partial meal replacements + **CB:** dietary advice, non-descript behaviour modification, weight & dietary self-monitoring with feedback.
		(b) F2F (group)	48	*12*	*36*	-	-	16	(b) **Diet:** LED (1400 kcal/day) with partial meal replacements **+ CB:** As in (a) + **PA**: Aerobic exercise sessions.
		(c) F2F (group)	48	*12*	*36*	-	-	16	(c) **Diet:** as in (b) **+ CB:** As in (a) + **PA**: As in (b) + strength training.
		(d) n/a (control)	-	-	-	-	-	4	(d) *No intervention control*.

Study	Length (months)	Mode	Treatment Intensity (contacts)					Freq [a]	Description
			Total	M	PA	E	Ph		
Leslie *et al.* (2002) [c] (103)	3	(a) F2F (ind)	6	*6*	-	-	-	2	(a) **Diet:** RED (600 kcal daily deficit; >50% carbohydrate, <35% fat, <20% protein) + **CB**: Dietary education.
		(b) F2F (ind)	6	*6*	-	-	-	2	(b) **Diet:** LED (1500 kcal/day; >50% carbohydrate, <35% fat, <20% protein) + **CB**: As in (a)
		(c) n/a (control)	-	-	-	-	-	-	(c) *Wait-list control*.
Morgan *et al.* (2009) (83, 84)	3	(a) F2F (group) + online + resources	8	*1*	-	*7*	-	2.7	(a) **CB:** Instruction on modification of dietary & PA habits tailored for men, website to self-monitor weight, diet & PA, individualised diet feedback (emailed).
		(b) F2F (group) + resources	1	*1*	-	-	-	0.3	(b) *Minimal intervention control*: **CB**: as in (a), without website or dietary feedback.
Morgan *et al.* (2011a) (104)	3.5	(a) F2F (group) + online + resources	8	*1*	-	*7*	-	2.3	(a) **CB:** Education on energy balance tailored for shift-workers, weight loss tips for men, self-monitoring, goal setting & social support & group based monetary incentives.
		(b) n/a (control)	-	-	-	-	-	-	(b) *Wait list control*.
Morgan *et al.* (2011b) (105)	3	(a) F2F (group) + online + resources	8	*5*	*3*	-	-	2.7	(a) **CB:** Education on reducing health risks via behaviour change & importance of role modelling healthy behaviour to kids + **PA**: '*Father & child/ren*' activity sessions.
		(b) n/a (control)	-	-	-	-	-	-	(b) *Wait list control*.
Nowson *et al.* (2005) (106)	3	(a) F2F (ind) + telephone + resources	6	*4*	-	-	*2*	2	(a) **Diet:** Non-prescriptive, modified DASH diet with targets for fruit, vegetable & dairy + **CB:** PA & diet goal setting, written material given with tips to encourage compliance + **PA**: Self-driven PA required for all/most days (30-min moderate intensity).
		(b) F2F (ind) + telephone + resources	6	*4*	-	-	*2*	2	(b) **Diet:** Non-prescriptive, low fat diet with general guidelines on increasing fruit and vegetables & reducing fat + **CB & PA**: as in (a)

Study	Length (months)	Mode	Treatment Intensity (contacts)					Freq [a]	Description
			Total	M	PA	E	Ph		
Pavlou *et al.* (1985) (107)	2	(a) F2F (group)	8	*8*	-	-	-	4	(a) **Diet**: One of the following dietary conditions (all conditions collapsed in analysis): LED (1000 kcal/day), VLED (800 kcal/day) or VLED (420 kcal/day) + **PA**: Combination of endurance interval training (walk, jog, run) & resistance training + **CB**: Diet & PA self-monitoring, nondescript behaviour modification, general nutrition education.
		(b) F2F (group)	32	*8*	*24*	-	-	16	(b) **Diet & CB**: as in (a).
Pritchard *et al.* (1997) (108)	12	(a) F2F (ind) + resources	12	*12*	-	-	-	1	(a) **Diet:** RED (500 kcal deficit [e]; 22-25% fat) + **CB:** Compliance review, barriers discussed.
		(b) F2F (ind) + resources	12	*12*	-	-	-	1	(b) **PA**: Self-selected aerobic exercise regime (65-75% max heart rate encouraged) + **CB:** As in (a).
		(c) F2F (ind)	12	*12*	-	-	-	1	(c) *Usual care control*: Assistance to maintain pre-study dietary & PA habits
Tanaka *et al.* (2010) (109)	1	(a) Online + resources	2	-	-	*2*	-	2	(a) **CB:** Weight & behaviour self-monitoring, computerised feedback with advice on changing behaviours.
		(b) Resources	0	-	-	-	-	0	(b) *Minimal intervention control*: **CB:** Weight control booklet only.
Weight Loss*: *Non-randomised Experimental Trials									
Matsuo *et al.* (2010) (110)	3.5	(a) F2F (group) + F2F (ind)	16	*14*	*2*	-	-	4.6	(a) **Diet:** LED (1680 kcal/daily) based on the *Four-Food-Group* method + **PA**: Basic instruction, walking & light resistance training + **CB**: Diet & weight self-monitoring, dietary feedback.
		(b) Indirect	0	-	-	-	-	0	(b) No direct intervention, but the men's partners received the intervention described in (a).
		(c) F2F (group)	1	*1*	-	-	-	0.3	(c) *Minimal intervention control*: Basic information on improving metabolic syndrome status.

Study	Length (months)	Mode	Treatment Intensity (contacts) Total	M	PA	E	Ph	Freq [a]	Description
Weight Loss: Pre-test / Post-test Trials									
Andersson *et al.* (1997) (111)	24	(a) F2F (group)	104	*104*	-	-	-	4.3	(a) **Diet**: LED (1600 kcal/day) encouraged + **PA**: Offered physical training sessions + **CB**: Self-monitoring, stimuli control, eating techniques, reinforcement, cognitive restructuring, education on nutrition & benefits of PA, importance of social support, goal setting. Program tailored for men.
Borg *et al.* (2002) [c] (112)	2	(a) F2F (group)	8	*8*	-	-	-	4	(a) **Diet**: LED (1200 kcal/day; week 1 & 8) with meal replacements and VLED (500 kcal per day; weeks 2-7) with meal replacements + **CB**: Weight self-monitoring, dietary instruction, education on weight maintenance, relapse prevention strategies.
Di Marzo *et al.* (2009) (113)	12	(a) F2F (ind)	24	*24*	-	-	-	2	(a) Nondescript personalised nutritional & physical activity exercise management program.
Drummond *et al.* (2004) (114)	3	(a) F2F (ind) + resources	1	*1*	-	-	-	0.3	(a) **Diet**: RED (600-700 kcal daily energy deficit; low fat, high carbohydrate, sugar containing diet) + **CB**: Dietary advice, social support strategies.
Egger *et al.* (1996) (115)	1.5	(a) F2F (group) + resources	6	*6*	-	-	-	4	(a) **Diet**: Not prescriptive, encouraged to reduce fat intake & increase fiber intake + **CB**: Education on energy balance, benefits of incidental PA, goal setting, 'trading off' alcohol for extra movement. Program tailored for men.
James *et al.* (1998) [c d] (116)	0.75	(a) F2F (group)	60	*40*	*20*	-	-	80	(a) **Diet**: Not prescriptive, but shown how to eat regular, healthy meals/snacks + **PA**: Aerobic exercise sessions (walking, cycling, and swimming). Encouraged to exercise at 60-75% max heart rate + **CB**: realistic goal setting, importance of self-monitoring, healthy lifestyle education, relaxation (3 week intensive program).
Maeda *et al.* (2006) (117)	3	(a) F2F (group)	13	*13*	-	-	-	4.3	(a) **Diet:** LED (1680 kcal/day; 50% carbohydrate, 25% protein, 25% fat) + **CB:** Nutritional advice & dietary self-monitoring.

Study	Length (months)	Mode	Treatment Intensity (contacts)					Freq [a]	Description
			Total	M	PA	E	Ph		
Miyatake *et al.* (2002) (118)	12	(a) Resources	0	-	-	-	-	0	(a) **PA**: Instruction to increase average daily step count by 1000 steps & maintain the increase for 1 year (given a pedometer) + **CB**: Goal setting.
Nakanishi *et al.* (2000) (119)	12	(a) F2F (group)	2	*2*	-	-	-	0.2	(a) **CB:** Education on controlling body weight, reducing alcohol intake, considering a nutritional balance.
Pasman *et al.* (1999) [c] (120)	4	(a) F2F (group)	61	-	*61*	-	-	15.3	(a) **Diet**: 2-month VLED (480 kcal/day), ad libitum diet for last 2 months + **PA**: Endurance training program (running/cycling at moderate intensity for 60-min).
Weight Loss Maintenance*: *RCTs									
Borg *et al.* (2002) (112)	6	(a) F2F (group) + resources	104	*26*	*78*	-	-	17.3	(a) **Diet**: Ad libitum, high carbohydrate, low fat weight maintenance diet + **PA**: Walking sessions at 60-70% of VO2max. + **CB**: Barriers to diet discussed, relapse prevention strategies covered.
		(b) F2F (group) + resources	104	*26*	*78*	-	-	17.3	(b) **Diet & CB**: as in (a) + **PA**: Resistance training at 60-80% of rep maximum with 8 reps & 3 sets per exercise.
		(c) n/a (control)	-	-	-	-	-	-	(c) **Diet & CB**: as in (a).
Pasman *et al.* (1999) (120)	12	(a) F2F (group)	182	-	*182*	-	-	15.3	(a) **PA**: Continuation of PA program from weight loss phase.
		(b) n/a	-	-	-	-	-	-	(b) *Control group*
Weight Loss Maintenance*: *Pre-test / Post-test Trials									
James *et al.* (1998) (116)	12	(a) F2F (group)	52	*52*	-	-	-	4.3	(a) **CB**: Weight, diet & PA self-monitoring with review, relapse prevention strategies, self-regulation techniques.
Leslie *et al.* (2002) (103)	3	(a) Online	5	-	-	*5*	-	1.7	(a) **Diet**: Weight maintenance diet + **CB**: Email contact to review of weight & eating habits & to discuss maintenance problems.
		(b) Online	5	-	-	*5*	-	1.7	(b) **Diet**: As in weight loss phase + **CB**: As in (a).

Study	Length (months)	Mode	Treatment Intensity (contacts)					Freq [a]	Description
			Total	M	PA	E	Ph		

Note. RCT = randomised controlled trial; M = meetings; CB = cognitive-behavioural components; PA = physical activity; E = email contacts; Ph = phone contacts; Freq = frequency of contact; F2F (ind) = individual face-to-face; F2F (group) = group face-to-face; RED = reduced energy diet; LED = low energy diet; VLED = very low energy diet; DASH = Dietary Approaches to Stop Hypertension.

[a] Contact frequency calculation = total number of contacts / duration of study (contacts/month). [b] Study contained another treatment arm that was not eligible for inclusion in review. [c] Followed by a weight loss maintenance intervention. [d] Treatment contacts estimated from 3-week schedule of activities/meetings. [e] Deficit on recommended dietary intake, not estimated energy requirements.

2.3.3 Risk of bias within studies

Table 2.2 displays the risk of bias assessments for all studies. Inter-rater reliability metrics for the quality assessments indicated substantial agreement for all 266 items (percentage agreement 98%, $\kappa = 0.96$). Quality scores varied, but were mostly poor for both weight loss studies (median score = 3, range = 1-9) and weight loss maintenance studies (median score = 3.5, range = 1 – 6). Three weight loss studies met the criteria to be considered at low risk of bias (83, 104, 105) and these were all from the authors' research group. No maintenance studies met the criteria.

For weight loss trials, only seven studies (30%) used intention-to-treat analysis (83, 101, 103-105, 109), five studies (22%) accounted for confounders in the analyses (83, 104-106, 110) and five studies (22%) provided a power calculation and were adequately powered (101, 103-105, 114). Fourteen studies (61%) met the criteria for adequate retention rates (dropout ≤ 20% for ≤ 6 month follow-up and ≤ 30% for > 6 month follow-up) (83, 100, 101, 104-106, 108-110, 112, 115, 117, 119, 120) and 14 studies (61%) assessed weight status at least 6 months after baseline assessments (83, 100, 103, 105, 108, 109, 111-113, 115, 116, 118-120). Twenty-one studies (91%) reported measuring weight objectively (83, 99-114, 117-120). However, only one study (4%) reported assessor blinding at all assessments (83) and only three RCTs (25%) described the randomisation procedure in sufficient detail (83, 104, 105).

Two weight loss maintenance studies had quality assessments indicating a high risk of bias (103, 116) and two were at moderate risk of bias (112, 120). None of the maintenance interventions reported assessor blinding or used intention-to-treat analysis, and neither of the RCTs described the randomisation process sufficiently. Three studies included sufficient follow-up (112, 116, 120), but only two reported adequate retention rates (112, 120). As mentioned above, these scores relate specifically to the maintenance interventions in studies that also included a weight loss intervention.

Table 2.2. Methodological quality and risk of bias assessment in male-only weight loss and weight loss maintenance studies.

Study	A) Baseline results reported separately for each group	B) Randomisation clearly described and adequately done	C) Dropout ≤ 20% for ≤ 6m follow-up and ≤ 30% for > 6m follow-up	D) Assessor blinding	E) Adiposity assessed ≥ 6m after baseline	F) Intention-to-treat analysis	G) Confounders accounted for in analyses	H) Summary results presented + estimated effect sizes + precision estimates	I) Power calculation reported and study adequately powered	J) An objective measure of weight was used	Score [/10] (risk of bias) [b]
Weight Loss: RCTs											
Dennis *et al.* (99)	✓	?	?	?	×	×	×	×	×	✓	2 (high)
Frey-Hewitt *et al.* (100)	✓	?	✓	?	✓	×	×	×	×	✓	4 (medium)
Hannum *et al.* (101)	✓	?	✓	×	×	✓	×	×	✓	✓	5 (medium)
Kraemer *et al.* (102)	✓	?	?	?	×	×	?	×	×	✓	2 (high)
Leslie *et al.* (103)	✓	?	×	?	✓	✓	×	✓	✓	✓	6 (medium)
Morgan *et al.* (83, 84)	✓	✓	✓	✓	✓	✓	✓	✓	?	✓	9 (low)
Morgan *et al.* (104)	✓	✓	✓	?	×	✓	✓	✓	✓	✓	8 (low)
Morgan *et al.* (105)	✓	✓	✓	×	✓	✓	✓	✓	✓	✓	9 (low)
Nowson *et al.* (106)	✓	?	✓	?	×	×	✓	×	×	✓	4 (medium)
Pavlou *et al.* (107)	✓	?	×	?	×	×	×	×	×	✓	2 (high)
Pritchard *et al.* (108)	✓	?	✓	×	✓	×	×	×	×	✓	4 (medium)
Tanaka *et al.* (109)	✓	?	✓	?	✓	✓	×	×	×	✓	5 (medium)
Weight Loss: Non-randomised Experimental Trials											
Matsuo *et al.* (110)	✓	n/a	✓	?	×	×	✓	×	×	✓	4 (medium)
Weight Loss: Pre-test/post-test Trials											
Andersson *et al.* (111)	n/a	n/a	×	×	✓	×	×	×	×	✓	2 (high)
Borg *et al.* (112)	n/a	n/a	✓	×	✓	×	×	×	×	✓	3 (high)
Di Marzo *et al.* (113)	n/a	n/a	?	×	✓	?	×	×	×	✓	2 (high)

Study	A) Baseline results reported separately for each group	B) Randomisation clearly described and adequately done	C) Dropout ≤ 20% for ≤ 6m follow-up and ≤ 30% for > 6m follow-up	D) Assessor blinding	E) Adiposity assessed ≥ 6m after baseline	F) Intention-to-treat analysis	G) Confounders accounted for in analyses	H) Summary results presented + estimated effect sizes + precision estimates	I) Power calculation reported and study adequately powered	J) An objective measure of weight was used	Score [/10] (risk of bias) [b]
Drummond *et al* (114)	n/a	n/a	×	×	×	×	×	×	✓	✓	2 (high)
Egger *et al.* (115)	n/a	n/a	✓	×	✓	×	×	×	×	×	2 (high)
James *et al.* (116)	n/a	n/a	?	×	✓	?	×	×	×	?	1 (high)
Maeda *et al.* (117)	n/a	n/a	✓	×	×	✓	×	×	×	✓	3 (high)
Miyatake *et al.* (118)	n/a	n/a	?	×	✓	×	×	×	×	✓	2 (high)
Nakanishi *et al.* (119)	n/a	n/a	✓	×	✓	×	×	×	×	✓	3 (high)
Pasman *et al.* (120)	n/a	n/a	✓	×	✓	×	×	×	×	✓	3 (high)
n (%)	13 (100 [a])	3 (25 [a])	14 (61)	1 (4)	14 (61)	7 (30)	5 (22)	4 (17)	5 (22)	21 (93)	
Weight Loss Maintenance: RCTs											
Borg et al. (112)	✓	?	✓	?	✓	×	✓	✓	×	✓	6 (medium)
Pasman et al. (120)	✓	?	✓	?	✓	×	×	×	×	✓	4 (medium)
Weight Loss Maintenance: Pre-test/post-test Trials											
Leslie et al. (103)	✓	n/a	×	×	×	×	×	×	✓	✓	3 (high)
James et al. (116)	n/a	n/a	?	×	✓	?	×	×	×	?	1 (high)
n (%)	3 (100) [a]	0 (0 [a])	2 (50)	0 (0)	3 (75)	0 (0)	1 (25)	1 (25)	1 (25)	3 (75)	

Note: RCT = randomised controlled trial; ✓ = present; × = absent; ? = unclear or inadequately described; n/a = not applicable.
[a] Calculated only for trials where this item was applicable. [b] Risk of bias: 0-3 (high), 4-7 (medium), 8-10 (low).

2.3.4 Effectiveness of male only interventions aiming to achieve weight loss

2.3.4.1 Summary of evidence from RCTs

Table 2.3 shows the weight loss results for all male-only weight loss studies. Results from the 12 RCTs will be discussed in detail, as these are considered the gold standard for experimental research (95). The first RCT with a low risk of bias (83) investigated the effectiveness of a weight loss program with internet support and dietary feedback to a minimal intervention, resources-only control. Both study arms received one group information session. No difference was observed between the groups at 3-month follow-up (-5.3 kg [5.7] vs. -3.5 kg [5.9], P = 0.23) or 9-month follow-up (-5.3 kg [6.4] vs. -3.1 kg [6.7], P = 0.41). However, at both 3- and 9-month follow-up, both groups weighed significantly less than at baseline (P < 0.001).

In the second low-risk of bias RCT (104), male shift workers were provided with a weight loss information session, a resources package, and access to a diet and exercise self-monitoring website. E-feedback on diet and exercise was provided on seven occasions. At post-test, the intervention group demonstrated significantly greater mean weight loss compared to the control group (3.5 month: -4.0 kg [4.4] vs. 0.3 kg [3.0], P < 0.001).

The third RCT with a low-risk of bias (105) investigated a weight loss program targeting fathers of children aged 5-12 years. The intervention involved five information sessions and three active sessions where fathers participated in various physical activities with their children. At post-test, the intervention group showed a significantly greater mean weight loss compared to the control group (3-month: -6.7 kg [3.9] vs. -0.4 kg [3.7], P < 0.001) and this difference was greater at 3-month follow-up (-7.6 kg [4.0] vs. 0.0 kg [3.7], P < 0.001).

Seven of the remaining nine RCTs included at least one intervention with a prescribed energy restriction. Three studies compared these dietary interventions to a no intervention or wait-list control group and reported similar results. In the first RCT (100), participants receiving a reduced energy diet lost significantly more weight on average than those in a no intervention control group (12 month: -6.68 kg [3.94] vs. 0.38 kg [3.66], P < 0.001). Another RCT (103) observed no significant difference at 3-

month post-test between a reduced energy diet group and a low energy diet group (-4.6 kg [3.4] vs. -5.6 kg [3.7], P = 0.22), with both demonstrating significantly greater weight loss than a wait-list control. A third RCT compared the effects of a stepped intervention with three components (reduced energy diet alone vs. reduced energy diet plus aerobic exercise vs. reduced energy diet plus aerobic exercise plus resistance training) to a no intervention control (102). After 3 months, a significantly greater weight loss was observed for all interventions compared to the control (P < 0.05) with no significant difference observed between interventions.

Two RCTs investigated the effectiveness of weight loss programs against usual care control groups. One identified a significant weight loss effect in both a reduced energy diet intervention and a physical activity intervention against the control (P < 0.05), with participants in the reduced energy diet condition losing significantly more weight on average than those in the physical activity condition (108). The second was conducted on-board a Navy vessel and investigated the additional effect of a reduced energy diet and lifestyle modification program to the Navy's standard fitness program (99). At post-test, average weight loss in the intervention group was significantly greater than in the control (4 month: -8.6 kg [5.0] vs. -5.0 kg [4.1], P < 0.05).

Three RCTs investigated dietary approaches to weight loss without using a control group (101, 106, 107). Although all groups demonstrated a significant time effect for weight loss, no studies identified a significant difference between groups at post-test. One of these investigated the effectiveness of a low energy diet with partial meal replacements to a low energy diet without meal replacements (101). The second RCT compared a low fat dietary condition to a dietary condition where participants had set daily fruit and vegetable targets (106). The third RCT originally randomised participants to eight study arms (one of two low energy diets or one of two very low energy diets, with or without physical activity). However, in reporting results the study arms were collapsed into two groups and no difference was observed between diet and exercise groups vs. diet without exercise for weight loss.

Table 2.3. Weight-related outcomes for male-only weight loss and weight loss maintenance interventions.

Study	Retention	Measurement	Results (kg)	Significance	% change [a]
Weight Loss: RCTs					
Dennis *et al.* (99)	PT: Unclear (?/39)	Mean weight change from baseline	a) n = unclear, 4m: -8.6 (5.0) b) n = unclear, 4m: -5.0 (4.1)	Post-test (4m): a > b Follow-up: none	a) -8.0% b) -4.0%
Frey-Hewitt *et al.* (100)	PT: 75% (77/103)	Mean weight change from baseline	a) n = 36, 12m: -6.68 (3.94) b) n = 41, 12m: +0.38 (3.66)	Post-test (12m): a > b Follow-up: none	a) -7.1% b) 0.0%
Hannum *et al.* (101)	PT: 85% (51/60)	Mean weight change from baseline	a) n = 30 [b], 2m: -4.5 (4.1) b) n = 30 [b], 2m: -6.1 (4.0)	Post-test (2m): a = b Follow-up: none	a) -4.5% b) -6.1%
Kraemer *et al.* (102)	PT: Unclear (?/35)	Mean weight	a) n = unclear, 0: 106.85 (15.08) 3m: 97.21 (14.20) b) n = unclear, 0: 95.66 (12.55) 3m: 86.67 (11.34) c) n = unclear, 0: 92.07 (13.09) 3m: 82.17 (10.61) d) n = unclear, 0: 92.91 (11.45) 3m: 92.56 (13.57)	Post-test (3m): [a, b & c] > d Follow-up: none	a) -9.0% b) -9.4% c) -10.8% d) 0.0%
Leslie *et al.* [c] (103)	PT: 75% (91/122)	Mean weight change from baseline	a) n = 40 [b], 3m: -4.6 (3.4) b) n = 38 [b], 3m: -5.6 (3.7) c) n = 44 [b], 3m: +0.5 (2.2)	Post-test (3m): [a & b] > c Follow-up: *maintenance intervention*	a) -4.7% b) -5.9% c) 0.0%
Morgan *et al.* (83, 84)	PT: 85% (55/65) FU1: 83% (54/65) FU2: 71% (46/65)	Mean weight change from baseline	a) n = 34 [b], 3m: -4.8 (4.4) 6m: -5.3 (5.7) 12m: -5.3 (6.4) b) n = 31 [b], 3m: -3.0 (4.4) 6m: -3.5 (5.9) 12m: -3.1 (6.7)	Post-test (3m): a = b Follow-up (3m): a = b Follow-up (9m): a = b	a) -5.3% b) -3.2%
Morgan *et al.* (104)	PT: 81% (89/110)	Mean weight change from baseline	a) n = 65 [b], 3.5m: -4.0 (4.4) b) n = 45 [b], 3.5m: +0.3 (3.0)	Post-test (3.5m): a > b Follow-up: none	a) -4.2% b) 0.0%
Morgan *et al.* *(105)*	PT: 83% (44/53) FU: 83% (44/53)	Mean weight change from baseline	a) n = 27 [b], 3m: -6.7 (3.9) 6m: -7.6 (4.0) b) n = 26 [b], 3m: -0.4 (3.7) 6m: 0.0 (3.7)	Post-test (3m): a > b Follow-up (3m): a > b	a) -7.1% b) 0.0%
Nowson *et al.* (106)	PT: 86% (54/63)	Mean weight	a) n = 27, 0: 88.2 (10.2) 3m: 83.3 (9.4) b) n = 27, 0: 98.2 (10.6) 3m: 93.6 (9.4)	Post-test (3m): a = b Follow-up: none	a) -5.6% b) -4.7%

Study	Retention	Measurement	Results (kg)	Significance	% change [a]
Pavlou *et al.* (107)	PT: 45% (72/160)	Mean weight change from baseline	a) n = 31, 2m: -11.8 (3.34) b) n = 41, 2m: -9.2 (1.9)	Post-test (2m): a = b Follow-up: none	a) -11.9% b) -9.1%
Pritchard *et al.* (108)	PT: 88% (58/66)	Mean weight	a) n = 18, 0:88.1 (10.5) 12m: 81.8 (9.9) b) n = 21, 0: 87.8 (10.1) 12m: 85.2 (10.4) c) n = 19, 0: 87.0 (10.9) 12m: 87.9 (10.5)	Post-test (12m): a > b > c Follow-up: none	a) -7.2% b) -3.0% c) +1.0%
Tanaka *et al.* (109)	PT: 96% (49/51) FU1: 92% (47/51) FU2: 90% (46/51)	Mean weight change from baseline	a) n = 23 [b], 1m: -1.1 (1.4) 3m: -2.2 (2.5) 7m: -2.4 (3.2) b) n = 28 [b], 1m: -0.3 (1.0) 3m: -1.2 (1.8) 7m: -1.6 (2.8)	Post-test (1m): a > b Follow-up (2m): NR Follow-up (6m): a = b	a) -3.2% b) -2.2%
Weight Loss: Non-randomised Experimental Trials					
Matsuo *et al.* (110)	PT: 84% (104/124)	Mean weight change from baseline	(a) n =34, 3.5m: -6.2 (3.3) (b) n = 36, 3.5m: -4.4 (3.7) (c) n = 34, 3.5m: -0.7 (1.4)	Post-test (3.5m): a > b > c Follow-up: none	a) -7.9% b) -5.7% c) -1.0%
Weight Loss: Pre-test/post-test Trials					
Andersson *et al.* (111)	PT: 66% (57/86)	Mean weight	a) n = 57, 0: 121 (19) 24m: 115 (19)	Post-test (24m): Weight < baseline Follow-up: none	a) -5.0%
Borg *et al.* [c] (112)	PT: 91% (82/90)	Mean weight	a) n = 82, 0: 106.0 (9.9) 2m: 91.7 (9.4)	Post-test (2m): Weight < baseline Follow-up: *maintenance intervention*	a) -13.5%
Di Marzo *et al.* (113)	PT: Unclear (?/49)	Mean weight	a) n = unclear, 0: 93.9 (12.5) 12m: 87.5 (13.4)	Post-test (12m): Weight < baseline Follow-up: none	a) -6.8%
Drummond *et al.* (114)	PT: 71% (76/107)	Mean weight	a) n = 76, 0: 106.0 (20.7) 3m: 100.5 (16.6)	Post-test (3m): Weight < baseline Follow-up: none	a) -5.2%

Study	Retention	Measurement	Results (kg)	Significance	% change [a]
Egger *et al*. (115)	PT: 100% (52/52) FU(1): Unclear (?/52) FU(2): Unclear (?/52) FU(3): 81% (42/52)	Mean weight change from baseline	a) n = 42, 1.5m: NR 6m: NR 12m: NR 24m: -5.27 (NR)	Post-test (1.5m): NR Follow-up (4.5m): NR Follow-up (10.5m): NR Follow-up (22.5m): Weight < baseline	a) -5.5%
James *et al*. [c] (116)	PT: Unclear (?/25)	Mean weight	a) n = unclear, 0: 110 (NR), 0.75m: 103 (NR)	Post-test: NR Follow-up: *maintenance intervention*	a) -6.4%
Maeda *et al*. (117)	PT: 100% (7/7)	Mean weight	a) n = 7, 0: 78.0 (7.9) 3m: 68.0 (5.3)	Post-test (3m): Weight < baseline Follow-up: none	a) -12.8%
Miyatake *et al.* (118)	PT: Unclear (?/31)	Mean weight	a) n = unclear, 0: 82.3 (7.4) 12m: 78.6 (7.4)	Post-test (12m): Weight < baseline Follow-up: none	a) -4.5%
Nakanishi *et al.* (119)	PT: 83% (296/355)	Mean weight change from baseline	a) n = 296, 12m: +0.3 (2.4)	Post-test (3m): Weight = baseline Follow-up: none	a) +0.4%
Pasman *et al.* [c] (120)	PT: 94% (15/16)	Mean weight change from baseline	a) n = 15, 4m: -12.6 (3.8)	Post-test (4m): Weight < baseline Follow-up: *maintenance intervention*	a) -13.2%
Weight Loss Maintenance: RCTs					
Borg et al. (112)	PT: 91% (82/90) FU: 76% (68/90)	Mean weight	a) n = 25, 6m: 93.7 (10.7) 29m: 102.0 (13.5) b) n = 28, 6m: 91.1 (8.0) 29m: 99.9 (10.9) c) n = 29, 6m: 93.9 (11.1) 29m: 100.7 (11.4)	Post-test (6m): a = b = c Follow-up (23m): a = b = c	a) -3.8% b) -5.6% c) -5.0%
Pasman et al. (120)	PT: 94% (15/16)	% of baseline weight	a) n = 7, 12m: 94.0% (3.6) b) n = 8, 12m: 96.0% (3.0)	Post-test (12m): a = b Follow-up: none	a) -6.0% b) -4.0%

Study	Retention	Measurement	Results (kg)	Significance	% change [a]
Weight Loss Maintenance: Pre-test/post-test Trials					
James et al. (116)	PT: unclear	Mean weight	a) n = unclear, 0 : 103 (NR) 12m : 101 (NR)	Post-test: NR Follow-up: none	a) -8.0%
Leslie et al. (103)	PT: 70% (85/122)	Mean weight change (6m-3m)	a) n = 45, 3m: +0.9 (2.0) b) n = 40, 3m: +1.4 (1.6) c) NR	Post-test (3m): a = b Follow-up: none	a) -3.8 b) -4.4 c) NR

Note: RCT = randomised controlled trial; NR = not reported; PT = post-test; FU = follow-up; FU(n) = denotes follow-up number ‘n’.

[a] % weight change at final assessment of weight loss or weight loss maintenance phase. If ≥ 5% weight loss achieved (if not reported, then was calculated as: mean weight loss / mean starting weight x 100). [b] Original sample size (intention-to-treat analysis was used). [c] Weight loss intervention was followed by a maintenance intervention.

a = b: no difference between groups a & b ($P > 0.05$); a > b: greater weight loss in group a compared to group b ($P < 0.05$); [a & b] > c: greater weight loss in a and b compared to c ($P < 0.05$); a > b > c: greater weight loss in a compared to b ($P < 0.05$) and in b compared to c ($P < 0.05$). Weight < baseline: Mean weight at post-test significantly lower than at baseline (reported for studies with no control); Weight = baseline: No difference between mean weight at post-test and baseline.

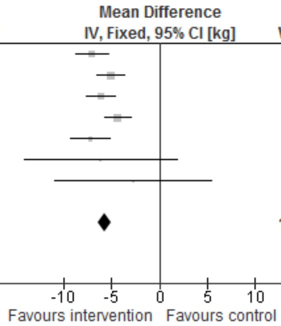
2.3.4.2 Meta-analysis of male-only weight loss interventions vs. true control groups

Results from RCTs with true control groups were pooled in a meta-analysis to establish the overall effect of male-only weight loss interventions compared to no-intervention controls (Figure 2.2). Three interventions from a study at high risk of bias were excluded. Included interventions were sufficiently homogenous (χ^2 = 9.89, d.f. = 6 [P = 0.13], I^2 = 39%), so the fixed effects model was used. This revealed a significant difference in weight change favouring interventions over controls at the last reported assessment prior to any additional maintenance intervention (WMD -5.66 kg [-6.35, -4.97] Z = 16.04 [P < 0.00001]). A funnel plot to assess publication bias was not generated as fewer than 10 interventions were included in the meta-analysis (94).

Figure 2.2. A meta-analysis comparing the effects of male-only weight loss interventions with true controls at the last reported assessment prior to any additional maintenance intervention (n = 7).

Study or Subgroup	Intervention Mean [kg]	Intervention SD [kg]	Intervention Total	Control Mean [kg]	Control SD [kg]	Control Total	Weight	Mean Difference IV, Fixed, 95% CI [kg]
Frey-Hewitt 90 (a vs b)	-6.68	3.94	36	0.38	3.66	41	16.4%	-7.06 [-8.77, -5.35]
Leslie 02 (a vs c)	-4.6	3.4	40	0.5	2.2	22	24.5%	-5.10 [-6.50, -3.70]
Leslie 02 (b vs c)	-5.6	3.7	38	0.5	2.2	22	21.5%	-6.10 [-7.59, -4.61]
Morgan 11a (a vs b)	-4	4.4	65	0.3	3	45	25.0%	-4.30 [-5.68, -2.92]
Morgan 11b (a vs b)	-7.6	4	27	-0.4	3.7	26	11.1%	-7.20 [-9.27, -5.13]
Pritchard 97 (a vs c)	81.8	9.9	18	87.9	10.5	10	0.8%	-6.10 [-14.05, 1.85]
Pritchard 97 (b vs c)	85.2	10.4	21	87.9	10.5	9	0.7%	-2.70 [-10.88, 5.48]
Total (95% CI)			**245**			**175**	**100.0%**	**-5.66 [-6.35, -4.97]**

Heterogeneity: Chi² = 9.89, df = 6 (P = 0.13); I² = 39%
Test for overall effect: Z = 16.04 (P < 0.00001)



2.3.4.3 Summary of evidence from other weight loss trials

Table 2.3 also displays results from the 11 male-only weight loss trials that did not use an RCT design. Results from these studies must be considered with caution, as the overall quality of these studies was low (median = 2, range = 1 – 4). Most studies investigated lifestyle interventions (110, 111, 115, 116, 119) or dietary interventions (112, 114, 117). Despite varying considerably in the approach, duration and intensity of contact, almost all intervention groups recorded a significantly reduced mean weight at post-test compared to baseline.

2.3.5 Effectiveness of male-only interventions aiming to achieve weight loss maintenance

Table 2.3 summarises the results from weight loss maintenance interventions. The small number of heterogeneous studies, including only two RCTs, limits investigation into the effectiveness of maintenance interventions. The first RCT investigated the impact of a walking or resistance training exercise program on weight maintenance versus a control group (112). After the 6-month intervention, weight regain was significant but comparable across all groups and this was also evident at 23-month follow-up. The second RCT also investigated the impact of an exercise program for weight maintenance (120), however, participants in the maintenance intervention demonstrated significant and comparable weight regain to those in the control group after the 12-months.

2.3.6 Characteristics of male only weight loss interventions that are commonly associated with effectiveness

Thirty-one individual interventions were identified from the 23 weight loss studies identified in this review. The mean weight loss for these interventions ranged from 3% (108) to 13.5% (112) (median loss: 6.25%). One intervention group gained weight during the study (+0.4%) (119). Twenty-three interventions (74%) were considered effective based on a mean weight loss ≥ 5% at the final weight loss phase assessment. Using the approach from a recent systematic review (98), a number of characteristics that were commonly associated with effectiveness were identified (Table 2.4). It is important to note that the studies were not designed to test these individual characteristics in isolation and no inferential statistics have been applied due to the variety of characteristics within each intervention.

Eighty-seven percent of interventions where the mean age of participants was less than or equal to the median for all intervention groups (42.8 years) were effective compared to 60% of interventions with a mean age greater than the median. Frequency of contact was strongly related to effectiveness whereas intervention length and the total number of contacts were not. Ninety-three percent of interventions with greater than the median

Table 2.4. Sample, methodological and intervention characteristics associated with effectiveness

	Characteristic	Total [a]	Effective [b]	
		n	n	%
Sample characteristics	Mean age > 42.8 [c]			
	Yes	15	9	60
	No	15	13	87
	Not reported	1	-	-
	Mean BMI > 31.05 [c]			
	Yes	15	12	80
	No	15	10	67
	Not reported	1	-	-
Methodology characteristics	Intervention length > 3 months [c]			
	Yes	12	8	67
	No	19	15	79
	Total contacts > 8 [c]			
	Yes	17	14	82
	No	14	9	64
	Frequency of contact > 2.7 / month [c]			
	Yes	15	14	93
	No	16	9	56
Intervention characteristics	Prescribed energy restriction			
	Yes	18	16	89
	No	13	5	46
	Prescribed physical activity plan			
	Yes	10	7	70
	No	21	16	76
	Individual face-to-face contact			
	Yes	10	7	70
	No	21	16	76
	Group face-to-face contact			
	Yes	20	17	85
	No	11	6	55
	Resources provided			
	Yes	10	7	70
	No	21	16	76

[a] This column displays the number of interventions that had or did not have a particular characteristic. [b] This column shows how many interventions, with or without a particular characteristic, were considered effective (based on achieving ≥ 5% weight loss at the final assessment) and the proportion of the total for each group. If the proportions differed by at least 20% the characteristic was considered more (or less) related to effectiveness. [c] Median value for all intervention samples.

(2.7) contacts per month were effective compared to 56% of interventions with less contact per month.

Including a prescribed energy restriction in the weight loss intervention was strongly related to effectiveness. Eighty-nine percent of interventions with a prescribed energy restriction achieved ≥ 5% weight loss compared to 46% that did not. When considering the dietary approach, all interventions that prescribed a very low energy diet were effective, eight of nine low energy diet interventions and four of five reduced energy diet interventions were also considered effective. Studies that used a group face-to-face mode of delivery were more often effective (85%) than those that did not (55%). The proportion of effective interventions did not differ substantially between those that did or did not include individual face-to-face contact, a set physical activity program or written health resources.

Several other characteristics of interest could not be investigated as they were not observed in sufficient interventions to allow for meaningful comparisons. For example, only three interventions used email contact as a mode of delivery (83, 104, 109), five studies used interventions that were gender-tailored for men (83, 104, 105, 111, 115) and three interventions were based on a theoretical framework (83, 104, 105).

2.4 Discussion

This is the first systematic review of overweight and obesity treatment studies that recruited men only. The aims of this review were: (i) to investigate the effectiveness of male-only weight loss and weight loss maintenance interventions and (ii) to identify which intervention characteristics were commonly associated with effectiveness. Twenty-three eligible weight loss studies were identified, four of which also included a subsequent weight loss maintenance intervention. Twelve weight loss interventions (52%) and two maintenance interventions used an RCT study design. Despite this, the overall risk of bias across studies was high. Using van Sluijs *et al.*’s flow chart for levels of evidence (96), this review demonstrates the evidence base for the effectiveness of male-only weight management programs is ‘limited’ (three small, high quality RCTs demonstrating consistent, positive results).

Trialing men-only weight management interventions is clearly a new and developing area of research. Although the earliest trial identified in this review was conducted in 1985 (107), more than 60% were conducted since 2000. These studies included interventions that varied greatly in treatment approach, duration, mode of delivery and intensity of contact. Despite these differences, a common limitation is the absence of participant follow-up beyond immediate post-test assessment. This was true for most weight loss interventions (99-102, 104, 106-108, 110, 111, 113, 114, 117-119) and weight loss maintenance interventions (103, 116, 120).

Effectiveness was assessed using a number of approaches. Meta-analysis revealed a favourable weight loss effect for participants in male-only weight loss interventions when compared to non-intervention control groups. The weighted mean difference between groups of -5.66 kg [-6.35, -4.97] is comparable to that of another meta-analysis investigating dietary and behaviour change weight loss approaches for both men and women (34). The intervention groups from the three RCTs with a low-risk of bias demonstrated a significant time effect for weight loss, with two of these three considered effective based on reporting a mean weight loss $\geq$ 5% by the final assessment (which ranged from 3.5 months to 12 months post-baseline) (83, 105). These three studies all investigated lifestyle modification programs and were conducted by the same research group (83, 104, 105).

When considering the totality of the evidence, 19 of the 23 weight loss studies included in this review (83%) included at least one group that was deemed effective. Although this appears promising, these results are undermined by the generally low study methodological quality of studies, indicating an increased risk of bias, and should be interpreted with caution. Sixteen studies did not use intention-to-treat analysis (70%) and nine studies (39%) did not achieve adequate retention rates of $\leq$ 20% dropout for $\leq$ 6-month follow-up (and $\leq$ 30% dropout for > 6-month follow-up). These factors are likely to bias the results by inflating both the success rate of participants and the magnitude of weight loss, as participants who drop out of weight loss studies may do so due to lack of success or unwillingness to follow the prescribed intervention (121). Despite this, the average participant dropout rate for studies in this review (22%) was lower than that reported in another review of behavioural weight loss studies (32%)

(122). The high proportion of effective studies identified in this review may also be related to publication bias, as studies with positive results may be more likely to be submitted or accepted for publication (123).

Insights into the effectiveness of male-only weight loss maintenance studies were limited by the lack of available research. Preliminary data from the two RCTs (112, 120) suggest that exercise alone may not be sufficient to achieve weight loss maintenance in men. However, it was unclear whether these studies were adequately powered to detect differences in weight regain between intervention and control groups and both studies reported difficulties with participant compliance. Poor adherence to physical activity protocols has been proposed previously as a key confounder of weight loss maintenance treatment effects (124). Evidence from future high quality and rigorously designed weight loss maintenance trials is needed to determine which intervention approaches and components can help men achieve long-term weight loss success.

This review identified several characteristics of interventions that may be linked to effectiveness in male-specific weight loss studies. These were: a prescribed energy restriction, inclusion of group face-to-face contact, higher frequency of contact (> 2.7 contacts/month) and a younger sample (mean age ≤ 42.8 years). It is important to note that not all interventions were designed to experimentally investigate these characteristics and some interventions with a particular characteristic may have other shared factors in common, particularly interventions from the same study or research group. To adjust for this, a more conservative cut off was used, than that of a previous study (98), to identify characteristics linked to effectiveness.

For this review, a weight loss intervention was defined as effective if the group demonstrated a mean weight loss of at least 5% by final assessment prior to a maintenance intervention. However, it is reasonable to assume that tracking participants over a long period of time would provide a more realistic indication of an intervention’s effectiveness. Further, it is possible that different treatment approaches (e.g., diet-only, exercise-only, combined lifestyle modification programs) and different treatment intensities may be more or less conducive to maintenance of lost weight. This could not be explored in the current review due to the heterogeneity of interventions. It is critical that future interventions include long-term follow-up in order to establish the long-term and more realistic effectiveness of the various approaches to weight loss in men.

Considering that men may be more likely to engage in male-only weight loss programs (86, 91), it would be of interest to compare the recruitment and overall success of men in male-only programs to men in mixed-sex programs. However, this was beyond the scope of this review. Of interest, only five included studies tested 'gender-tailored' weight loss interventions (i.e., designed specifically for men) (83, 104, 105, 111, 115), whereas the majority trialled a standard, gender-neutral weight loss program. A similar proportion of 'gender tailored' programs was identified in a recent systematic review of health promotion interventions targeting men (125). Further evidence is needed to determine whether providing gender specific approaches to weight loss for males is more or less effective than a standardised approach.

2.4.1 Strengths and limitations

This review had several strengths: a comprehensive search strategy across multiple databases with no date restrictions, high agreement levels for quality assessments, and detailed data extraction to allow for comparisons between studies. The conduct and reporting of this review also aligned with the PRISMA statement for transparent reporting of systematic reviews and meta-analyses (126).

This review also had some limitations that should be acknowledged. Firstly, studies were required to be published in English and in a prominent database. In addition, this review reported on a relatively small and heterogeneous sample of studies. Due to this, any synthesis of results must be interpreted with caution. Finally, this review reported on weight outcomes and did not present results relating to other obesity-related health outcomes such as waist circumference, blood pressure or body composition.

2.4.2 Recommendations for practice

Currently, the evidence base for male-only weight management programs is limited in both quantity and quality. However, the existing evidence suggests that men-only weight loss programs may be an effective way to engage and assist men with weight loss. Preliminary evidence suggests that men-only weight loss interventions are more likely to be successful if they include some prescribed energy restriction within the dietary intervention, group face-to-face contact and three or more contacts per month on average.

2.4.3 Recommendations for research

To improve the current evidence base for male-only weight loss and weight loss maintenance approaches, future studies should use a randomised controlled design and adhere to the guidelines outlined in the CONSORT statement. Further, all research should include follow-up assessments over a substantial period of time after the intervention has finished (a minimum of one year but ideally for a number of years). Although this places additional burdens on participants, researchers and resources, this evidence is essential. More evidence is needed to determine which components of weight loss maintenance programs are linked to successful, long term weight loss outcomes in men. A standard timeframe is required to guide when a weight loss intervention ceases and the maintenance intervention begins. Preferably, this maintenance intervention should extend for a number of years. Finally, future research should investigate whether there is a difference in recruitment, retention and success rates of male participants in ‘gender sensitive’ programs compared to those that provide a standard weight loss program to a male-only or mixed-sex population.

CHAPTER 3

SOCIAL COGNITIVE THEORY AND PHYSICAL ACTIVITY: A SYSTEMATIC REVIEW AND META-ANALYSIS

Preface:

This chapter presents the results of meta-analytic review, which I conducted to investigate *Secondary Aim 2* of this thesis (i.e., to systematically review the evidence for the utility of Social Cognitive Theory as a framework to explain physical activity).

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Abstract

Objectives: This review investigated three research questions: (1) What is the utility of Social Cognitive Theory (SCT) to explain physical activity? (2) Is the effectiveness of SCT moderated by sample or methodological characteristics? (3) What is the frequency of significant associations between the core SCT constructs and physical activity?

Methods: Ten electronic databases were searched with no date or sample restrictions. Forty-four studies were retrieved containing 55 SCT models of physical activity. Methodological quality was assessed using a standardised tool.

Results: A random-effects meta-analysis revealed that SCT accounted for 31% of the variance in physical activity. However, methodological quality was mostly poor for these models. Methodological quality and sample age moderated the physical activity effect size, with increases in both associated with greater variance explained. Although self-efficacy and goals were consistently associated with physical activity, outcome expectations and socio-structural factors were not.

Conclusions: SCT is a useful framework to explain physical activity behaviour. Higher quality models explained more variance, but overall methodological quality was poor. High quality studies examining the utility of SCT to explain physical activity are warranted.

3.1 Introduction

Regular physical activity is essential for optimal physical and psychological health. Engaging in regular physical activity decreases the risk of all-cause mortality (127, 128), increases quality of life (129) and reduces the risk of many chronic health conditions such as heart disease, hypertension, type II diabetes and depression (130). In addition, participating in regular physical activity is a key strategy for the prevention of weight gain, for weight loss, and for the prevention of weight regain after weight loss (64). Despite these benefits, recent prevalence data show that physical activity rates are declining internationally in both young people and adults (131). This has likely contributed to rising global obesity rates, which have substantially increased in the past 30 years (2, 3). Although behavioural interventions have demonstrated efficacy to increase activity levels, the effects are typically modest and not often maintained (132, 133). Thus, improving the capacity of interventions to create lasting changes in physical activity is an urgent public health priority and an important strategy to manage obesity at the population level.

Understanding the correlates and determinants of physical activity is a critical step in developing and implementing effective interventions (134, 135). Indeed, evidence suggests that theory-based interventions are more effective than a-theoretical approaches (88). Although the variables that influence physical activity are wide and varied (136), health psychologists have mostly focused on cognitive variables, which are believed to be (i) the most proximal factors to behaviour, and (ii) more open to change than other factors (e.g., socio-demographic variables) (72). In attempts to provide overarching explanations of human behaviour, theorists have structured these cognitive variables into explanatory frameworks called ‘social cognitive theories’ or ‘social cognition models’. These theories, which focus on the social foundations of human learning, include the *Theory of Planned Behaviour (TPB)* (137), the *Health Belief Model* (138), the *Trans-theoretical Model* (139), *Protection Motivation Theory* (140) and Bandura’s *Social Cognitive Theory* (SCT) (69, 71, 73). As detailed in the following section, although SCT has received widespread attention in the literature, it has often been misinterpreted and the overall utility of the theory in the physical activity domain has not been systematically examined.

3.1.1 Social Cognitive Theory

The two primary constructs in SCT are self-efficacy and outcome expectations (see Figure 1.1). According to Bandura (2004), *self-efficacy* is the pivotal construct within SCT and is suggested to have a direct effect on behaviour as well as indirect effects through all other model components. Within the health domain, Bandura (2004, p.144) describes self-efficacy as the confidence one has to '*exercise control over one's health habits*' (71). Self-efficacy is widely regarded as the most significant contribution of SCT to the physical activity literature (74) with a large body of research showing consistently strong associations between the two variables (75). Alternatively, *outcome expectations* are the second SCT construct and represent one's judgments of the likely consequences that will occur as a result of performing, or not performing, a particular behaviour. (71). Central to SCT is the assumption that people will act in ways that they believe will lead to positive and valued outcomes, while avoiding behaviours that they expect to result in unfavourable outcomes (141). Bandura proposes the following three major classes of outcome expectations: (i) physical (i.e., bodily sensations and material gains or losses), (ii) social (i.e., anticipated approval or disapproval), and (iii) self-evaluative (i.e., how one expects that they will feel about themselves after performing a behaviour) (73).

As seen in Figure 1.1, *goals* are the third core construct within SCT. In addition to exhibiting a direct effect on behaviour, goals are also seen to mediate the influence of all other model constructs (71). According to Bandura, goals can be distal, to serve as a general guide, or specific and proximal to inform current actions (73). However, he also notes that having a behavioural goal or intention is not a sufficient condition to perform a behaviour. Goal attainment requires concrete self-regulatory skills such as self-monitoring, specific goal setting and self-reward. Thus, for this review, behavioural goals/intentions and self-regulatory skills were both considered to represent the goals construct. The final construct outlined in SCT is *socio-structural factors*. Socio-structural factors include the various facilitators and impediments to behaviour and are hypothesised to affect health behaviour indirectly via an influence on goal setting (71). These factors are also purported to mediate the influence of self-efficacy on behaviour. For example, people with higher self-efficacy for PA should focus more on positive cues in their environment and build social relationships with likeminded people who will support their goals (72). For the purpose of this review, the following three factors were considered to represent the socio-structural factors construct: (i) social support, (ii) impediments, and (iii) perceived environment.

Although Bandura clearly details a network of socio-cognitive constructs (Figure 1.1), self-efficacy has received far more attention than the other model components (74). As such, many researchers have misinterpreted SCT as a 'one-factor theory' (72). This is reflected in the literature, where the majority of SCT research in the physical activity domain has focused solely on self-efficacy, or examined self-efficacy in combination with only one or two other variables (74). To advance the understanding of SCT and its utility for understanding physical activity, it is important to examine the role of self-efficacy in the context of the other SCT variables, rather than in isolation (75, 76).

With recent advances in meta-analytic techniques, researchers are now able to systematically collect and combine data concerning the explanatory power of social cognition models. These meta-analytic reviews have been conducted for a number of prominent health behaviour theories, including the *TPB* (142, 143), *Protection Motivation Theory* (144, 145) and the *Trans-theoretical Model* (146). However, this process has not been comprehensively applied to SCT. Although one previous review included a meta-analysis of SCT models of physical activity, (147) this review was limited to adolescent populations and identified only three tests of SCT. To the authors' knowledge, Allen conducted the only other review of SCT models of physical activity (148), but the review was restricted to samples of people with diabetes, contained only a narrative synthesis, and examined a number of studies that only included self-efficacy. To date, no reviews have systematically investigated the utility of SCT to explain physical activity in all populations. As such, a comprehensive meta-analytic review that consolidates the evidence for all SCT models, with no sample restrictions, is warranted.

Thus, the current review was conducted to answer the following three research questions: (1) What is the utility of SCT to explain physical activity behaviour in all populations? (2) Is the effectiveness of SCT moderated by key sample or methodological characteristics? (3) What is the frequency of significant association between the SCT constructs and physical activity?

3.2 Methods

The conduct of this review adhered to the guidelines in the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) statement (93).

3.2.1 Eligibility criteria

To be eligible for this review, studies were required to (i) explicitly test a SCT model, (ii) use a measure of physical activity as the dependent variable, (iii) provide an R^2 or report the 'explained variance' in the dependent variable, and (iv) include self-efficacy and outcome expectations at a minimum. Although SCT now includes goals and socio-structural factors, self-efficacy and outcome expectations are generally regarded as the original constructs of the theory (72, 74) given their prominence in early SCT literature (149). Studies were excluded if: (i) the model did not include a measure of both self-efficacy and outcome expectations, (ii) an integrated theory was tested, including core constructs from other prominent theories, or (iii) the model involved analysis of an intervention effect, where participants were treated differently during the study (e.g., mediation analysis).

3.2.2 Information sources and search

To maximise sensitivity, 10 electronic databases were searched in May 2013 using a standardised protocol with no date or sample restrictions. These databases were PsycINFO, Cumulative Index to Nursing and Allied Health Literature (CINAHL), SPORTDiscus, EBSCO, ERIC, ScienceDirect, Web of Science, SCOPUS, EMBASE and PubMed. Search terms were divided into two groups: (i) theory (e.g., 'social cognitive theory' OR 'SCT') and (ii) behaviour (e.g., physical activit* OR exercis* OR walk*). In addition to physical activity terms, the behaviour search term group included a number of dietary terms in order to retrieve studies for an independent review. Of note, while the review was also designed to review the utility of SCT to explain sedentary behaviour, this investigation was precluded by a lack of published research in the area. To ensure all studies included at least one term from each group, the Boolean phrase ‘AND’ was used between groups and the phrase ‘OR’ was used within groups. Where possible, the following limits were applied: ‘peer reviewed’, ‘English’, ‘human’, ‘article or review’. Unpublished studies and non-English studies were not considered for this review.

3.2.3 Study selection

In the first stage of study selection, one reviewer (MDY) removed all duplicates and screened the titles and abstracts of remaining records for relevance in a non-blinded, standardised approach. A second author (PJM) checked all decisions and disagreements were resolved by discussion. In the second stage, full text articles were retrieved for all remaining studies and independently screened by one author (MDY) and a trained research assistant. Discrepancies were referred to a co-author (PJM) with consensus achieved for all studies. In the third stage, the reference lists of all included studies and 26 reviews identified in the search were cross-referenced for additional studies. Finally, a citation search was performed in Web of Science on a seminal article from the SCT literature (71).

3.2.4 Data collection and methodological quality assessment

For each model, the lead author (MDY) extracted data relating to participant characteristics (e.g., country of study, age, sex), methodology (e.g., design, analysis type, SCT constructs measured) and results (e.g., association of each construct with physical activity, variance explained in physical activity).

The lead author (MDY) and a trained research assistant also independently conducted a methodological quality assessment of all models using a tool with items relating to participant selection, study design, measurement and analysis (Table 3.1). This tool was informed by and adapted from three sources: (i) the *Strengthening of Reporting of Observational Studies in Epidemiology* (STROBE) statement (150) and Consolidated Standards of Reporting Trials (CONSORT) (95) statements, (ii) study assessments from two recent theoretical reviews (76, 147) and (iii) a list of ‘strong model characteristics’ described in a highly-cited commentary on behaviour-change theory (151). Multiple models from a single paper were considered in isolation. Each item was independently scored as (i) present (✓), (ii) absent (✗), (iii) unclear or inadequately described’ (?) or

(iv) not applicable (n/a). All scoring discrepancies were resolved by consultation with another reviewer (PJM). Inter-rater reliability was assessed on a dichotomous scale (✓ = 1, ✗ or ? = 0) using percentage agreement and Cohen's Kappa (κ). Items deemed not applicable were not included in percentage agreements.

3.2.5 Synthesis of results

The primary aim of this systematic review was to investigate the utility of SCT to explain physical activity. To investigate this aim, the R^2 values from all SCT models (n = 55) were pooled in a meta-analysis using Field and Gillett's (152) SPSS macros (SPSS Inc. Chicago, IL). If multiple models were drawn from the same sample, the sample size was split to avoid double counting (94). In the meta-analysis, the square root of each R^2 value was used to create *r* effect sizes, which were then converted to fisher-transformed coefficients and meta-analysed using Hedges and Vervea's (1998) random-effects models (153). Once the fisher-transformed correlation coefficients were meta-analysed, they were back-transformed into correlations and then to R^2 values for ease of interpretation and to allow for comparison with other meta-analyses of social cognitive theories in the literature (142, 143, 147, 154). A random effects approach is recommended over a fixed effects approach when meta-analysing 'real-world' effect sizes that are likely to demonstrate considerable variation (155). In addition, random effects models allow for inferences to be drawn from the meta-analysed studies to the general population (152).

Publication bias was assessed with Begg and Mazumdar's (1994) rank correlation test (156) and was supplemented with Rosenthal's (1979) fail safe N (157). Begg and Mazumdar's (1994) rank correlation represents the association between the effect sizes and associated sample sizes, with a strong, significant correlation providing evidence of publication bias (156). The fail safe N quantifies the number of negative studies that would need to be published and included to result in a non-significant effect size (157).

Table 3.1. Methodological quality assessment criteria.

	✓ **(Present)**	✘ **(Absent)**	? **(Unclear / inadequately described)**
1. Participants were randomly selected from the target population.	Study sample was randomly selected from the target population	Study sample was **not** randomly selected from target population	Detail on sample selection unclear
2. Non-college/university student sample used	Sample was not drawn from college/university student pool	Sample was college/university students	Sample source unclear
3. Longitudinal design used	Longitudinal model: Theory tested across at least two time points greater than 1 week apart	All measures taken within 1 week	Study design unclear
4. If longitudinal, then adequate retention at follow up. *(If cross-sectional, then n/a)*	Attrition ≤20% for ≤ 6 months and ≤30% for > 6 months (or imputation method was used)	Attrition >20% for ≤ 6 months or > 30% for > 6 months (no imputation method used)	Attrition not reported and no explicit mention of 100% retention
5. Power calculation provided and study shown to be powered for analyses	Power calculation reported and study was reported to be adequately powered.	Study explicitly reported to be underpowered	No power calculation stated
6. Sample size ≥200	Sample size included in model ≥200 participants	Sample size included in model <200 participants	Sample size included in model unclear
7. Validated physical activity measure used	Validation data cited or provided by authors for measure. *Note: If multiple measures (e.g., to create a latent variable), ≥50% must have demonstrated validity & reliability*	Measure validity below acceptable standards.	Validation data for physical activity measure not available (i.e., not reported or cited).

	✓ **(Present)**	✘ **(Absent)**	? **(Unclear / inadequately described)**
8. Objective measure of physical activity used	At least one objective physical activity measure used in model (e.g., pedometer, accelerometer)	Self-report measure(s) of physical activity used only	Method of physical activity assessment inadequately described
9. Acceptable reliability for SCT measures	Study reports ***adequate internal consistency*** for all SCT scales (Cronbach's alpha > 0.60) **AND** Study reports ***adequate test-retest reliability*** for all SCT scales (ICC > 0.70 OR Pearson correlation > 0.80)	Study reports ***inadequate internal consistency*** for any SCT scale (Cronbach's alpha ≤ 0.60) **OR** Study reports ***inadequate test-retest reliability*** for any SCT scale (ICC ≤ 0.70 OR Pearson correlation ≤ 0.80)	Complete reliability data (i.e., internal consistency and test-retest reliability) not available for all SCT constructs *Note: If partial data is available, and indicates inadequate reliability for any scale, then* ✘
10. Structural equation modelling / Path analyses used	Structural equation modelling or path analyses used for model	Structural equation modelling or path analyses not used (multiple/hierarchical regression used)	Method of analysis unclear
11. Model adjusts for past behaviour	Model adjusts for past behaviour *If authors explored data and determined no need to adjust for past behaviour this is also acceptable*	Model does not adjust for past behaviour	Unclear if adjustments made for past behaviour

ICC = intra-class correlation coefficient; n/a = not applicable; SCT = Social Cognitive Theory.

To investigate the second study aim, theory-guided moderator analyses were conducted using Field and Gillett's (2010) macro (152). This analysis also followed a random effects approach. The macro uses multiple weighted regressions to determine the influence of specified moderators on the effect size estimate. For categorical variables, a chi-squared test is used to determine if the weighted effect size is significantly different between categories. For continuous moderators, the macro calculates a regression coefficient to quantify the association between the effect size and the moderator (152). Six hypothesised moderators were selected based on previous reviews of social cognitive theories (142, 147, 158). These included three categorical variables: (i) study design (i.e., cross-sectional vs. longitudinal), (ii) adjustment for past behaviour (i.e., adjusted vs. unadjusted), (iii) method of physical activity measurement (i.e., self-report vs. objective) and three continuous variables: (i) the total score from the methodological quality assessment, (ii) the mean age of the sample, and (iii) the proportion of females in the sample. Although ethnicity was also considered as a moderator, this information was not presented consistently enough to include in the analysis.

The third aim was to examine the frequency of significant association for each SCT construct and physical activity. Given that SCT specifies a network of pathways from constructs to behaviour, this analysis considered the direct, indirect, and total effects of each construct, where appropriate. For the purpose of this review, β coefficients from multiple regression models were considered as direct effects and grouped with the direct effect pathways from structural equation models or path models. To determine the frequency of association between SCT constructs and behaviour, the number of significant effects reported for each construct was represented as a proportion of the total number of effects estimated from that construct in the models. Significant effects were only included if they influenced physical activity in the expected direction (e.g., a positive association for self-efficacy or negative association for perceived impediments). Direct, indirect, and total effects were considered in isolation.

3.3 Results

3.3.1 Study selection

The search provided a total of 2,966 unique citations. After culling on titles and abstracts, the full-texts for 189 citations were retrieved for further investigation (Figure 3.1). From this, 44 studies were deemed eligible for inclusion (159-202). The majority of studies were conducted in North America, with 32/44 studies (73%) from the USA (159-164, 167-173, 175, 179, 181-183, 186-194, 197, 199-202), 5/44 studies (11%) from Canada (166, 174, 178, 184, 185) and 1/44 (2%) with participants from both (196). In addition, the following countries each contributed one study to the review: the United Kingdom (165) , Germany (176), Taiwan (177), China (180), India (195), and Iran (198). Overall, these studies included 55 distinct models of physical activity, which are independently described below. Extensive information regarding the methods and results of each model is located in Table 3.2.

3.3.2 Model characteristics

As this review did not include any sample-based restrictions, a wide range of target participant groups were represented across the 55 models. The mean age of participants ranged from 9.4-80.0 years. Men were considerably underrepresented, with only 12/55 models (22%) using a sample with a male majority (165, 166, 175, 176, 178, 180, 182, 184, 185, 195, 199). Further, only 1/55 (2%) used a male-only sample (199) compared to 11/55 (20%) with female-only samples (164, 167, 177, 179, 183, 198, 199, 201). Twenty models (36%) included participants from groups who had experienced, or were experiencing, a significant health concern such as breast cancer (n = 4) (177, 183), diabetes (n = 4) (184, 185), osteoarthritis (n = 2) (174), multiple sclerosis (n = 2) (170, 197), or lung cancer (n = 2) (169). Participants in 19/55 models (35%) were drawn from educational institutions including elementary schools (n = 9) (164, 175, 180, 186, 194, 195, 199), high schools (n = 4) (182, 198, 202) and colleges/universities (n = 6) (171-173, 181, 192). Further, 6/55 (11%) included community samples of adults (159-163, 179) and 10/55 (18%) specifically targeted older adults (i.e., over 60 years of age) (167, 168, 176, 187-190, 193, 200, 201).

Figure 3.1. PRISMA flowchart of studies through the review process.

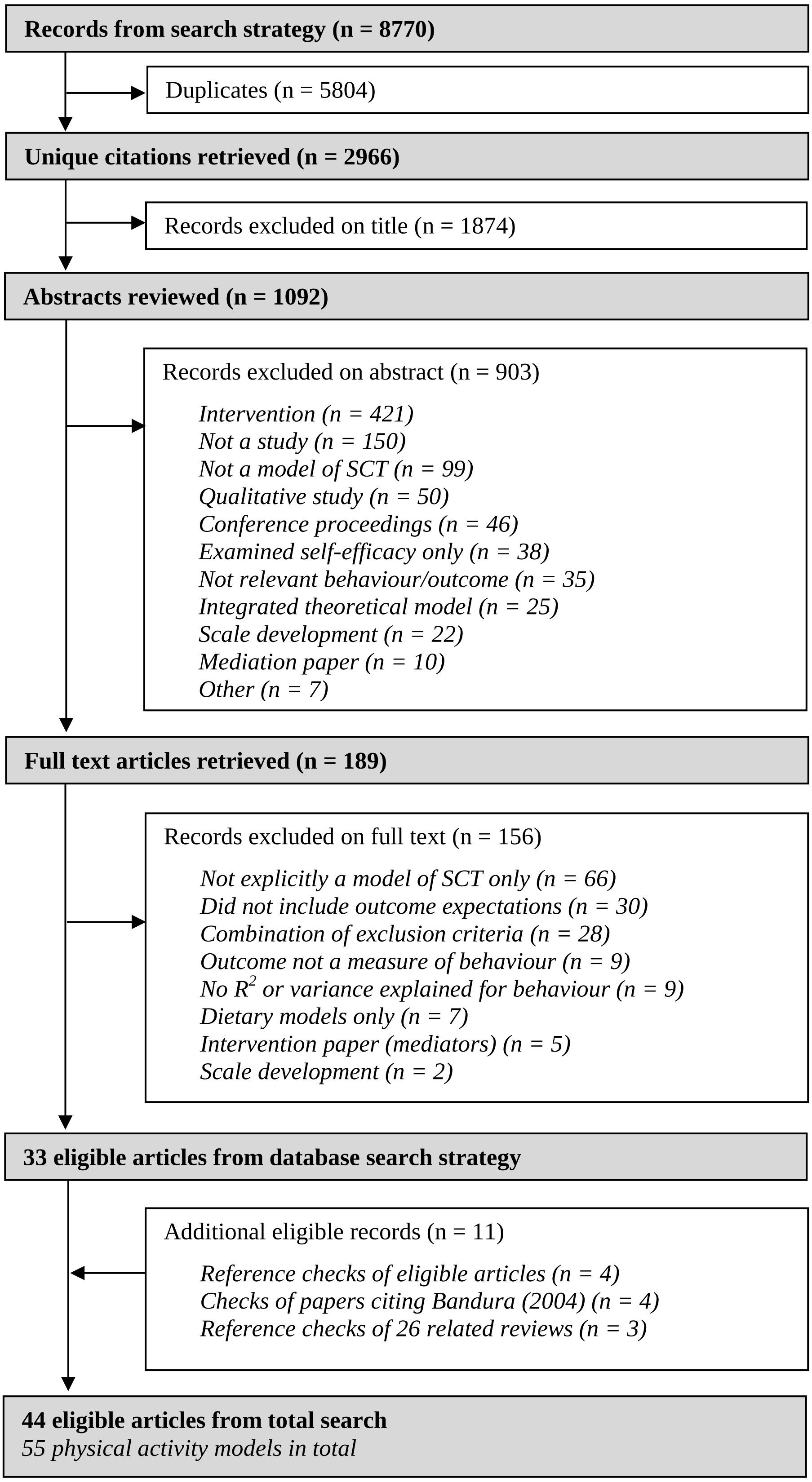

Table 3.2. Characteristics and results of SCT models of physical activity.

First author (year), [ref] country. *Sample (n; sex; race; mean age [SD])*	**Design (retention [a])** *[Analysis]*	**PA Behaviour (time [a]) [Measure]**	**Core SCT Constructs in Model (time) [T1 α] [b c d]**	**Associations with PA [e f]**	**Other variables / covariates / interactions in model [f g]**	**R^2**
Anderson (2006), (159) USA. *n = 999 adult church members (66% female; 77% Caucasian, 21% African American; 52.7 [14.6] yrs)*	Cross-sectional *[Latent variable SEM]*	PA latent variable *[PA diary + pedometry]*	• **SELF-REGULATION**: Various [0.83] • **OUTCOMES (+)**: Physical [0.81] • **EFFICACY**: Barrier [0.91]; Routine [0.89] • **SOCIAL SUPPORT**: Family [0.68] • **OUTCOMES (-)**: Time [0.85]	**(D) 0.36***** (I) ne **(T) 0.36***** **(D) -0.12*** (I) 0.03 (T) -0.09 (D) 0.08 (I) 0.04 **(T) 0.12*** (D) -0.04 **(I) 0.20*** (T) 0.16**** (D) 0.00 **(I) -0.04*** (T) -0.04	• **AGE: (D) -0.53***** • **RACE: (D) -0.25***** • Sex: (D) 0.06	0.46
Anderson-Bill (2011), (160) USA. *n = 703 adult church members (66% female; 23% African American; 58.1 [11.1] yrs)*	Cross-sectional *[Latent variable SEM]*	PA latent variable *[PA diary + pedometry]*	• **SELF-REGULATION:** Various [0.83] • **EFFICACY:** Barrier [0.91]; Routine [0.89] • Outcomes (+): Physical & self-evaluative [0.81] • Outcomes (-): Physical, social & self-evaluative [0.85] • **SOCIAL SUPPORT:** Family [0.68]	**(D) 0.17**** (I) ne **(T) 0.17**** **(D) 0.14*** (I) -0.02 **(T) 0.12*** (D) -0.08 (I) 0.01 (T) -0.07 (D) 0.06 (I) 0.00 (T) 0.06 (D) 0.01 **(I) 0.10*** (T) 0.12****	• **AGE: (D) -0.43***** • **RACE: (D) -0.24**** • **HEALTH: (D) -0.13**** • Sex: (D) 0.02	0.18
Anderson-Bill (2011) (161) USA. *n = 963 non-active adults (83% female; 91% Caucasian; 44.4 [11.0] yrs)*	Cross-sectional *[Latent variable SEM]*	PA latent variable *[PA diary + pedometry]*	• **EFFICACY:** Barrier [0.95] • **SELF-REGULATION:** Various [0.77-0.91] • **SOCIAL SUPPORT:** Family [0.94]; Friends [0.96] • **OUTCOMES (+):** Physical [0.89]; Self-evaluative [0.89] • Outcomes (-): Social [0.85]	**(D) 0.23***** (I) 0.02 **(T) 0.25***** **(D) 0.23***** (I) ne **(T) 0.23***** **(D) 0.21** (I) 0.09*** (T) 0.30***** **(D) -0.14**** (I) 0.03 (T) -0.11 (D) -0.11 (I) 0.00 (T) -0.11	None	0.22
Anderson-Bill (2011) [i], (162) USA. *n = 272 non-active adults (86% female; 92% Caucasian; 43.7 [10.4] yrs)*	Longitudinal (42%) *[Latent variable SEM]*	PA latent variable (16m Δ) *[PA diary + pedometry]*	• **SELF-REGULATION (6m Δ):** Various [0.77-0.91] • **EFFICACY (6m Δ):** Barrier [0.95] • **SOCIAL SUPPORT (6m Δ):** Family [0.94]; Friends [0.96]	**(D) 0.45**** (I) ne **(T) 0.45**** (D) 0.13 **(I) 0.17** (T) 0.30*** (D) 0.06 **(I) 0.20** (T) 0.26***	None	0.30
Ayotte (2010), (163) USA. *n = 232 married adults (116 couples) (50% female; 98% Caucasian; 58.9 [7.2] yrs)*	Cross-sectional *[Latent variable SEM]*	PA latent variable *[PAQ + YPAS + PA diary]*	• **SELF-REGULATION**: Goals [0.94]; Plans [0.77] • **EFFICACY**: Barrier [0.93]; Task [0.96] • **OUTCOMES (+)**: Various [0.93] • **IMPEDIMENTS**: Personal & environmental [0.80] • **SOCIAL SUPPORT**: Family [0.92]	**(D) 0.68**** (I) ne **(T) 0.68**** **(D) 0.48** (I) 0.24** (T) 0.72***** (D) 0.16 **(I) 0.26** (T) 0.42***** (D) -0.15 **(I) -0.27** (T) -0.42***** (D) 0.05 **(I) 0.34*** (T) 0.39*****	• Health: (D) 0.06 • Age: (D) 0.05 • Sex: (D) -0.02	0.71
Bean (2012), (164) USA. *n = 90 elementary school girls (100% female; 71% African American, 23% Hispanic, 6% Caucasian; 9.4 [1.0] yrs)*	Longitudinal (93% [h]) *[Hierarchical regression]*	VPA: frequency (3m) *[Single item; Youth Risk Behaviour Survey]*	• **OUTCOMES (+) (3m Δ):** Various [0.67] • **EFFICACY (3m Δ):** Not specified [0.81] • Social support (BL): Family & friends [0.73] • Outcomes (+) (BL): Various [0.67] • Social support (3m Δ): Family & friends [0.73] • Efficacy (BL): Various [0.81]	**(β) 0.37**** **(β) 0.34**** (β) 0.15 (β) 0.12 (β) -0.07 (β) 0.02	• **PAST BEHAVIOUR: (β) 0.31****	0.37

First author (year), [ref] country. *Sample (n; sex; race; mean age [SD])*	**Design (retention [a])** ***[Analysis]***	**PA Behaviour (time [a]) [Measure]**	**Core SCT Constructs in Model (time) [T1 α] [b c d]**	**Associations with PA [e f]**	**Other variables / covariates / interactions in model [f g]**	**R^2**
	Longitudinal (70% [h]) *[Hierarchical regression]*	VPA: frequency (6m) *[Single item; Youth Risk Behaviour Survey]*	• **EFFICACY (6m Δ):** Not specified [0.81] • **EFFICACY (BL):** Not specified [0.81] • **SOCIAL SUPPORT (BL):** Family & friends [0.73] • Outcomes (+) (6m Δ): Various [0.67] • Outcomes (+) (BL): Various [0.67] • Social support (6m Δ): Family & friends [0.73]	**(β) 0.50**** **(β) 0.41**** **(β) 0.25*** (β) 0.14 (β) -0.07 (β) -0.01	• **PAST BEHAVIOUR: (β) 0.25****	0.34
Bennett (1999), (165) UK. *n = 37 patients in coronary care (27% female; 62.0 [nr] yrs)*	Longitudinal (90%) *[Hierarchical regression]*	LPA: frequency (3m) *[Self-report item]*	• **GOAL (BL):** Intention [single item] • Efficacy (BL): Not specified [single item] • Outcomes (+) (BL): Various [single item]	**(β) 0.64***** x x	• Past behaviour: x	0.51
Blanchard (2011), (166) Canada. *n = 280 coronary patients in home rehab (27% female; 95% Caucasian; 62.8 [11.5] yrs)*	Longitudinal (nr) *[Path analysis]*	MVPA: frequency (3m) *[Modified GLETQ]*	• **EFFICACY:** Barrier [0.93] (BL) • **ENVIRONMENT:** PA equipment [nr] (BL) • Outcomes (+): Various [0.90] (BL) • Social support: Family [0.91] & friends [0.89] (BL)	**(D) 0.21*** (I) nr (T) nr **(D) 0.15*** (I) nr (T) nr (D) nr [NS] (I) ne (T) nr [NS] (D) ne (I) nr (T) nr	• Past behaviour (BL): (D) not est. • Modelling (BL): (D) not est. • Mood (BL): (D) not est. *Analyses controlled for age, sex, comorbidities, metabolic syndrome*	0.30
Conn (1997), (167) USA. *n = 225 free living older women (100% female; 74.3 [6.5] yrs)*	Cross-sectional *[Multiple regression]*	PA *[Baecke PA scale]*	• **EFFICACY:** Barrier [0.89] • **OUTCOMES (+):** Various [0.88]	**(β) 0.39***** **(β) 0.14***	• **HEALTH: (β) 0.20**** • **INCOME: (β) 0.13*** • Smoking history: (β) -0.08	0.38
Conn (1998), (168) USA. *n = 147 free living older adults (69% female; 95% Caucasian; 78.5 [8.7] yrs)*	Cross-sectional *[Path analysis]*	PA: combined variable *[Health Promoting Lifestyle Profile + Baecke PA]*	• **EFFICACY:** Barrier [0.89] • **IMPEDIMENTS:** Various [0.86] • **OUTCOMES (+):** Various [0.97]	**(D) 0.35***** (I) 0.09 (T) 0.44 **(D) -0.28***** (I) -0.21 (T) -0.49 **(D) 0.17*** (I) ne **(T) 0.17***	• **AGE: (D) -0.21***** • **PAST BEHAVIOUR: (D) 0.13*** • Health: (D) 0.00	0.60
Coups (2009), (169) USA. *n = 175 survivors of lung cancer (63% female; 93% Caucasian, 3% African American, 2% Asian, 1% Hispanic; 68.7 [9.6] yrs)*	Cross-sectional *[Multiple regression]*	MVPA: total *[Modified GLTEQ]*	• **EFFICACY:** Barrier [0.93] • **OUTCOMES (+):** Various [0.66-0.89] • **ENVIRONMENT:** Street lighting [single item] • Impediments: Various [0.72] • Social support: Friends [0.89] • Social support: Family [0.86] • Environment: Various [single items]	**(b) 49.69***** **(b) 24.18***** **(b) -11.81*** (b) -18.11 (b) 1.38 (b) -1.04 (b) -7.90 to 4.55	None	0.38

First author (year), [ref] country. *Sample (n; sex; race; mean age [SD])*	**Design (retention [a])** ***[Analysis]***	**PA Behaviour (time [a]) [Measure]**	**Core SCT Constructs in Model (time) [T1 α] [b c d]**	**Associations with PA [e f]**	**Other variables / covariates / interactions in model [f g]**	**R^2**
	Cross-sectional *[Multiple regression]*	Walking: total *[YPAS]*	• **EFFICACY:** Barrier [0.93] • Outcomes (+): Various [0.66-0.89] • Impediments: Various [0.72] • Social support: Family [0.86] • Social support: Friends [0.89] • Environment: Various [single items]	**(b) 0.92***** (b) 0.42 (b) -0.08 (b) -0.01 (b) 0.06 (b) -0.70 to 0.32	None	0.19
Dlugonski (2011), (170) USA. *n = 54 inactive adults with multiple sclerosis (83% female; 89% Caucasian; 46.1 [9.9] yrs)*	Cross-sectional *[Multiple regression]*	PA: total *[GLETQ]*	• **SELF-REGULATION:** Goal setting [0.93] • Efficacy: Task [0.99] • Outcomes (+): Physical, social & self-evaluative [0.86] • Impediments: Functional limitations [0.92]	**(β) 0.31*** x x x	None	0.10
Doerkson (2009), (171) USA. *n = 69 college freshmen (57% female; 78% Caucasian, 13% Asian, 4% Hispanic, 3% African American, ; 18.2 [0.5] yrs)*	Longitudinal (93%) *[Hierarchical regression]*	MPA: duration (3m) *[Actigraph accelerometer]*	• Goal (BL): PA goal [single item] • Efficacy (BL): Situational [≥0.81] • Efficacy (BL): Other demands [≥0.81] • Outcomes (+) (BL): Various [0.88]	**(β)** 0.19 **(β)** 0.06 **(β)** -0.06 **(β)** 0.01	• **BMI: 0.29***	0.16
	Longitudinal (93%) *[Hierarchical regression]*	VPA: duration (3m) *[Actigraph accelerometer]*	• **EFFICACY (BL):** Situational [≥0.81] • **GOAL (BL):** PA goal [single item] • Efficacy (BL): Other demands [≥0.81] • Outcomes (+) (BL): Various [0.88]	**(β) 0.39*** **(β) 0.31*** (β) -0.18 (β) -0.15	• BMI: -0.08	0.16
Dzewoltowski (1989), (172) USA. *n = 328 college students (59% female)*	Longitudinal (79%) *[Hierarchical regression]*	PA: frequency (1.75m) *[PA diary]*	• **EFFICACY (BL):** Barrier [≥ 0.80] • Outcomes (+) (BL): Various [≥ 0.80]	**(β) 0.29*** (β) 0.03	• **OUTCOMES (V) x DISSATISFACTION: (β) 0.57*** • **DISSATISFACTION: (β): 0.15** • Efficacy x Dissatisfaction: (β) 0.47 • Efficacy x ↑ Outcomes (): (β) -0.05 *Adjusted for 'class choice'*	0.11
Dzewoltowski (1990), (173) USA. *n = 254 college students (52% female)*	Longitudinal (nr) *[Hierarchical regression]*	MVPA: energy expended (1m) *[7-day PA recall]*	• **EFFICACY (BL):** Barrier & task [nr] • Outcomes (+) (BL): Various [nr]	**(β) 0.14*** (β) 0.03	• **PAST BEHAVIOUR: (β) 0.66*** • Self-evaluative (outcome): (β) -0.08 • Self-evaluative (behaviour): (β) 0.01	0.56
Fiala (2013), (174) Canada. *n = 78 adults with osteoarthritis (67% female; 51% Caucasian; 69.0 [9.1] yrs)*	Cross-sectional *[Hierarchical regression]*	MVPA: leisure score index *[GLTEQ]*	• **IMPEDIMENTS:** Pain [0.95] • Self-regulation: Various strategies [0.92] • Efficacy: Task [0.78] • Environment: Neighbourhood [0.70] • Efficacy: Barrier [0.92] • Outcomes (+): Various [0.89]	**(β) -0.33*** (β) 0.20 (β) 0.14 (β) -0.13 (β) -0.07 (β) 0.02	• Physical function: (β)0.16	0.17

First author (year), [ref] country. *Sample (n; sex; race; mean age [SD])*	**Design (retention [a]) *[Analysis]***	**PA Behaviour (time [a]) [Measure]**	**Core SCT Constructs in Model (time) [T1 α] [b c d]**	**Associations with PA [e f]**	**Other variables / covariates / interactions in model [f g]**	**R^2**
	Cross-sectional *[Hierarchical regression]*	Walking: frequency *[Modified GLTEQ]*	• **EFFICACY:** Task [0.91] • **SELF-REGULATION:** Various strategies [0.92] • Efficacy: Barrier [0.92] • Outcomes (+): Various [0.89] • Environment: Neighbourhood [0.70] • Impediments: Pain [0.95]	**(β) 0.55***** **(β) 0.23*** (β) -0.10 (β) -0.07 (β) -0.05 (β) -0.01	• Physical function: (β) -0.09	0.33
Gao (2012), (175) USA. *n = 120 school children (45% female; 100% Hispanic; 10.8 [nr] yrs)*	Cross-sectional *[Hierarchical regression]*	MVPA: total duration *[Actigraph accelerometer]*	• **EFFICACY:** Task [0.82] • Social support: Parent, peer & teacher [0.74] • Environment: Physical & social [0.78] • Outcomes (+): Various [0.80]	**(β) 0.21*** (β) 0.14 (β) 0.10 (β) -0.01	None	0.11
Gellert (2012), (176) Germany. *n = 335 older adults (47% female; 66.7 [4.9] yrs)*	Longitudinal (80%) *[Latent variable SEM]*	PA: total duration (12m) *[PAQ-50+]*	• **OUTCOMES (+) (6m):** Affective [r = 0.75] • **GOAL (6m):** Intention [r = 0.82] • Outcomes (+) (6m): Health [0.74] • Efficacy (BL): Various forms [0.91]	**(D) 0.14***** (I) nr (T) nr **(D) 0.14*** (I) ne **(T) 0.14*** (D) -0.06 (I) nr (T) nr (D) -0.02 (I) nr (T) nr	• **PAST BEHAVIOUR: (D) 0.43*****	0.24
Hsu (2011), (177) Taiwan. *n = 196 survivors of breast cancer (100% female, 100% Asian; 47.0 [9.9] yrs)*	Longitudinal (97%) *[Hierarchical regression]*	MVPA: frequency (3m) *[PA diary]*	• **IMPEDIMENTS (BL):** Various [0.87] • Social support (BL): 'Social relationships' [0.89] • Impediments (BL): Fatigue [single item] • Efficacy (BL): Barrier [0.94] • Outcomes (+) (BL): Mental & physical [0.89]	**(B) 0.56*** (B) -0.64 (B) -0.08 (B) -0.07 (B) -0.03	• **AGE x SUPPORT: (B) 1.45*** • **AGE: (B) -1.17*** • **MENTAL x BARRIERS: (B) -0.91*** • **MENTAL HEALTH: (B) 0.88*** • **PAST BEHAVIOUR: B = 0.35***** • Physical health: (B) -0.12 • Education: (B) 0.01	0.23
	Longitudinal (97%) *[Hierarchical regression]*	MVPA: frequency (6m) *[PA diary]*	• **SOCIAL SUPPORT (BL):** 'Social relationships' [0.89] • **OUTCOMES (+) (BL):** Mental & physical [0.89] • Impediments (BL): Various [0.87] • Impediments (BL): Fatigue [single item] • Efficacy (BL): Barrier [0.94]	**(B) -1.11**** **(B) 0.16*** (B) 0.16 (B) 0.04 (B) 0.01	• **AGE x SUPPORT: (B) 1.95*** • **AGE (B): -1.43**** • **IMPEDIMENTS x PAST BEHAVIOUR: (B) -0.27*** • **PAST BEHAVIOUR: (B) 0.21**** • Mental health: (B) 0.07 • Physical health: (B) -0.04 • Education: (B) -0.02	0.20
Martin-Ginis (2011), (178) Canada. *n = 160 adults with spinal cord injury (26% female; 95% Caucasian; 47.4 [12.9] yrs)*	Longitudinal (nr) *[Latent variable SEM]*	MVPA latent variable (1m) *[PA Recall Instrument for People with Spinal Cord Injury]*	• **SELF-REGULATION (BL):** Plans [0.96]; Intention [r = 0.93] • **OUTCOMES (+) (BL):** Instrumental [0.90]; Affective [0.88] • Efficacy (BL): Task (moderate) [0.94]; Task (vigorous) [0.93] • **EFFICACY (BL):** Self-regulatory [0.79-0.90] • Social support (BL): 'People close to you' [single item]	**(D) 0.72***** (I) ne **(T) 0.72***** (D) -0.20 **(I) 0.26*** (T) 0.07 (D) 0.11 (I) -0.03 (T) 0.08 (D) -0.02 **(I) 0.53* (T) 0.51*** (D) ne (I) 0.08 (T) 0.08	None	0.39

First author (year), [ref] country. *Sample (n; sex; race; mean age [SD])*	**Design (retention [a])** ***[Analysis]***	**PA Behaviour (time [a]) [Measure]**	**Core SCT Constructs in Model (time) [T1 α]** [b c d]	**Associations with PA** [e f]	**Other variables / covariates / interactions in model** [f g]	**R^2**
Mehta (2009), (179) USA. *n = 200 middle-aged women (100% female; 100% Asian/Indian; 44.9 [6.6] yrs)*	Cross-sectional *[Multiple regression]*	PA: duration *[Survey on Exercise in Minority Communities]*	• **OUTCOMES (+):** Various [0.93] • **SELF-REGULATION:** Goal setting & rewards [0.61] • Efficacy: Not specified [0.81]	**(β) 0.33**** **(β) -0.20*** x	• **EDUCATION: (β) -0.22*** • Age: x • Employment status: x • Residency: x	0.14
Murnan (2006), (180) China. *n = 282 primary school children (45% female; 100% Asian; 10.3 [0.7] yrs)*	Cross-sectional *[Multiple regression]*	PA: duration *[24-hr recall]*	• **EFFICACY:** Task & barrier [>0.70] • Outcomes (+): Various [>0.70] • Self-regulation: Goal setting & rewards [>0.70]	**(β) 0.37***** x x	• **PA SCHOOL LESSONS: (β) 0.17**** • Age: x • Sex: x	0.20
Petosa (2003), (181) USA. *n = 350 college students (63% female; 86% Caucasian, 5% African American, 4% Asian American, 3% Hispanic; 21.0 [NR] yrs)*	Longitudinal (nr) *[Hierarchical regression]*	VPA: frequency (1m) [7-day PA recall]	• **EFFICACY (BL):** Barrier [0.97] • **OUTCOMES (+) (BL):** Various [0.70-0.78] • **SOCIAL SUPPORT (BL):** Family [0.91] • **SOCIAL SUPPORT (BL):** Friends [0.61] • **SELF-REGULATION (BL):** Various strategies [0.88]	**(β) nr*** **(β) nr*** **(β) nr*** **(β) nr*** **(β) nr***	• **PA IDENTITY: (β) nr*** • **ENJOYMENT: (β) nr***	0.27
Petosa (2005), (182) USA. *n = 256 high school students (49% female; 96% Caucasian, 3% African American)*	Cross-sectional *[Hierarchical regression]*	MVPA: frequency *[24 hour recall]*	• **SELF-REGULATION:** Not specified [nr] • **EFFICACY:** Task [nr] • **EFFICACY:** Barrier [nr] • **OUTCOMES (+):** Social [nr] • Outcomes (+): Health-related / Appearance / Various (-)[nr] • Social support: Not specified [nr]	**(β) 0.36*** **(β) 0.17*** **(β) 0.15*** **(β) -0.12*** x x	None	0.31
Phillips (2013), (183) USA. *n = 1527 survivors of breast cancer (100% female; 97% Caucasian, 2% African American; 56.2 [9.4] yrs)*	Longitudinal (nr [h]) *[Latent variable SEM]*	PA: leisure score index (6m Δ) *[GLTEQ]*	• **EFFICACY (6m Δ):** Task & barrier [nr] • **SELF-REGULATION (6m Δ):** Goal setting [nr] • Outcomes (+) (6m Δ): Physical [nr] • Outcomes (+) (6m Δ): Social [nr] • Outcomes (+) (6m Δ): Self-evaluative [nr] • Social support (6m Δ): Family & friends [nr] • Impediments (6m Δ): Fatigue [nr]	**(D) 0.33*** (I) nr (T) nr **(D) 0.08*** (I) ne **(T) 0.08*** (D) nr ^{NS} (I) nr (T) nr (D) nr ^{NS} (I) nr (T) nr (D) nr ^{NS} (I) nr (T) nr (D) nr ^{NS} (I) nr (T) nr (D) nr ^{NS} (I) nr (T) nr	• Past behaviour: (D) nr • T1 SCT cognitions: (D) not est. *Analyses controlled for age, education, income, comorbidities, BMI, time since diagnosis, disease stage*	0.50
n = 370 survivors of breast cancer [random subsample of above] (100% female; 97% Caucasian, 1% Asian, 1% African American, 1% American Indian; 56.5 [9.3] yrs)	Longitudinal (nr [h]) *[Latent variable SEM]*	PA: Activity counts (6m Δ) [Actigraph accelerometer]	• **EFFICACY (6m Δ):** Task & barrier (6m Δ) [nr] • **SELF-REGULATION (6m Δ):** Goal setting (6m Δ) [nr] • Outcomes (+) (6m Δ): Physical (6m Δ) [nr] • Outcomes (+) (6m Δ): Social [nr] • Outcomes (+) (6m Δ): Self-evaluative [nr] • Social support (6m Δ): Family and friends[nr] • Impediments (6m Δ): Fatigue [nr]	**(D) 0.40*** (I) nr (T) nr **(D) 0.14*** (I) ne **(T) 0.14*** (D) nr ^{NS} (I) nr (T) nr (D) nr ^{NS} (I) nr (T) nr (D) nr ^{NS} (I) nr (T) nr (D) nr ^{NS} (I) nr (T) nr (D) nr ^{NS} (I) nr (T) nr	• Past behaviour: (D) nr • T1 SCT cognitions: (D) not est. *Analysis controlled for age, education, income, comorbidities, BMI, time since diagnosis, disease stage*	0.89

First author (year), [ref] country. *Sample (n; sex; race; mean age [SD])*	**Design (retention [a])** ***[Analysis]***	**PA Behaviour (time [a]) [Measure]**	**Core SCT Constructs in Model (time) [T1 α] [b c d]**	**Associations with PA [e f]**	**Other variables / covariates / interactions in model [f g]**	**R^2**
Plotnikoff (2008), (184) Canada. *n = 524 adults with Type I diabetes (54% female; 51.1 [17.1] yrs)*	Longitudinal (75%) *[Manifest variable SEM]*	MVPA: total duration (6m) *[Modified GLTEQ]*	• **EFFICACY (BL):** Barrier [0.95] • **GOAL (BL):** 'Likelihood of getting regular PA' [single item] • Outcomes (+) (BL): Various [0.88] • Impediments (BL): Various [0.72] • Social support (BL): Social network [r = 0.59]	**(D) 0.22**** (I) nr (T) nr **(D) 0.17**** (I) ne **(T) 0.17**** (D) 0.01 (I) nr (T) nr (D) ne (I) nr (T) nr (D) ne (I) nr (T) nr	None	0.14
n = 1193 adults with Type II diabetes (49% female; 63.0 [12.1] yrs)	Longitudinal (75%) *[Manifest variable SEM]*	MVPA: total duration (6m) *[Modified GLTEQ]*	• **EFFICACY (BL):** Barrier [0.95] • **GOAL (BL):** 'Likelihood of getting regular PA' [single item] • Outcomes (+) (BL): Various [0.88] • Impediments (BL): Various [0.73] • Social support (BL): Social network [r = 0.59]	**(D) 0.19**** (I) nr (T) nr **(D) 0.11**** (I) ne **(T) 0.11**** (D) 0.03 (I) nr (T) nr (D) ne (I) nr (T) nr (D) ne (I) nr (T) nr	None	0.09
Plotnikoff (2011), (185) Canada. *n = 222 adults with Type II diabetes (46% female; 60.9 [11.2] yrs)*	Longitudinal (77%) *[Multiple regression]*	PA (3m) [Modified GLTEQ]	• **EFFICACY (BL):** Barrier [nr] • Impediments (BL): Various [nr] • Outcomes (+) (BL): Various [nr] • Social support (BL): Social network [nr] • Environment (BL): Various (x7) [single items]	**(β) 0.38***** (β) -0.09 (β) -0.04 (β) -0.04 (β) -0.09 to 0.06	• **DISABILITY: (β) -0.18*** • Sex: (β) 0.13 • Smoking: (β) 0.13 • Marital status: (β) -0.13 • Income: (β) 0.11 • Chronic condition; BMI; Age; Diabetes duration; Education: (β) -0.03 to 0.04	0.22
	Longitudinal (74%) *[Multiple regression]*	Resistance training: total duration (3m) *[Modified GLTEQ]*	• **EFFICACY (BL):** Barrier [nr] • Impediments (BL): Various [nr] • Outcomes (+) (BL): Various [nr] • Social support (BL): Social network [nr] • Environment (BL): Facilities [single item]	**(β) 0.45***** (β) -0.10 (β) 0.02 (β) -0.05 (β) 0.10	• **MARITAL STATUS: (β) -0.18*** • Diabetes duration: (β) 0.11 • Age: (β) 0.10 • Sex: (β) 0.08 • Education: (β) 0.08 • Disability; Smoking; Health; BMI; Income: (β) -0.05 to 0.06	0.22
Ramirez (2012), (186) USA. *n = 479 school children (50% female; 44% Caucasian, 36% Hispanic, 7% African American [9.8 [8-14] yrs)*	Cross-sectional *[Latent variable SEM]*	Step counts *[Yamax SW200]*	• **GOAL:** Intention [single] • Efficacy: Barrier [0.76] • Impediments: Various [0.77] • Outcomes (+): Health, sports, & appearance [0.60] • Social support: Friends & family [0.73]	**(D) 0.13*** (I) ne **(T) 0.13*** (D) nr [NS] (I) nr (T) nr (D) nr [NS] (I) nr (T) nr (D) ne (I) nr (T) nr (D) ne (I) nr (T) nr	None	0.02
Resnick (2000), (187) USA. *n = 59 older adults in long-term care (78% female; 99% Caucasian; 88.0 [6.9] yrs)*	Cross-sectional *[Multiple regression]*	PA: participation *[Verbal report – Yes/No]*	• **OUTCOMES (+):** Various [0.72-0.93] • **EFFICACY:** Barrier [0.92]	**(β) 0.62*** **(β) 0.50***	• Cognition: x • Health: x	0.57

First author (year), [ref] country. *Sample (n; sex; race; mean age [SD])*	**Design (retention [a])** *[Analysis]*	**PA Behaviour (time [a]) [Measure]**	**Core SCT Constructs in Model (time) [T1 α] [b c d]**	**Associations with PA [e f]**	**Other variables / covariates / interactions in model [f g]**	**R^2**
Resnick (2001), (188) USA. *n = 175 older adults in long-term care (78% female; 99% Caucasian; 86.0 [5.7] yrs)*	Cross-sectional *[Manifest variable SEM]*	MPA: energy expended *[YPAS]*	• **OUTCOMES (+):** Various [0.93] • **EFFICACY:** Barrier [0.93]	**(D) 0.30*** (I) ne **(T) 0.30*** **(D) 0.19*** (I) nr (T) nr	• **PHYSICAL HEALTH: (D) 0.26*** • Age: (D) -0.04 • Mental health: (D) -0.03	0.30
Resnick (2002), (189) USA. *n = 74 older adults in long-term care (85% female; 'mostly Caucasian'; 85.6 [5.5] yrs)*	Cross-sectional *[Manifest variable SEM]*	PA: participation *[single item]*	• **EFFICACY:** Barrier [0.92] • **OUTCOMES (+):** Various [0.72-0.93] • Social support: Friends [0.84]	**(D) 0.40*** (I) nr (T) nr **(D) 0.32*** (I) ne **(T) 0.32*** (D) 0.14 (I) nr (T) nr	• **Age: (D) 0.16***	0.53
Resnick (2004), (190) USA. *n = 78 older adults in long-term care (83% female; 99% Caucasian; 84.4 [5.1] yrs)*	Longitudinal (39%) *[Manifest variable SEM]*	PA: participation (48m Δ) *[single item]*	• **EFFICACY (48m Δ):** Barrier [≥0.88] • Outcomes (+) (48m Δ): Various [≥0.88]	**(D) 0.33*** (I) nr (T) nr (D) nr [NS] (I) nr (T) nr	• Sex; Age; Mental health; Physical health: (D) nr [NS]	0.16
Rogers (2007), (191) USA. *n = 150 adults in outpatient care (100% African American)*	Cross-sectional *[Path analysis]*	MVPA: leisure activity score *[CARDIA PA history]*	• **EFFICACY:** Task [0.86] & Barrier [0.78] • Impediments: Various [0.77] • Outcomes (+): Various [0.81]	**(D) 0.34**** (I) nr (T) nr (D) 0.09 (I) ne (T) 0.09 (D) 0.02 (I) ne (T) 0.02	*Analyses controlled for sex, age, income, BMI, arthritis*	0.28
n = 243 adults in outpatient care (100% Caucasian)	Cross-sectional *[Path analysis]*	MVPA: leisure activity score *[CARDIA PA history]*	• **EFFICACY:** Task [0.86] & Barrier [0.78] • **IMPEDIMENTS:** Various [0.77] • Outcomes (+): Various [0.81]	**(D) 0.45**** (I) nr (T) nr **(D) -0.18*** (I) ne **(T) -0.18*** (D) 0.02 (I) ne (T) 0.02	*Analyses controlled for sex, age, income, BMI, arthritis*	0.25
Rovniak (2002), (192) USA. *n = 277 college students (69% female; 83% Caucasian, 7% Asian, 3% African American, 2% Hispanic; 19.6 [1.4] yrs)*	Longitudinal (80%) *[Latent variable SEM]*	PA latent variable (2m) *[Stage of Change + ACLS]*	• **SELF-REGULATION (BL):** Goals [0.89]; Plans [0.87] • Outcomes (+) (BL): Various [0.81 – 0.88] • **EFFICACY (BL):** Time; Resisting relapse [nr] • **SOCIAL SUPPORT (BL):** Friends [0.91]	**(D) 0.48*** (I) ne **(T) 0.48*** (D) 0.16 (I) 0.05 (T) 0.21 (D) 0.14 **(I) 0.57*** (T) 0.71 (D) ne **(I) 0.28*** (T) 0.28*****	None	0.55
Schuster (1995), (193) USA. *n = 108 free-living older adults (69% female)*	Cross-sectional *[Hierarchical regression]*	PA (frequency) *[Single item]*	• **EFFICACY:** Not specified [0.76] • **OUTCOMES (+):** Mental, body image & health [0.70-0.78] • **IMPEDIMENTS:** Obstacles, effort, time [0.47-0.78] • **SOCIAL SUPPORT:** Not specified [0.84]	**(β) nr*** **(β) nr*** **(β) nr*** **(β) nr***	• **ENJOYMENT: (β) nr*** • Knowledge: x • Social norm: x	0.52

First author (year), [ref] country. *Sample (n; sex; race; mean age [SD])*	**Design (retention [a])** ***[Analysis]***	**PA Behaviour (time [a]) [Measure]**	**Core SCT Constructs in Model (time) [T1 α] [b c d]**	**Associations with PA [e f]**	**Other variables / covariates / interactions in model [f g]**	**R^2**
Sharma (2005), (194) USA. *n = 134 school children (54% female; 65% Caucasian, 23% African American, 2% American Indian; 10.3 [0.5] yrs)*	Cross-sectional *[Multiple regression]*	PA: duration [24 hour recall]	• **EFFICACY:** Task & barrier [≥0.70] • Outcomes (+): Various [≥0.70] • Self-regulation: Goals & rewards [≥0.70]	**(β) 0.21*** x x	• **LESSONS ON PA: (β) 0.21*** • Age: x • Sex: x • Race: x • School diet lessons: x	0.07
Sharma (2008), (195) India. *n = 324 school children (45% female; 100% Asian/Indian, 10.3 [0.7] yrs)*	Cross-sectional *[Multiple regression]*	PA: duration *[24 hour recall]*	• Efficacy: Task & barrier [≥0.70] • Outcomes (+): Various [≥0.70] • Self-regulation: Goals & rewards [≥0.70]	x x x	• **LESSONS ON PA: (β) 0.15*** • Age: x • Sex: x • School diet lessons: x	0.02
Shaughnessy (2006), (196) USA/Canada. *n = 312 survivors of stroke (57% female; 70% Caucasian, 22% African American; 62.9 [11.7] yrs)*	Cross-sectional *[Manifest variable SEM]*	PA: frequency *[single item]*	• **EFFICACY:** Barrier [0.86] • **OUTCOMES (+):** Various [0.90] • Impediments: Fatigue [nr]	**(D) 0.33*** (I) nr (T) nr **(D) 0.12*** (I) nr (T) nr (D) nr [NS] (I) nr [NS] (T) nr [NS]	• **PAST BEHAVIOUR: (D) 0.32*** • **DOCTOR ADVICE: (D) 0.13*** • Age: (D) nr[NS] • Sex: (D) nr[NS] • Time since stroke: (D) nr[NS] • Race: (D) nr[NS]	0.33
Suh (2011), (197) USA. *n = 218 adults with relapsing, remitting multiple sclerosis (90% female; 91% Caucasian; 43.5 [10.0] yrs)*	Cross-sectional *[Latent variable SEM]*	PA latent variable *[GLTEQ + IPAQ]*	• **SELF-REGULATION:** Goal setting [0.93] • **IMPEDIMENTS:** Functional limitations (reverse) [0.93] • **OUTCOMES (+):** Self-evaluative [0.87] • Outcomes: Physical [0.81] • Self-efficacy: Task [0.99] • Outcomes (+): Social [0.81]	**(D) 0.48***** (I) ne **(T) 0.48***** **(D) 0.20**** (I) nr (T) nr **(D) 0.19*** (I) nr (T) nr (D) -0.13 (I) nr (T) nr (D) 0.09 (I) nr (T) nr (D) -0.01 (I) nr (T) nr	None	0.40
Taymoori (2010), (198) Iran. *n = 558 junior high/high school students (100% female; 14.4 [1.6] yrs)*	Cross-sectional *[Path analysis]*	PA: duration *[Child-Adolescent Activity Log]*	• **SELF-EFFICACY:** Barrier [0.86] • **OUTCOMES (+):** Various [0.81] • Self-regulation: Various [0.83] • Social support: Mother [≥0.83] / Father [≥0.83] / Siblings [0.75] • Social support: Friends [0.84]	**(D) 0.61*** (I) nr (T) nr **(D) 0.17*** (I) nr (T) nr (D) nr [NS] (I) ne (T) nr [NS] (D) ne (I) nr (T) nr (D) ne (I) nr (T) nr	None	0.52
Trost (1997), (199) USA. *n = 110 school girls (100% female; 67% African American, 33% Caucasian; 11.5 [0.5] yrs)*	Longitudinal (88%) *[Multiple regression]*	MVPA: duration (12m) *['Previous day PA recall']*	• **ENVIRONMENT (BL):** Local sports [single item] • **SELF-EFFICACY (BL):** Barrier [0.71] • Self-efficacy (BL): Support seeking [0.71] • Self-efficacy (BL): Competing activities [0.54] • Outcomes (+) (BL): Various [0.75] • Social support (BL): Family or friends [0.75] • Environment (BL): Other (x3) [single items]	**(β) 0.14***** **(β) 0.10**** x x x x x	• Age: x • Race: x • TV/video games: x • PA modelling: x • PE enjoyment: x	0.17

First author (year), [ref] country. *Sample (n; sex; race; mean age [SD])*	**Design (retention [a])** ***[Analysis]***	**PA Behaviour (time [a]) [Measure]**	**Core SCT Constructs in Model (time) [T1 α] [b c d]**	**Associations with PA [e f]**	**Other variables / covariates / interactions in model [f g]**	**R^2**
n = 92 school boys (0% female; 61% African American, 39% Caucasian; 11.7 [0.7] yrs)	Longitudinal (88%) *[Multiple regression]*	MVPA: duration (12m) *['Previous day PA recall']*	• **ENVIRONMENT (BL):** Local sports [single item] • **OUTCOMES (+) (BL):** Various [0.75] • Self-efficacy (BL): Barrier [0.71] • Self-efficacy (BL): Support seeking [0.71] • Self-efficacy (BL): Competing activities [0.54] • Social support (BL): Family or friends [0.75] • Environment (BL): Other (x3) [single items]	**(β) 0.08**** **(β) 0.07**** x x x x x	• Age: x • Race: x • TV/video games: x • PA modelling: x • PE enjoyment: x	0.17
White (2012), (200) USA. *n = 321 middle-aged & older adults (80% female; 89% Caucasian; 63.8 [9.6] yrs)*	Longitudinal (71% [h]) *[Manifest variable SEM]*	PA: total duration (18m Δ) *[PA Scale for the Elderly]*	• **SELF-EFFICACY (18m Δ):** Task [0.99] • **OUTCOMES (+) (18m Δ):** Social [0.81] • **OUTCOMES (+) (18m Δ):** Physical [0.82] • Outcomes (+) (18m Δ): Self-evaluative [0.84] • Self-regulation (18m Δ): Goal setting [0.96] • Impediments (18m Δ): Disability [0.83]	**(D) 0.19*** (I) nr (T) nr **(D) 0.14*** (I) nr (T) nr **(D) 0.13*** (I) nr (T) nr (D) nr [NS] (I) nr (T) nr (D) nr [NS] (I) ne (T) nr [NS] (D) ne (I) nr (T) nr	• **PAST BEHAVIOUR: (D) 0.45*** • T1 SCT cognitions: (D) not est. *Analyses controlled for 'demographic factors' (e.g., age, sex, race, income)*	0.40
Wilcox (2003), (201) USA. *n = 102 older women (100% female; 59% Caucasian, 41% African American; 70.6 [9.2] yrs)*	Cross-sectional *[Hierarchical regression]*	PA: total duration *[PA Scale for the Elderly]*	• **OUTCOMES (+):** Various [nr] • **ENVIRONMENT:** Sidewalks [nr] • **ENVIRONMENT:** Safety [nr] • Social support: Family & friends [nr] • Environment: Traffic [nr] • Environment: Other (x3) [nr] • Self-efficacy: Barrier [nr]	**(β) 0.22*** **(β) -0.21*** **(β) 0.20*** (β) 0.16 (β) 0.14 (β) nr [NS] (β) nr [NS]	• **AGE: (β) -0.28**** • **GP DISCUSSIONS: (β) -0.27**** • **DEPRESSION: (β) -0.21*** • Stress: (β) 0.20 • Education: (β) nr [NS] • Marital status: (β) nr [NS] • Race: (β) nr [NS]	0.46
Winters (2003), (202) USA. *n = 248 high school students (60% female; 15.0 [NR] yrs*	Cross-sectional *[Hierarchical regression]*	MPA: frequency *[GLTEQ]*	• **SELF-EFFICACY:** Barrier [0.89] • **OUTCOMES (+):** Various [0.93] • **SELF-REGULATION:** Various strategies [0.90] • Social support: Family & friends [0.88]	**(β) nr*** **(β) nr*** **(β) nr*** (β) nr [NS]	None	0.11
	Cross-sectional *[Hierarchical regression]*	VPA: frequency *[GLTEQ]*	• **SELF-REGULATION:** Various strategies [0.90] • **OUTCOMES (+):** Various [0.93] • **SOCIAL SUPPORT:** Family & friends [0.88] • **SELF-EFFICACY:** Barrier [0.89]	**(β) nr*** **(β) nr*** **(β) nr*** **(β) nr***	**SEX: (β) nr***	0.35

Note: ITT = intention-to-treat analyses used; SEM = structural equation modelling; PA = physical activity; PAQ = physical activity questionnaire = YPAS, Yale physical activity survey; GLETQ = Godin leisure time exercise questionnaire; BMI = body-mass index; SCT = Social Cognitive Theory; Tx = variable measured at Time x; Tx Δ = change in variable from Time 1 to Time x; ACLS = Aerobics centre longitudinal study physical activity questionnaire; IPAQ = international physical activity questionnaire; nr = not reported.

[a] Reported for longitudinal studies only. [b] T1 α = Cronbach's alpha of scale used at Time 1. [c] Constructs in bold and capitals demonstrated at least 1 significant association with PA (direct effect, total indirect effect, total effect, or standardised β). Constructs in descending order of absolute value of the magnitude of direct effect (SEM/Path models) or standardised β (multiple regression models). [d] SCT construct abbreviations: Outcomes (+); Positive outcome expectations (higher score represents more positive expectations); Outcomes (-); Negative outcome expectations (higher score represents more negative expectations); Environment, perceived environment; Goal, general goal/intention. [e] (D) = direct effect on PA (i.e., effect unmediated by other variables in model); (I) = sum of indirect effects on PA (i.e., sum of effects mediated by other variables in model; (T) = total effect on PA (i.e., sum of direct and indirect effects on PA). [f] Direct effect (D) or standardised beta (β) reported only. [g] Variable 1 x variable 2 = interaction term between variables 1 and 2. [h] Full sample included (intention-to-treat). [i] Outcome expectations were assessed and removed due to no association with PA.

* $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$; nr = value and significance not reported; nr*; value not reported, but significant; nr[NR], value not reported but not significant; ne, effect not estimated; x, not significant / not included in model.

In addition to varied populations, the 55 models also tested various types of physical activity behaviour and included different combinations of SCT constructs. Nineteen (35%) used a measure of total physical activity as the dependent variable (167, 170, 172, 176, 179, 180, 183, 185, 187, 189, 190, 193-196, 198, 200, 201) and 15 (27%) used MVPA (166, 169, 173-175, 177, 178, 182, 184, 191, 199). In addition, five (9%) used vigorous physical activity (164, 171, 181, 202), three (5%) used moderate physical activity (171, 188, 202), and one (2%) used light physical activity (165). Three models (5%) investigated walking behaviour or step counts (169, 174, 186) and one (2%) focused on resistance training (185). Eight models (15%) measured physical activity with several outcome measures and combined these into an overarching latent or combined variable (159-163, 168, 192, 197). As required, all 55 models (100%) included at least one measure of both self-efficacy and outcome expectations. The goals construct (i.e., goal/intention or self-regulation) was represented in 31 models (56%) (159-163, 170, 174, 178-183, 192, 194, 195, 197, 198, 200, 202) and the socio-structural factors construct (i.e., social support, impediments or perceived environment) was represented in 42 models (76%) (159-164, 166, 168-170, 174, 175, 177, 178, 181-186, 189, 191-193, 196-202). Twenty-two of the 55 models (40%) included all of the major SCT constructs illustrated in Figure 1.1 (159-163, 170, 174, 178, 181-183, 192, 197, 198, 200, 202).

3.3.3 Critical appraisal

The complete critical appraisal results for the models are located in Table 3.3. Inter-rater reliability metrics demonstrated excellent agreement for all 605 items (percentage agreement 88%, kappa = 0.75) (203). As mentioned previously, multiple models from a single paper were considered in isolation during the critical appraisal.

The methodological quality of the physical activity models was mostly poor (median score = 4/11, range = 1-8). As reported in Table 3.3, 31 models (56%) included a validated physical activity measure (159, 163, 166-171, 173, 175, 178, 179, 181-186, 188, 192, 197, 199-202), but only two (4%), from a single study (191), provided evidence for adequate internal consistency and test-retest reliability for all SCT measures. Thirty models (55%) included a large sample size (≥200) (159-163, 166, 167, 172, 173, 176, 179-186, 191, 192, 195-198, 200, 202), but only one (2%) justified the sample size with a power calculation (179). Twenty-five models (45%) employed a longitudinal, prospective design (median follow-up = 3 months; range = 1 to 48 months) (162, 164-166, 171-173, 176-178, 181, 183-185, 190, 192, 199, 200), but only 14 of these (56%) demonstrated adequate retention at follow up (i.e., ≤20% dropout for ≤6 months or ≤30% dropout for >6 months) (164, 165, 171, 176, 177, 183, 192, 199, 200). Twenty-four models (44%) used a form of analysis that allowed for investigation of indirect and total effects variables, such as structural equation modelling or path analysis (159-163, 166, 168, 176, 178, 183, 184, 186, 188-192, 196-198, 200) and 14 models (25%) controlled for past behaviour (162, 164-166, 168, 176, 177, 183, 190, 196, 200). Forty-nine models (89%) used a non-college sample (159-170, 174-180, 182-191, 193-202), but only four models randomly selected participants from the target population (172, 185, 189, 198). Finally, nine models (16%) used an objective measure (e.g., a pedometer) (159-162, 171, 175, 183, 186).

Table 3.3. Critical appraisal of methodological quality for SCT models of physical activity.

First author (year) [a b]	*Selection*	*Selection*	*Design*	*Design*	*Design*	*Design*	*Measures*	*Measures*	*Measures*	*Analysis*	*Analysis*	
	Random selection	*Non-college sample*	*Longitudinal design*	*Adequate Retention* [c]	*Evidence of adequate power*	*Strong sample size (≥200)*	*Valid PA measure* [d]	*Objective PA measure*	*Reliable SCT measures* [e]	*SEM/Path analyses*	*Adjusted for past behaviour*	*Total (/11)*
Anderson *et al.* (2006) (159)	✗	✓	✗	-	✗	✓	✓	✓	?	✓	✗	5
Anderson-Bill *et al.* (2011) (160)	✗	✓	✗	-	✗	✓	?	✓	?	✓	✗	4
Anderson-Bill *et al.* (2011) (161)	✗	✓	✗	-	✗	✓	?	✓	?	✓	✗	4
Anderson-Bill *et al.* (2011) (162)	✗	✓	✓	✗	✗	✓	?	✓	?	✓	✓	6
Ayotte *et al.* (2010) (163)	✗	✓	✗	-	✗	✓	✓	✗	?	✓	✗	4
Bean *et al.* (2012) [3-month] (164)	✗	✓	✓	✓	✗	✗	?	✗	✗	✗	✓	4
Bean *et al.* (2012) [6-month] (164)	✗	✓	✓	✓	✗	✗	?	✗	✗	✗	✓	4
Bennett *et al.* (1999) (165)	?	✓	✓	✓	✗	✗	?	✗	?	✗	✓	4
Blanchard *et al.* (2011) (166)	✗	✓	✓	?	✗	✓	✓	✗	?	✓	✓	6
Conn (1997) (167)	✗	✓	✗	-	✗	✓	✓	✗	?	✗	✗	3
Conn (1998) (168)	✗	✓	✗	-	✗	✗	✓	✗	?	✓	✓	4
Coups *et al.* (2009) [MVPA] (169)	✗	✓	✗	-	✗	✗	✓	✗	?	✗	✗	2
Coups *et al.* (2009) [Walking] (169)	✗	✓	✗	-	✗	✗	?	✗	?	✗	✗	1
Dlugonski *et al.* (2011) (170)	✗	✓	✗	-	✗	✗	✓	✗	?	✗	✗	2
Doerkson *et al.* (2009) [MPA] (171)	✗	✗	✓	✓	✗	✗	✓	✓	?	✗	✗	4
Doerkson *et al.* (2009) [VPA] (171)	✗	✗	✓	✓	✗	✗	✓	✓	?	✗	✗	4
Dzewoltowski (1989) (172)	✗	✗	✓	✗	✗	✓	?	✗	?	✗	✗	2
Dzewoltowski *et al.* (1990) (173)	✗	✗	✓	?	✗	✓	✓	✗	?	✗	✗	3
Fiala *et al.* (2013) [MVPA] (174)	✗	✓	✗	-	✗	✗	?	✗	?	✗	✗	1
Fiala *et al.* (2013) [Walking] (174)	✗	✓	✗	-	✗	✗	?	✗	?	✗	✗	1
Gao (2012) (175)	✗	✓	✗	-	✗	✗	✓	✓	?	✗	✗	3
Gellert *et al.* (2012) (176)	✗	✓	✓	✓	✗	✓	?	✗	?	✓	✓	6
Hsu *et al.* (2011) [3-month] (177)	✗	✓	✓	✓	✗	✗	?	✗	?	✗	✓	4
Hsu *et al.* (2011) [6-month] (177)	✗	✓	✓	✓	✗	✗	?	✗	?	✗	✓	4
Martin Ginis *et al.* (2011) (178)	✗	✓	✓	?	✗	✗	✓	✗	?	✓	✗	4
Mehta *et al.* (2009) (179)	✗	✓	✗	-	✓	✓	✓	✗	?	✗	✗	4
Murnan *et al.* (2006) (180)	✗	✓	✗	-	✗	✓	?	✗	?	✗	✗	2
Petosa *et al.* (2003) (181)	✗	✗	✓	?	✗	✓	✓	✗	✗	✗	✗	3
Petosa *et al.* (2005) (182)	✗	✓	✗	-	✗	✓	✓	✗	?	✗	✗	3
Phillips *et al.* (2013) [Self-report] (183)	✗	✓	✓	✓	✗	✓	✓	✗	?	✓	✓	7

First author (year) [a] [b]	Selection	Selection	Design	Design	Design	Design	Measures	Measures	Measures	Analysis	Analysis	
	Random selection	*Non-college sample*	*Longitudinal design*	*Adequate Retention* [c]	*Evidence of adequate power*	*Strong sample size (≥200)*	*Valid PA measure* [d]	*Objective PA measure*	*Reliable SCT measures* [e]	*SEM/Path analyses*	*Adjusted for past behaviour*	*Total (/11)*
Phillips *et al.* (2013) [Objective] (183)	✗	✓	✓	✓	✗	✓	✓	✓	?	✓	✓	8
Plotnikoff *et al.* (2008) [T1DM] (184)	✗	✓	✓	✗	✗	✓	✓	✗	✗	✓	✗	5
Plotnikoff *et al.* (2008) [T2DM] (184)	✗	✓	✓	✗	✗	✓	✓	✗	✗	✓	✗	5
Plotnikoff *et al.* (2011) [MVPA] (185)	✓	✓	✓	?	✗	✓	✓	✗	?	✗	✗	5
Plotnikoff *et al.* (2011) [RT] (185)	✓	✓	✓	?	✗	✓	?	✗	?	✗	✗	4
Ramirez *et al.* (2012) (186)	✗	✓	✗	-	✗	✓	✓	✓	?	✓	✗	5
Resnick (2000) (187)	✗	✓	✗	-	✗	✗	?	✗	?	✗	✗	1
Resnick (2001) (188)	✗	✓	✗	-	✗	✗	✓	✗	?	✓	✗	3
Resnick *et al.* (2002) (189)	✓	✓	✗	-	✗	✗	?	✗	?	✓	✗	3
Resnick (2004) (190)	✗	✓	✓	✗	✗	✗	?	✗	✗	✓	✓	4
Rogers *et al.* (2007) [African American] (191)	✗	✓	✗	-	✗	✗	?	✗	✓	✓	✗	3
Rogers *et al.* (2007) [Caucasian] (191)	✗	✓	✗	-	✗	✓	?	✗	✓	✓	✗	4
Rovniak *et al.* (2002) (192)	✗	✗	✓	✓	✗	✓	✓	✗	?	✓	✗	5
Schuster *et al.* (1995) (193)	✗	✓	✗	-	?	✗	?	✗	✗	✗	✗	1
Sharma *et al.* (2005) (194)	✗	✓	✗	-	✗	✗	?	✗	?	✗	✗	1
Sharma *et al.* (2008) (195)	✗	✓	✗	-	✗	✓	?	✗	?	✗	✗	2
Shaughnessy *et al.* (2006) (196)	✗	✓	✗	-	✗	✓	?	✗	?	✓	✓	4
Suh *et al.* (2011) (197)	✗	✓	✗	-	✗	✓	✓	✗	?	✓	✗	4
Taymoori *et al.* (2010) (198)	✓	✓	✗	-	✗	✓	?	✗	?	✓	✗	4
Trost *et al.* (1997) [Girls] (199)	✗	✓	✓	✓	✗	✗	✓	✗	✗	✗	✗	4
Trost *et al.* (1997) [Boys] (199)	✗	✓	✓	✓	✗	✗	✓	✗	✗	✗	✗	4
White *et al.* (2012) (200)	✗	✓	✓	✓	✗	✓	✓	✗	?	✓	✓	7
Wilcox *et al.* (2003) (201)	✗	✓	✗	-	✗	✗	✓	✗	✗	✗	✗	2
Winters *et al.* (2002) [MPA] (202)	✗	✓	✗	-	✗	✓	✓	✗	?	✗	✗	3
Winters *et al.* (2002) [VPA] (202)	✗	✓	✗	-	✗	✓	✓	✗	?	✗	✗	3
n (%)	4 (7)	49 (89)	25 (45)	14 (56 [f])	1 (2)	30 (55)	31 (56)	9 (16)	2 (4)	24 (44)	14 (25)	

Note: MVPA = moderate-to-vigorous physical activity; MPA = moderate physical activity; VPA = vigorous physical activity; T1DM = type 1 diabetes mellitus; T2DM = type 2 diabetes mellitus; RT = resistance training; SCT = Social Cognitive Theory; SEM = structural equation model; PA = physical activity; ✓ = present; ✗ = absent; ? = unclear or inadequately described; - (dash) = n/a.

[a] For additional detail on the methodological quality assessment criteria, see Table 3.1. [b] Square brackets used to distinguish between multiple models from a single paper. [c] Attrition ≤20% for ≤ 6 months and ≤30% for > 6 months (or imputation method was used). [d] Validation data cited or provided by authors. [e] Study reports adequate internal consistency (α > 0.60) and test-retest reliability (intra-class correlation coefficient > 0.70 or Pearson's correlation > 0.80) for all scales used. [f] Percentage refers to longitudinal models only.

3.3.4 Research question 1: What is the utility of SCT to explain physical activity behaviour in all populations?

Table 3.4 shows the results of the random-effects meta-analysis of the SCT models. The effect sizes were not found to be significantly heterogeneous (Q = 41.08, $p = 0.90$) and when pooled explained 31% of the variance in physical activity ($p < 0.001$). Although publication bias is a considerable problem for all meta-analyses, Begg and Mazumdar's rank correlation was very small and non-significant, τ ($N = 55$) = 0.05, $p = 0.62$, which provided evidence against the need to adjust for this. This was supported by Rosenthal's fail safe N, which indicated that 87,690 non-significant results would need to be published and included in the meta-analysis to render the effect size non-significant. Following Rosenthal's (1995) recommendations (204), the planned moderator analyses were performed even though the statistical tests of heterogeneity was not significant and the results are presented below.

Table 3.4. Meta-analysis of SCT models of physical activity with hypothesised moderators.

	k	**Total n**	**Moderator statistics**		**Estimated population effect size [a]**	
			χ^2	**p-value [b]**	**R^2**	**95% CIs**
Total sample	55	13,358			0.31	0.24, 0.37
Categorical moderators						
Design						
Cross-sectional	30	6,643	0.06	0.80	0.30	0.22, 0.38
Longitudinal	25	6,715			0.31	0.21, 0.44
Past behaviour						
Adjusted for	14	3,595	3.44	0.06	0.41	0.25, 0.55
Not adjusted for	41	9,763			0.27	0.21, 0.34
PA measurement						
Objective	9	3,000	0.00	0.97	0.30	0.08, 0.55
Self-report	46	10,358			0.31	0.25, 0.37
Continuous moderators			**β [c]**	**p-value [d]**		
Mean age [e]	49	12,019	**0.004**	**<0.05**		
Percent female	55	13,358	0.003	0.054		
Model quality score [f]	55	13,358	**0.053**	**<0.05**		

Note: k = number of models in analysis; n = number of participants in analysis; Q = Q test statistic for heterogeneity in effect sizes; R^2 = variance explained in PA; χ^2 = chi-square test statistic; - (dash) = not applicable; β = beta.

[a] Homogeneity in effects observed (Q = 41.08, p = 0.90). [b] p < 0.05 indicates significant difference in effect sizes for each category in moderator variable. [c] Beta coefficient relative to Fisher-transformed correlations. [d] p < 0.05 indicates significant association between moderator variable and effect size. [e] Moderator analysis only includes models where age of participants was available (6 models not included). [f] Total score from model critical appraisal (see Table 3.3).

3.3.5 Research question 2: Is the effectiveness of SCT moderated by sample or methodological characteristics?

The results of the moderator analyses are presented in Table 3.4. None of the categorical moderators significantly moderated the meta-analysed effect size, although adjusting for past behaviour approached significance ($\chi 2$ (1) = 3.44, p = 0.06). Mean age of participants emerged as a significant moderator of the variance explained in physical activity ($\beta = 0.004$, $p < 0.05$), indicating that the variance explained increased with the mean age of the sample. The total model quality score also emerged as a significant moderator ($\beta = 0.053$, $p < 0.05$) indicating that higher quality models explained more variance in physical activity than lower quality models. A positive regression coefficient was identified between the proportion of females in the sample and the physical activity effect size, which approached significance ($\beta = 0.003$, $p = 0.054$).

3.3.6 Research question 3: What is the frequency of significant associations between the SCT constructs and physical activity behaviour?

In total, 67 ‘self-efficacy’ variables were examined for associations with physical activity across the 55 models. As seen in Table 3.5, 40/67 direct effects estimated from self-efficacy to physical activity were significant (60%). Although indirect effects were estimated between self-efficacy and physical activity on 25 occasions, the significance of total indirect effects were only reported for nine of these pathways (36%). When reported, the total indirect effect of self-efficacy on physical activity was significant on 4/9 occasions (44% of reported; 16% of all estimated total indirect effects). The significance of the total effect of self-efficacy on physical activity was also reported for 9/25 self-efficacy variables (36%). However this was significant on 6/9 occasions (67% of reported, 24% of all estimated total effects).

Table 3.5. Frequency of significant association between SCT constructs and physical activity.

Effect	SCT construct	Number of times				Significant effect ratios	
		Construct included in models	Effect estimated	*p*-value reported	Effect significant ($p < 0.05$)	Significant / Estimated (%)	Significant / Reported (%)
Direct effect [a b]	Self-efficacy	67	67	67	40	60	60
	Outcome expectations	71	70	70	21	30	30
	Goals						
	Self-regulation	23	23	23	16	70	70
	Goal / Intention	7	7	7	6	86	86
	Socio-structural factors						
	Impediments	24	21	21	5	24	24
	Social support	40	30	30	6	20	20
	Environment	38	38	38	6	16	16
Total indirect effect [c]	Self-efficacy	67	25	9	4	16	44
	Outcome expectations	71	29	9	3	10	33
	Goals						
	Self-regulation	23	0	-	-	-	-
	Goal / Intention	7	0	-	-	-	-
	Socio-structural factors						
	Impediments	24	10	3	1	10	33
	Social support	40	18	7	6	33	86
	Environment	38	1	0	-	0	-
Total effect [d]	Self-efficacy	67	25	9	6	24	67
	Outcome expectations	71	35	15	4	11	27
	Goals						
	Self-regulation	23	12	12	10	83	83
	Goal / Intention	7	4	4	4	100	100
	Socio-structural factors						
	Impediments	24	12	5	2	17	40
	Social support	40	18	7	6	33	86
	Environment	38	1	0	-	0	-

Note: SCT = Social Cognitive Theory; PA = physical activity; - (dash) = not applicable

[a] β estimates from multiple regression models were considered as 'direct effects' for this analysis. Data from multiple regression models represented: 42/67 self-efficacy effects (63%), 35/71 outcome expectations effects (49%), 3/7 goal/intention effects (43%), 11/23 self-regulation effects (48%), 12/24 impediments effects (50%) and 22/40 social support effects (55%). [b] The unique effect the variable has on the outcome (i.e., the effect that is unmediated by any other variable in the model). [c] The total effect of a construct on PA via its influence on other constructs in the model (i.e., sum of mediated effects to PA in model). [d] Sum of the direct effects plus indirect effects (i.e., the total effect of the variable on the outcome, directly and through other constructs).

All models were required to contain at least one ‘outcome expectations’ construct and these were also conceptualised in many different ways (Table 3.2). As 11 models included more than one outcome expectations variable, 71 unique outcome expectation constructs were modelled in total. Outcome expectations were not consistently associated with physical activity. For example, only 21/70 direct effects of outcome expectations were significant (30%). When reported, the total indirect effect of outcome expectations on physical activity was significant on 3/9 occasions (33%), however the significance of the indirect effect was only reported 9/29 times (31%). Similarly, the significance of the total effect of outcome expectations on physical activity was only reported on 15/35 occasions (43%), and only 4/15 were significant (27% of reported; 11% of all estimated effects). Overall, 7/55 SCT models of physical activity (13%) explicitly measured all three of the major types of outcome expectations (i.e., physical, social, and self-evaluative).

Thirty variables representing the ‘goals’ construct were included across 30 distinct SCT models. In 23/30 cases (77%) this construct was represented with a measure of ‘self-regulation’ (e.g., goal setting, planning) and the remaining cases used a measure of behavioural goal/intention. As seen in Table 3.5, the goals construct was consistently associated with physical activity across all models. In total, there were 16/23 significant direct effects from self-regulation (70%) and 6/7 significant direct effects from behavioural goal (86%). Indirect effects of goals on physical activity were not estimated in any of the models.

Forty-one distinct SCT models included at least one variable to represent ‘socio-structural factors’, as defined in this review. One-hundred and two socio-cultural variables were included across all models. In total, 38/102 of these were represented with perceived environment variables (37%), 24/102 were represented with measures of behavioural impediments (24%) and 40/102 represented this construct with measures of social support (39%). Overall, these factors were not consistently associated with physical activity, either directly or indirectly. For example, only 5/21 direct effects from behavioural impediments reached statistical significance (24%). In addition, the significance of the indirect effect of impediments on physical activity was only reported for 3/10 estimated effects (33%) and only one reached significance (33% of reported;

10% of all estimated effects). Similarly, of all direct effects estimated from social support to physical activity, only 6/30 were statistically significant (20%). The significance of the total indirect effect of social support on physical activity was only reported for 7/18 pathways (39%), but 6/7 of these were positive and significant (86% of reported, 33% of all total indirect effects estimated). Finally, only 6/38 direct effects from perceived environment to physical activity were reported as significant (16%).

3.4 Discussion

To the authors' knowledge, this is the first meta-analytic review to assess the utility of SCT to explain physical activity with no sample restrictions. This review retrieved 44 eligible studies that included a total of 55 distinct tests of SCT. A random-effects meta-analysis revealed that these models accounted for 31% of the variance in physical activity. Overall study quality and the age of the sample significantly moderated the effectiveness of SCT, with higher scores for quality and greater mean age associated with more variance explained. Of the core SCT constructs, self-efficacy and goals were consistently and positively associated with physical activity, but outcome expectations and socio-structural factors were not.

Overall, SCT explained almost one third of the variance in physical activity, which meets Baranowski et al.'s criterion for a theory to be considered a useful framework for intervention design ($R^2 \geq 0.30$) (134). In a recent meta-analysis of social cognitive models in adolescents, Plotnikoff and colleagues (147) noted that SCT accounted for 24% of physical activity variance. However, this previous investigation into SCT and physical activity was limited as only three models were identified. The current review suggests that SCT explains a comparable proportion of variance in physical activity to other theories. For example, two of the first meta-analytic theoretical reviews independently determined that the TPB accounted for 27% of physical activity variance (142, 205). However, a more recent review reported this estimate to be closer to 24% (143).

Of interest, the proportion of physical activity variance explained by SCT was significantly moderated by the methodological quality score. This is an important finding, as the median model quality score was only 4/11. Of particular concern, only

4% of the models measured all SCT constructs using scales with adequate internal consistency and test-retest reliability. This is not an uncommon finding in social cognitive research, with two other meta-analytic reviews reporting that evidence of adequate internal consistency and test-retest reliability for all scales was only provided in 13% of studies (147, 206). As poor construct reliability would reduce the precision of any meta-analysis, this is an area that should be improved in future SCT research.

Of the sample-based characteristics, age was found to significantly moderate the physical activity effect size with SCT models explaining more variance in samples with a higher mean age. This may indicate that physical activity behaviour in younger people is driven more by external factors, such as parental control, and less by the cognitive factors outlined in SCT. However, it should also be noted that the cognitive limitations of young children may preclude them from accurately completing theory-based questionnaires (207). Further, while several of the primary school studies attempted to simplify the social-cognitive measures to improve comprehension, the dichotomised answer formats may also have artificially reduced the variance in the measures. A positive association was also observed in this review between the proportion of females in the sample and the variance explained, which approached significance ($p = 0.054$). As males were considerably under-represented in this review, further investigation into the utility of SCT to explain physical activity in men may be warranted.

In this review, cross-sectional SCT tests did not explain more variance than longitudinal SCT tests. This is an interesting finding, given that this effect is commonly observed in theory testing, where consistency effects inflate correlations between social cognitive constructs and behaviour if all measures are completed in a single survey (208). Indeed, McEachan and colleagues noted that study design significantly moderated the behavioural effect sizes in their recent meta-analytic review of the TPB, where models with a shorter time frame explained more variance than models using a longer time frame (143). In contrast, a large study of physical activity in a population-sample of adults noted that that the difference in physical activity explanation between cross-sectional and longitudinal designs was negligible (208). Despite this, it is important to acknowledge that cross-sectional research designs do not include appropriate temporal spacing, which is necessary for determining causality (209). As such, more high-quality longitudinal studies are required to improve understanding of the possible causal associations between social-cognitive variables and physical activity.

The method of assessment did not moderate the effect size, with the SCT models explaining 30% of the variance in objectively measured physical activity and 31% of the variance in self-reported physical activity. This finding does not reflect the majority of the literature, where models generally explain more variance in self-reported physical activity (210). This effect is partially attributed to common-method biases, where the variance in self-reported physical activity is inflated due to the shared measurement method (211). A recent meta-analytic review of the TPB noted that the theory only accounted for 12% of the variance in objectively measured physical activity compared to 26% of the variance in self-reported physical activity (143). However, in agreement with the current findings, Plotnikoff and colleagues determined that the measurement method did not moderate the physical activity effect size in their meta-analysis of multiple theories in adolescent samples (147). However, as only nine objective models were identified in this review, further models using an objective physical activity measure are required to increase the precision of this estimate.

As the literature would suggest, this review found that models that adjust for past behaviour explain more physical activity variance than those that do not. However, this difference only approached statistical significance ($p = 0.06$). Plotnikoff et al. also failed to identify adjustment for past behaviour as a moderator of physical activity effect size in their meta-analytic review (147). However, it was unlikely their analysis was sufficiently powered as they only identified four objective physical activity models. In general, the wider evidence suggests that past behaviour is one of the largest contributors to the explanation of physical activity. For example, a previous review determined that the inclusion of past behaviour to the TPB explained an additional 18% of the variance in physical activity after controlling for the other model constructs (142). Further, a recent meta-analysis that integrated the TPB and self-determination theory identified that past behaviour was the strongest predictor of current/future behaviour and that the inclusion of past behaviour significantly attenuated the influence of all other socio-cognitive constructs (154).

Of the four major SCT constructs, self-efficacy and goals were the most likely to be associated with behaviour. Although this further corroborates the established body of evidence demonstrating that self-efficacy is strongly linked to physical activity behaviour (75), this also provides strong evidence for the relative importance of the 'goals' construct, which also demonstrated a consistent, positive association with physical activity. Of interest, while intention is consistently associated with physical activity (e.g., (142, 212)), given that self-regulation was also commonly associated with physical activity these findings support Bandura's (1997, p. 284) notion that "*intention is not the sole proximal determinant of behaviour*" (73) and that the "*adoption and maintenance of lifestyle activity patterns requires the development of self-regulatory capabilities*" (Bandura, 1997, p. 415) (73). In contrast, less evidence was found to support the influence of a direct effect of outcome expectations or socio-structural factors on physical activity. Williams and colleagues conducted a review on the role of outcome expectations in physical activity research and also reported mixed findings (141). However, the authors determined that the predictive power of outcome expectations may be moderated by several characteristics, including age (i.e., more influence among older adults). Thus, the inconsistent influence of outcome expectations observed in the current review may be partially attributed to the wide variety of age groups represented. In addition, direct effects between socio-structural factors and physical activity were not often observed, with a small number reaching significance for impediments (24%), social support (20%) and environmental factors (16%). Although it is possible that outcome expectations and socio-structural factors may have had stronger indirect effects on physical activity, these effects were not investigated or reported consistently enough to allow for meaningful interpretation.

Recently, researchers have suggested that theoretical integration may be a viable way to improve our understanding of physical activity by reducing complexity through the elimination of redundant variables (213). Indeed, theorists have noted that many of the core constructs from competing theories are conceptually very similar (214, 215). For example, Bandura has acknowledged that self-efficacy and goals from SCT share considerable overlap with perceived behavioural control and intention from the TPB, respectively (71). Similarly, outcome expectations (SCT) are very similar to pros/cons (Trans-theoretical Model), behavioural beliefs (TPB), and perceived benefits (Health

Belief Model) (141). Of note, in their meta-analytic review of the TPB and physical activity, Hagger and colleagues determined that the addition of self-efficacy to the TPB increased the predictive power of the model, but did not nullify the contribution of perceived behavioural control, which suggests that both variables may contribute unique variance to the explanation of physical activity (142). Clearly, more research is required to determine whether these variables do indeed represent the same constructs (151), and if so, how the evidence from competing theories can be synthesised (74). However, this investigation was outside the scope of the current review, which focused solely on the utility of SCT to explain physical activity, as specified by Bandura (71).

In addition to considering theoretical augmentation, researchers should also strive to publish more robust tests of SCT as it is currently specified. This review determined that study quality significantly moderated the explanatory power of SCT in the current meta-analysis, with higher quality models explaining more variance than lower quality models. However, overall methodological quality was poor, with common weaknesses including non-random selection of participants, reliance on cross-sectional study designs, no power calculation provided, lack of adjustment for past behaviour and insufficient evidence provided for the reliability of the SCT scales. In addition, only 40% of the models included all core SCT constructs detailed in Figure 1.1. Thus, this review suggests that high-quality, methodologically-rigorous SCT tests are warranted.

Finally, it is important to briefly acknowledge the reasons why this review focused on the 'global' explanatory power of SCT rather than identifying the magnitude of association between individual SCT constructs and behaviour. As Hagger and Chatzisarantis (2009) noted in their meta-analytic review of the TPB and *Self-Determination Theory*, establishing the equivalence of measures is a key challenge for meta-analysts (154). However, several of the core SCT constructs do not currently have widely accepted operational definitions and are often measured with a variety of scales (Table 3.2). For example, Luszczynska & Schwarzer (2005) have noted the difficulty of adequately representing the socio-structural factors construct, which could encompass a large range of diverse factors such as social support, ethnic group membership, education, affluence, local resources and governmental policy (72). As such, SCT models generally include more variation in the conceptualisation and measurement of model constructs than other theories, such as the TPB, where the model constructs are almost invariantly measured with similar items/scales informed by Azjen's guidelines (154). Therefore, it was deemed inappropriate to perform the meta-analysis at this level of specificity.

3.4.1 Strengths and limitations

This was a complex review with several strengths. A comprehensive search strategy, which maximised sensitivity, was applied to 10 databases to retrieve all relevant research. This search did not exclude studies based on year of publication or any sample-based characteristics including age group, sex, or functional limitations. As such, this review provided a novel synthesis of 55 theory tests from over 20 years of SCT research. A random-effects meta-analysis was employed to allow for extrapolation of the results to the wider population and the conduct and reporting of this review adhered to the PRISMA statement. There are also some limitations to acknowledge. As we only considered published journal articles written in the English language, some non-Caucasian ethnic groups may have been under-represented in the analysis. In addition, some caution is required when interpreting the results of the construct analysis (research question 3), given the variation in the conceptualisation and measurement of the various SCT constructs between studies. For example, the operationalisation of outcome expectations varied between studies and the models included different combinations of physical, social, self-evaluative, or general outcome expectations variables (Table 3.2). As noted above, these inter-study variations also precluded a meaningful meta-analysis of the unique associations of each SCT construct with physical activity. Finally, the aim of this review was to examine SCT models of physical activity only. Thus, while the review contributed unique information to the literature on SCT, it was unable to contribute to cumulative knowledge across multiple social cognitive theories.

3.4.2 Recommendations for research

In order to comprehensively assess SCT, researchers should strive to include all core SCT constructs in future theory-tests and ensure these constructs are measured using scales with adequate reliability. At a minimum, future studies should include details of the internal consistency and test-retest reliability of all scales used. Researchers should also ensure that these SCT models are correctly specified, with the appropriate direct and indirect pathways (Figure 1.1). Reporting of the direct, indirect and total effects from all constructs to behaviour in future studies will also allow for more rigorous examination of the theory. Given that methodological quality was a significant moderator of physical activity variance explained, but overall model quality was low, additional high quality SCT theory tests are needed to ensure a valid determination of the true utility of SCT in the physical activity domain.

3.4.3 Recommendations for practice

This review provides good evidence for the usefulness of SCT as a framework to apply when designing physical activity behaviour change interventions, particularly in older populations. Current evidence suggests that physical activity interventions may be more effective if they include a distinct focus on enhancing self-efficacy and teaching key self-regulatory strategies such as goal setting, planning, self-monitoring and reward provision. Researchers designing future physical activity interventions should consult the rapidly expanding literature on behaviour change techniques (e.g., (216)) to identify which intervention strategies are most effective when operationalising the behaviour change constructs delineated in SCT.

CHAPTER 4

BEHAVIOURAL MEDIATORS OF WEIGHT LOSS IN THE SHED-IT COMMUNITY RANDOMISED CONTROLLED TRIAL FOR OVERWEIGHT AND OBESE MEN

Preface:

This chapter presents the results of mediation analysis, which I conducted to investigate *Secondary Aim 3* of this thesis (i.e., to identify behavioural mediators of sustained weight loss in a previous male-only weight loss study).

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Abstract

Background: Little is known about which behavioural strategies are most important to target in weight loss interventions for men.

Objective: To identify behavioural mediators of weight loss in the male-only SHED-IT Community Weight Loss randomised controlled trial (RCT).

Methods: A RCT with 159 overweight/obese men [mean (SD) age = 47.5(11.0) years; Body-mass Index (BMI) = 32.7(3.5) kg/m^2] assessed at baseline, three months (post-test) and six months (follow-up).

Results: In an intention-to-treat, multiple-mediator model, the significant intervention effect on weight at 6 months (−3.70 kg; p<0.001) was mediated by increases in physical activity (steps/day) and decreases in take-away meals (kilojoules/day) and portion size at 3 months. The largest mediation effect was for physical activity (-0.6 kg; 95% CI -1.4,-0.1). Overall, the targeted mediators accounted for 47% of the intervention's effect on weight.

Conclusions: Daily step counts, takeaway food, and portion size may be key areas to target in future weight loss programs for men.

4.1 Introduction

Obesity is a chronic health condition with many physical and psychological co-morbidities (1). Although behavioural interventions can effectively generate modest weight loss (8), these programs may not necessarily work for men, who are significantly under-represented in weight loss research (38). This is concerning, as men generally store excess fat abdominally, which increases their risk of obesity-related illness (23). Further, while much research has investigated the efficacy of various weight loss approaches, less is known about which program components are most important, particularly in male-only samples (217).

Mediation analysis is an important statistical technique to identify possible mechanisms for success in behavioural interventions. In theory, a mediator variable is situated between an independent variable (e.g., treatment) and a dependent variable (i.e., study outcome) on a causal chain (218). While the best evidence to isolate causal effects of different weight loss strategies would be obtained by randomising participants to interventions that focus on a single strategy (e.g., increasing daily steps), identifying substantive mediators of multi-component programs can provide useful information to inform future research and more targeted interventions, as important components can be emphasised and less important components removed. Although many studies have investigated mediation effects in physical activity and nutrition interventions (e.g., (219, 220)), fewer have considered mediators of weight loss (e.g., (221, 222)). Further, although sustainable behaviour change is essential for success, most weight loss mediation studies have not examined behavioural mediators (e.g., (223)). As noted above, these studies generally include an over-representation of women (38) and often obscure sex-specific effects by statistically adjusting for sex instead of presenting results for men and women separately (23). As such, little evidence exists to illuminate which health behaviours are most important to target in weight loss programs specifically for men.

The SHED-IT (Self-help, Exercise and Diet using Information Technology) Community Weight Loss randomised controlled trial (RCT) (81, 82) investigated the effectiveness of two versions of a gender-tailored weight loss program for men (online self-monitoring vs. paper-based self-monitoring), compared to a control. In addition to recruiting men only, the programs were designed to appeal specifically to men with a series of evidence-based, gender-tailored weight loss messages. At 3 months (post-test) and 6 months (follow-up), significant treatment effects were observed for weight in both the Online group and Resources (paper-based) group compared to the control (81). The aim of the current study was to investigate which of the weight loss behaviours specifically targeted in the intervention also served as mediators of the intervention effect on weight at 6 months.

4.2 Methods

4.2.1 Participants

In August 2010, 159 men (18-65 years; BMI 25-40 kg/m^2) were recruited from Newcastle, Australia. All men passed an eligibility screener (82) and provided consent. To be eligible for the study, the men were required to: i) be overweight or obese (BMI 25-40 kg/m^2), ii) be aged 18-65 years, iii) agree to refrain from participating in other weight loss programs during the study, iv) have access to a computer with internet facilities, v) own a mobile phone, vi) have been weight stable for the previous 6 months (i.e.., no more than 5% weight loss in the previous 6 months), and vii) have not taken medication to lose or gain weight in the previous 3 months.

4.2.2 Design and interventions

The SHED-IT Community Weight Loss Trial was an assessor-blinded RCT that evaluated the effectiveness of two gender-tailored weight loss interventions for men. Extensive details on the methods (82) and results (77, 81) of this study can be found elsewhere. Briefly, men were randomised to one of the three study arms: (i) Resources (i.e., the SHED-IT Program with paper-based self-monitoring), (ii) Online (i.e., the SHED-IT Program with online self-monitoring), or (iii) no intervention for 6 months (wait-list control). The two programs differed only in terms of self-monitoring modality (i.e., online vs. paper-based) and e-feedback, with the Online group also receiving seven dietary and physical activity feedback emails. The study received institutional ethics approval and was registered with the Australian New Zealand Clinical Trials Registry (ACTRN12610000699066).

Both SHED-IT programs were theoretically-based and operationalised Bandura's Social Cognitive Theory, targeting key cognitions such as self-efficacy, self-regulation, perceived barriers, and social support. Men were provided with a weight loss resource package, which consisted of: 1) a 25-minute DVD on weight loss for men; 2) the *Weight Loss Handbook for Blokes* and the *Weight Loss Support Book for Blokes;* 3) a pedometer, tape measure for waist circumference and a kilojoule (kJ) counter book. Rather than a strict dietary regime, men were taught the 'mathematics of weight loss' and advised to achieve a negative energy balance by setting a daily kJ intake target and implementing key dietary messages, which targeted specific behaviours of particular concern for Australian men (i.e., portion sizes, energy-dense nutrient-poor snacks, take-away foods (i.e., fast-foods) and sugar-sweetened beverages) (86). Of interest, other male-only weight loss programs internationally have also focused on these areas (224), which may indicate some global commonalities in men's poor dietary habits. Importantly, men were not required to completely avoid all energy-dense foods and drinks (e.g., alcohol), but were encouraged to plan these extras into their daily kJ allowance. The SHED-IT program resources were 'masculinised' using anecdotes, statistics and strategies that men could relate to. This process was guided by formative work with overweight and obese men (86), and the men's health literature (82).

4.2.3 Sample size

The primary study (81) was designed to detect a between-group difference of 4 kg (SD 5 kg) at 6 months. Thus, for 80% power ($p = 0.015$, two-sided) a sample of 150 men was required to allow for a predicted attrition rate of 28%. This sample size also powered the current analysis to detect medium-to-large effects with the bias-corrected bootstrap procedure (225).

4.2.4 Assessments

Measures were obtained from all men at baseline and follow up data were collected from 82% of the sample at 3 months (post-test) and 81% at 6 months (follow-up), with no significant difference in retention between groups. Measures were taken by trained, blinded research assistants who adhered to standardised procedures. The primary outcome was weight (kg), measured to 0.01 kg on a digital scale (CH-150kp, A&D

Mercury Pty Ltd, Australia). A participant flowchart for this trial is provided elsewhere (81).

All hypothesised behavioural mediators of the treatment effect on weight were assessed with validated measures (82). *Physical activity* was objectively measured for seven consecutive days using Yamax SW-200 pedometers, which are reliable and valid (Yamax Corporation, Kumamoto City, Japan). *Sitting time* was assessed using the Sitting Questionnaire, which has been shown to be both a valid and reliable measure of sedentary time (226). Energy from *sugar-sweetened drinks, kJ-dense snacks and take-away meals* were assessed with the Australian Eating Survey, which is a validated, semi-quantitative food frequency questionnaire (227). Portion size was assessed with a validated subscale from the Dietary Questionnaire for Epidemiological Studies Version 2 (228). The time referent for the mediator measures matched the time difference between assessments (i.e., the previous 3 months) with the exception of step count data, which were collected in the week prior to baseline assessments and the week after post-test and follow-up assessments. Importantly, each mediator was targeted during the intervention and was represented as a key weight loss message for men. Additional detail on the mediator measures is available elsewhere (82).

4.2.5 Statistical analyses

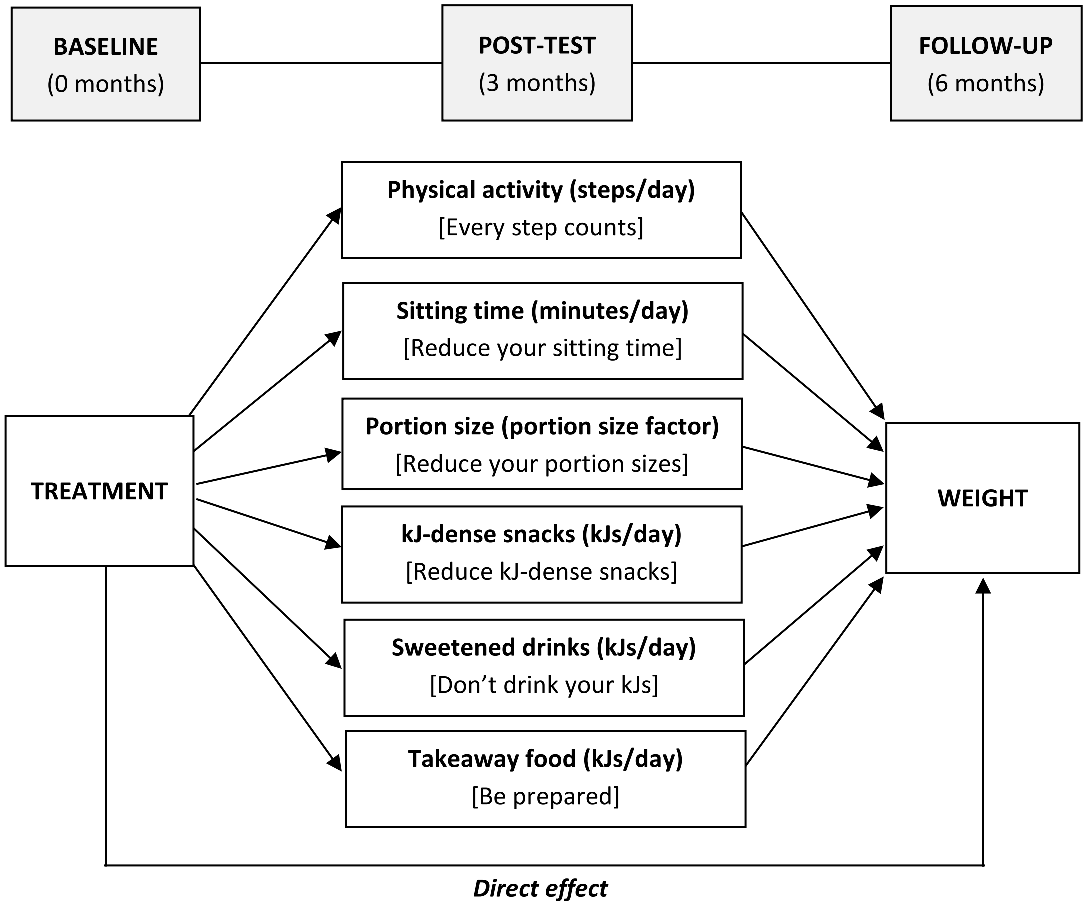
In the RCT, significantly intervention effects were observed at 6 months. Compared to the control, the *Online* group lost an additional 4.2 kg (95% CI 2.5, 5.9) and *Resources* group lost an additional 3.2 kg (95% CI 1.5, 4.9). However, the difference between intervention groups was not significant ($p>0.05$). Therefore, to maximise power, both intervention groups were combined and compared to the control in the current analyses.

The mediation analyses were conducted in SPSS Statistics Version 21 (SPSS Inc, Chicago, Illinois, USA) using the INDIRECT Macro (229). This macro was used to: i) calculate the regression coefficients for the effect of the intervention on the hypothesised mediators (Pathway A), ii) examine the association between the mediator variable at 3 months and the outcome variable at 6-months, independent of group assignment (Pathway B), and iii) estimate the total (Pathway C), direct (Pathway C') and indirect (Pathway AB) intervention effects. All analyses were adjusted for baseline values. This approach is preferred to using change score variables, which are affected by regression to the mean (230). The macro also generated bias-corrected bootstrapped 95% asymmetrical confidence intervals around the indirect effect (229). Significant mediation was established if these confidence intervals did not include zero. Finally, the proportion of the intervention effect attributed to each mediator was calculated by dividing the indirect effect (Pathway AB) by the total effect (Pathway C' + Pathway AB).

As recommended in the literature (231), an appropriate temporal sequence was employed to strengthen the evidence for mediation in the current analysis, which investigated whether weight loss at follow-up (6 months) was mediated by post-treatment scores for each hypothesised behavioural mediator at 3 months (Figure 4.1). To adjust for pre-treatment effects, baseline values for weight and all mediator variables were included as covariates in the model. The multiple-mediator model followed an intention-to-treat approach, where missing data were imputed using the expectation maximisation procedure in SPSS. This approach was deemed appropriate as Little's test did not reject the assumption that the data were missing completely at random (χ^2 = 161.6, df = 144, p = 0.15). The amount of missing data for each variable was: weight (baseline: 0%; 6 months: 19%), step counts (baseline: 10%; 3 months: 27%), sitting time (baseline: 1%, 3 months: 18%), portion size, sweetened drinks, kJ-dense snacks, and takeaway food (baseline: 0%; 3 months: 18%). As noted above, the majority of missing data was due to participant drop-out at 3 months (18%) and 6 months (19%).

For sensitivity purposes, a multiple-mediator model was also conducted for with the completers sample. As that the INDIRECT macro only includes participants with complete data for every variable, the completers sample included 68% of the participants and the intention-to-treat analyses included 100%. Finally, simple mediation models were conducted for each mediator. While not discussed here, these results will allow for comparisons with previous research and for the inclusion of single mediators in future meta-analyses, as recommended in the literature (231).

Figure 4.1. A schematic representation of the multiple-mediation model. For clarity, baseline covariates for weight and the mediators are not depicted.



4.3 Results

Details of the study sample are provided elsewhere (81). Briefly, the mean (SD) weight of the study sample was 103.4 (14.0) kg and the mean (SD) age was 47.5 (11.0) years. The majority of the sample was born in Australia (91%) and had a waist circumference greater than 102 cm (91%). Table 4.1 presents summary data for weight and each mediator during the trial. The total effect of the intervention on weight at 6 months was significant ($p<0.001$) in both the intention-to-treat (−3.70 kg) and completers (-4.56 kg) analyses. Tables 4.2 and 4.3 present the results of the multiple-mediator and single-mediator models respectively.

After controlling for baseline values, significant intervention effects were observed at 3 months for physical activity (A = +1726 steps/day, $p < 0.001$), takeaway food (A = -201 kJ/day, $p <0.01$), portion size (-0.11 units, $p <0.001$) and kJ-dense snacks (-512 kJ/day, $p<0.001$) (Table 4.2). The intervention did not significantly influence sitting time ($p = 0.65$), but a marginal effect was observed for sweetened drink intake ($p = 0.06$). The completers-only, sensitivity analysis reflected the same pattern of significant effects. In addition, significant associations were observed between weight and physical activity (B = -0.0004, $p = 0.01$), kJs from takeaway food (B = 0.0028, $p <0.001$), and portion size (B = 5.0212, $p <0.01$), with the completers model only identifying an association between weight and energy from takeaway meals ($p <0.001$).

As seen in Table 4.2, the multiple mediator model identified that 47% of the total intervention effect on weight at follow-up (6 months) could be attributed to changes in the hypothesised mediators during the intervention (Combined AB = -1.74 kg; 95% CI -2.78, -0.81). The largest mediated effect was observed through increases in physical activity, which explained 16.5% of the intervention effect on weight (AB = -0.61 kg; 95% CI -1.37, -0.08). Significant mediated effects were also observed for kJ from takeaway food (15.4%; AB = -0.57, -1.49, -0.16) and portion size (14.3%; AB = -0.53 kg; 95% CI -1.11, -0.12). Although each variable mediated a similar proportion of the intervention effect on weight in both the intention-to-treat and completers-only populations, mediation was only established for physical activity and takeaway food intake in the completers-only, sensitivity analysis.

Table 4.1. Participants' values for weight (baseline and follow-up [6 months]) and hypothesised mediators (baseline and post-test [3 months]).

Model outcome	**Analysis**	**SHED-IT**		**Control**	
		Baseline	**6-month**	**Baseline**	**6-month**
		Mean (SD)	*Mean (SD)*	*Mean (SD)*	*Mean (SD)*
Weight (kg)	Intention-to-treat [a]	103.2 (13.5)	98.4 (14.6)	103.8 (15.0)	102.9 (14.8)
	Completers [b]	103.3 (14.1)	98.0 (15.6)	102.4 (13.2)	101.9 (13.2)

Hypothesised mediator ***[SHED-IT tip]***	**Analysis**	**SHED-IT**		**Control**	
		Baseline	**3-month**	**Baseline**	**3-month**
		Mean (SD)	*Mean (SD)*	*Mean (SD)*	*Mean (SD)*
Physical activity (steps/day)	Intention-to-treat	6951.0 (2830.9)	9312.1 (3043.7)	6776.3 (2712.5)	7334.7 (2675.8)
[Every step counts]	Completers	7207.1 (2760.2)	9573.3 (3414.2)	7133.5 (2745.2)	7360.3 (2913.0)
Sitting time (minutes/day) [c]	Intention-to-treat	492.7 (199.3)	456.0 (192.7)	551.2 (196.1)	503.3 (211.7)
[Reduce your sitting time]	Completers	499.6 (208.5)	459.0 (209.6)	538.8 (211.5)	514.5 (238.8)
Portion size (portion size factor) [d]	Intention-to-treat	1.2 (0.3)	1.1 (0.3)	1.2 (0.3)	1.1 (0.2)
[Reduce portion sizes]	Completers	1.1 (0.3)	1.0 (0.3)	1.1 (0.3)	1.2 (0.2)
kJ-dense snacks (kJs/day)	Intention-to-treat	1746.6 (1406.2)	894.9 (675.7)	1626.5 (1117.5)	1355.8 (1177.4)
[Reduce kJ-dense snacks]	Completers	1766.6 (1478.6)	844.3 (704.0)	1720.4 (1250.0)	1504.3 (1339.3)
Sugar-sweetened drinks (kJs/day)	Intention-to-treat	518.8 (798.7)	350.9 (475.7)	492.9 (590.0)	449.1 (595.1)
[Don't drink your kJs]	Completers	425.4 (562.3)	305.2 (432.0)	485.0 (596.0)	485.7 (666.2)
Take-away food (kJs/day)	Intention-to-treat	1093.5 (654.1)	756.0 (617.7)	1123.1 (830.7)	1005.7 (778.0)
[Be prepared]	Completers	1025.7 (554.9)	732.9 (668.6)	1101.9 (843.3)	1033.2 (803.6)

[a] Intention-to-treat sample using all randomised participants (expectation maximisation technique used to impute missing data) (n = 159 [107 intervention, 52 control]). [b] *Completers* = completers sample from multiple mediator model (i.e., complete outcome data for all mediators in model required) (n = 108 [70 intervention, 38 control]). [c] Non-work day sitting time. [d] Participants were shown a set of three portion size photographs of varying serving size for a number of foods. By indicating whether they ate less than, equivalent to, between, or more than the serving sizes shown, seven serving size options were available for each food. Using portion size distribution data from 810 adults, the first photo represented the 25th percentile, the second photo represented the median, and the third photo represented the 75th percentile. Participant responses to the foods were then averaged to create a portion size factor indicating whether on average a person ate median size serves (= 1), more than the median (> 1), or less than the median (< 1) for main meals.

Table 4.2. Results of the multiple mediator model examining the intervention effect on the mediators at post-test (3 months), and the association between changes in mediators at post-test and changes in weight at follow-up (6 months).

Hypothesised Mediator [a]	Analysis [b]	C' (SE) [c]	A (SE) [d]	B (SE) [e]	AB (SE) [95% CI] [f]	AB [mediated effect] / (C'+ AB) [total effect] [g]
Physical activity (steps/day)	Intention-to-treat	-	**1725.6 (391.0)*** **	**-0.0004 (0.0001)***	**-0.6 (0.3) [-1.4, -0.1]**	**16.5%**
	Completers	-	**2130.3 (545.3)*** **	-0.0003 (0.0002)	**-0.7 (0.4) [-1.9, -0.1]**	**15.3%**
Takeaway food (kJs/day)	Intention-to-treat	-	**-200.8 (71.1)** **	**0.0028 (0.0008)*** **	**-0.6 (0.3) [-1.5, -0.2]**	**15.4%**
	Completers	-	**-216.4 (97.8)***	**0.0031 (0.0010)** **	**-0.7 (0.5) [-1.9, -0.1]**	**14.9%**
Portion size [h] (portion size factor)	Intention-to-treat	-	**-0.1 (0.0)*** **	**5.0212 (1.8445)** **	**-0.5 (0.3) [-1.1, -0.1]**	**14.3%**
	Completers	-	**-0.2 (0.0)*** **	3.8201 (2.4611)	-0.6 (0.5) [-1.7, 0.2]	13.6%
Sitting time (minutes/day) [i]	Intention-to-treat	-	-13.3 (29.3)	0.0026 (0.0018)	-0.0 (0.1) [-0.3, 0.1]	1.1%
	Completers	-	-32.6 (39.0)	0.0034 (0.0023)	-0.1 (0.2) [-0.7, 0.1]	2.4%
kJ-dense snacks (kJs/day)	Intention-to-treat	-	**-512.3 (117.1)*** **	0.0000 (0.0005)	-0.0 (0.3) [-0.6, 0.7]	0.3%
	Completers	-	**-651.8 (161.6)*** **	-0.0002 (0.0006)	0.1 (0.5) [-0.8, 1.1]	-3.1%
Sweetened drinks (kJs/day)	Intention-to-treat	-	-122.9 (64.9)	-0.0001 (0.0008)	0.0 (0.2) [-0.3, 0.3]	-0.5%
	Completers	-	-145.9 (81.5)	-0.0005 (0.0011)	0.1 (0.2) [-0.3, 0.6]	-1.5%
Total effects	Intention-to-treat	**-2.0 (0.7)** **	-	-	**-1.7 (0.5) [-2.8, -0.8]**	**47.0%**
	Completers	**-2.7 (1.1)***	-	-	**-1.9 (0.8) [-3.4, -0.4]**	**41.8%**

Note: SE = standard error; CI = confidence interval; kJ = kilojoule; ITT = intention-to-treat (expectation maximisation imputation).

[a] Mediators presented in relation to magnitude of unique mediated effect on weight (largest to smallest; intention-to-treat analysis). [b] Completers sample from multiple mediator model (i.e., complete outcome data for all mediators in model required) (n = 108 [70 intervention, 38 control]); Intention-to-treat sample used all randomised participants (expectation maximisation technique used to impute missing data) (n = 159 [107 intervention, 52 control]). [c] C' = Direct effect of the intervention on weight. [d] A = Intervention effect on mediators. [e] B = Association between mediators and weight. [f] AB = Indirect or 'mediated' effect (product of coefficients estimate). [g] Unique proportion of intervention effect on weight that was mediated (calculated from non-rounded results). [h] Indicates whether on average a person ate median size serves (=1), more than the median (> 1), or less than the median (< 1) for main meals. [i] Non-work-day sitting time.

* p <0.05; ** p < 0.01; *** p <0.001; bold denotes significant effect.

Table 4.3. Results of the single mediator models examining the intervention effect on the mediators at post-test (3 months), and the association between changes in mediators at post-test and changes in weight at follow-up (6 months).

Hypothesised Mediator [a]	Analysis [b]	C' (SE) [c]	A (SE) [d]	B (SE) [e]	AB (SE) [95% CI] [f]	AB[mediator] / (C'+ AB[mediator]) [g]
Physical activity (steps/day)	Intention-to-treat	**-2.9 (0.7)*** **	**1862.9 (393.4)*** **	**-0.0005 (0.0001)*** **	**-1.0 (0.4) [-1.8, -0.4]**	**24.7%**
	Completers	**-3.6 (1.0)*** **	**2255.8 (537.3)*** **	**-0.0005 (0.0002)** **	**-1.1 (0.4) [-2.1, -0.4]**	**23.2%**
Takeaway food (kJs/day)	Intention-to-treat	**-3.1 (0.7)*** **	**-229.0 (71.1)** **	**0.0035 (0.0008)*** **	**-0.8 (0.4) [-1.8, -0.3]**	**20.5%**
	Completers	**-3.6 (0.8)*** **	**-250.9 (86.8)** **	**0.0035 (0.0008)*** **	**-0.9 (0.5) [-2.1, -0.3]**	**19.9%**
kJ-dense snacks (kJs/day)	Intention-to-treat	**-3.2 (0.7)*** **	**-505.3 (122.3)*** **	**0.0015 (0.0005)** **	**-0 .7 (0.3) [-1.4, -0.3]**	**18.8%**
	Completers	**-3.7 (0.9)*** **	**-593.2 (148.4)*** **	**0.0013 (0.0005)* **	**-0.8 (0.3) [-1.5, -0.2]**	**17.3%**
Portion size (portion size factor) [h]	Intention-to-treat	**-3.3 (0.7)*** **	**-0.1 (0.0)*** **	**5.8611 (1.9966)** **	**-0.6 (0.3) [-1.3, -0.1]**	**15.9%**
	Completers	**-3.8 (0.9)*** **	**-0.1 (0.0)*** **	**5.0256 (2.2639)* **	**-0.7 (0.4) [-1.6, -0.1]**	**15.1%**
Sitting time (minutes/day) [i]	Intention-to-treat	**-3.7 (0.7)*** **	-17.9 (29.4)	0.0034 (0.0019)	-0.1 (0.1) [-0.5, 0.1]	1.9%
	Completers	**-4.3 (0.9)*** **	-22.7 (36.2)	0.0034 (0.0022)	-0.1 (0.1) [-0.5, 0.1]	1.8%
Sweetened drinks (kJs/day)	Intention-to-treat	**-3.9 (0.7)*** **	-112.1 (64.0)	0.0003 (0.0009)	-0.0 (0.2) [-0.4, 0.2]	0.8%
	Completers	**-4.5 (0.9)*** **	-152.8 (78.4)	0.0002 (0.0010)	-0.0 (0.2) [-0.5, 0.4]	0.7%

Note: SE = standard error; CI = confidence interval; kJ = kilojoule; ITT = intention-to-treat (expectation maximisation imputation).

[a] Mediators presented in relation to magnitude of mediated effect on weight (largest to smallest; intention-to-treat analysis). [b] Completers sample from multiple mediator model (i.e., complete outcome data for all mediators in model required) (n = 108 [70 intervention, 38 control]); Intention-to-treat sample used all randomised participants (expectation maximisation technique used to impute missing data) (n = 159 [107 intervention, 52 control]). [c] C' = Direct effect of the intervention on weight. [d] A = Intervention effect on mediators. [e] B = Association between mediators and weight. [f] AB = Indirect or 'mediated' effect (product of coefficients estimate). [g] Proportion of intervention effect on weight that was mediated (calculated from non-rounded data). [h] Indicates whether on average a person ate median size serves (= 1), more than the median (> 1), or less than the median (< 1) for main meals. [i] Non-work day sitting time.

* p <0.05; ** p < 0.01; *** p <0.001; bold denotes significant effect

4.4 Discussion

The aim of this study was to investigate whether any of the specifically-targeted behavioural strategies in the *SHED-IT Weight Loss Program* for men significantly mediated the intervention effect on weight at follow-up. At 6 months, the SHED-IT intervention had a significant total effect on weight. Of the included variables, increased physical activity (steps/day) represented the largest mediation effect. Mediation was also established for reduced portion size, and reduced kJs from take-away meals. Overall, the targeted mediators accounted for 47% of the total intervention effect on weight.

To date, men have been greatly under-represented in weight loss research (38) and male-only weight loss studies are limited in quality and quantity (217). As such, relatively little is known about successful strategies to enhance weight loss in men. In line with recent behavioural mediation analyses of the male-only 'Healthy Dads, Healthy Kids' trial (221) and female-only '40-Something' trial (232), increasing men's daily step counts mediated the largest proportion of the SHED-IT Program's effect on weight. Strong evidence from randomised trials shows that physical activity has a unique and clinically important influence on weight loss (233). However, as these studies often examine the impact of physical activity via closely supervised exercise programs (233), the current results provide novel and important findings as the SHED-IT Program involved no face-to-face contact. Of interest, a process evaluation of SHED-IT revealed that the majority of the physical activity goals men set related to increasing walking, rather than other higher-intensity exercises (85). Although increasing moderate-to-vigorous physical activity is a strongly supported weight loss strategy (8), these results provide good evidence for the role of targeting improvements in incidental physical activity during weight loss. In the SHED-IT Program, men were encouraged to increase their incidental activity and provided with a pedometer to self-monitor their step counts and encouraged to set goals and graph their weekly step average (85). Given the important mediation effect established for physical activity in the current study, future weight loss programs for men may benefit by including these physical activity self-monitoring strategies.

In addition to the physical activity effects, this study revealed that intervention effects on kJs from take-away meals mediated 15% of the SHED-IT interventions effect on weight at follow-up. While the benefit of diet plus physical activity interventions compared to physical activity interventions is well established (233), these results are novel given that, to the authors' knowledge, no studies have specifically isolated the influence of fast-food consumption on weight loss. In a systematic review examining the association between fast food access and obesity, White (234) noted that longitudinal, experimental data are urgently required to provide insight into the causal influence of this obesogenic factor. Of interest, Coughlin et al. recently identified that reducing take-away food consumption significantly mediated long-term weight loss maintenance in a sample of 1032 overweight/obese men and women (235). In contrast, results from the recent female-only '40-something' weight control study (232) indicated that the intervention effect on 'meals eaten outside of the home' was not a significant mediator of the treatment effect. Although this may indicate a potential sex difference in the importance of targeting take-away/fast food consumption during weight loss, this hypothesis requires further validation in future research. Of note, the SHED-IT Program was also successfully tested in a pilot study with the associated mediation analysis finding no significant mediation effects for any dietary variables (80), in contrast to the current study. However, the pilot did not include a true control and the effect of the minimal intervention may have confounded the results. Further, the current SHED-IT program was improved with additional components and extensive theoretical- and gender-tailoring (82).

The current results suggest that targeting portion size may be an effective strategy in future weight loss studies for men. In the multiple-mediator model, intervention effects on portion size in the first three months mediated 14% of the weight loss effect at follow-up. Portion size was also noted as a significant mediator of long-term weight loss maintenance in a mediation analysis from a recent study (235). This is a noteworthy finding, given that a recent systematic review identified no RCTs specifically examining the role of portion size in weight loss (236). The authors also recommended that portion size intervention studies are urgently required to determine which types of strategies work for various target groups (236). In the context of the current findings, studies examining the utility of targeting portion size for weight loss certainly appear warranted, particularly in men.

Despite the intervention effect on sugar-sweetened drinks approaching significance, changes in this variable did not mediate the intervention's effect on weight at follow-up. However, it is important to note that floor effects in this mediator may have affected the results, with great variation observed at baseline between men in the lowest consumption quartile (0 – 51 kJ/day) compared to men in the highest quartile (657 – 4445 kJ/day). While beyond the scope and statistical power limitations of the current study, future research could investigate whether pre-treatment sugar sweetened beverage consumption acts as a moderator of this mediation effect. Similarly, although reducing sedentary time was specifically targeted during the intervention, participants did not significantly reduce sitting time compared to the control group. As such, more research is required to identify effective ways to target this variable.

This study contained several strengths including use of data from a methodologically-rigorous RCT with a true control and validated measures, a multiple-mediator, intention-to-treat analysis with adjustment for baseline values, high retention, blinded assessors, and objectively measured weight and physical activity. By examining the effect of mediators at post-test on weight loss at follow-up, this analysis also included appropriate temporal sequencing, which is an essential, but often overlooked, criteria to establish mediation (218). The study also had some limitations. As the study did not include measures to capture three SHED-IT weight loss messages (read food labels, keep a healthy lifestyle diary, and surf the urge (i.e., resisting unnecessary snacking)) (81), the importance of these tips could not be established. In addition, although the dietary mediators were measured with a validated questionnaire (227), they may have included more measurement error than the physical activity mediator, which was measured objectively. As such the model may have implicitly favoured physical activity.

In conclusion, this study provides important evidence to inform the design of future weight loss programs for men. Intervention effects on reducing portion sizes, increasing daily step counts and reducing intake of take-away/fast food in the first three months accounted for just under half of the intervention effect on weight at follow-up. These findings have important implications for future research and practice. Initially, the current findings could be tested in replication studies with men from varied cultures and demographic groups (e.g., men from rural communities). Future research could also investigate moderated-mediation effects, given that indirect effects may vary according to different levels of an additional variable (e.g., baseline BMI category). The inclusion of other variables (e.g., fruit and vegetable intake, resistance training) may strengthen the mediation effect in future trials. Finally, given that the strongest causal evidence is generated through randomisation, future studies could consider randomising men to interventions targeting each mediator in isolation. In a practical sense, this study presents good evidence that male-only weight loss studies may benefit by including an explicit focus on increasing men's daily step counts, and reducing portion sizes and consumption of take-away/fast food.

CHAPTER 5

THE SHED-IT WEIGHT LOSS MAINTENANCE TRIAL PROTOCOL: A RANDOMISED CONTROLLED TRIAL OF A WEIGHT LOSS MAINTENANCE PROGRAM FOR OVERWEIGHT AND OBESE MEN

Preface:

This chapter presents the protocol paper for the *SHED-IT Weight Loss Maintenance Trial*, which provides extensive detail on the study design, program components, assessment procedures, and statistical analysis plan.

The content presented in this chapter is not the final version of the article which is published in *Contemporary Clinical Trials.* Permission was granted by *Elsevier* to use the content presented here.

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Abstract

Background: Despite short-term efficacy, many weight loss studies demonstrate poor long-term results and have difficulty recruiting men. Cost-effective treatments that help men achieve long-term weight loss are required.

Methods: Using a two-phase, assessor-blinded, parallel-group randomised controlled trial design this study will test the effectiveness and cost-effectiveness of a male-only weight loss maintenance intervention. In Phase I (3 months) 209 men received the *SHED-IT (Self-help, Exercise and Diet using Information Technology) Weight Loss Program*. In Phase II (12 months) 92 men who lost 4kg or more were randomised to either (i) a maintenance group who received the gender-tailored *SHED-IT Weight Loss Maintenance Program,* that includes no face-to-face contact (n=47), or (ii) self-help control (n=45). Randomisation was stratified by weight loss (4kg-7.4kg,≥7.5kg) and Body-mass Index (<30kg/m^2,≥30kg/m^2). Assessments occurred at study entry (start of Phase I), baseline (start of Phase II), 6-month (post-test) and will occur at 12-month (follow-up; primary endpoint). The primary outcome is weight change in Phase II (i.e., from baseline at 12 months after randomisation). Secondary outcomes include waist circumference (umbilicus and narrowest), blood pressure, body composition, objectively measured physical activity, sedentary time, portion size, dietary intake, quality of life, depressive symptoms, and behavioural cognitions. Costing data will be collected for cost-effectiveness analysis. Generalised linear mixed models (intention-to-treat) will assess outcomes for treatment (maintenance vs. control), time (baseline, 6-month and 12-month) and the treatment-by-time interaction.

Conclusions: This will be the first study to evaluate a male-only, gender-tailored weight loss maintenance program. Results will provide evidence regarding feasible and theoretically-driven obesity treatments for men with potential for long-term impact and widespread dissemination.

5.1 Introduction

Since 1980, the international prevalence of obesity in men has almost doubled (3). This has had a dramatic effect in Australia, where 70% of men are now overweight or obese (6) and the average male body-mass index (BMI) is increasing faster than in most high-income countries (3). This is concerning as increases in BMI are associated with increased risks of cardiovascular disease, type 2 diabetes and several cancers (12). Furthermore, obesity is linked to a rapidly expanding list of co-morbidities such as osteoarthritis, hypertension, asthma, sleep apnoea, chronic back pain, sexual dysfunction and depression (1, 8). Developing engaging and effective weight loss strategies for men that could be practically implemented within strained healthcare budgets is an issue of global importance.

Behavioural weight loss interventions have well-documented short-term efficacy to help people achieve modest weight loss and clinically important health benefits (8, 33, 90). However, these benefits are often confounded by poor long-term success rates (237), with participants regaining approximately 30-35% of lost weight in the first year after treatment alone (42). Without additional intervention, most will return to their pre-treatment weight within 5 years (42). This seemingly intractable problem is likely due to a combination of biological, psychological, social and environmental factors (8) and it is evident that current weight loss approaches are not sufficient for long term success (50). This provides a strong rationale for the development and evaluation of weight loss maintenance interventions, where participants develop additional knowledge and skills to halt the weight regain trajectory and achieve lasting weight loss.

In addition to the problem of weight regain, a second major shortfall of weight management research is the considerable under-representation of men (38, 217). A recent systematic review (38) reported that the average proportion of men in 244 behavioural weight loss randomised controlled trials (RCTs) was only 27%. This is supported by other systematic reviews of weight loss studies, where the proportion of men has ranged from 23% (33) to 27% (90). Although research shows that men prefer a male-only approach (86) and may respond well to gender-tailored or male-focused interventions (81, 83, 84, 104, 105, 224), very few weight loss studies have exclusively recruited men (~5%) (38). In addition, another review (217) recently highlighted that the evidence base for male-only studies was limited in quality as well as quantity and recommended that high quality weight loss studies with long-term maintenance were urgently required.

Previously, we have conducted an extensive program of research to establish the efficacy and effectiveness of the *SHED-IT (Self-help, Exercise and Diet using Information Technology) Weight Loss Program* for men (77, 79-84, 86). This paper describes the design, measurement protocols and analysis plan for the SHED-IT Weight Loss Maintenance trial, which will investigate the effectiveness of an additional weight loss maintenance program designed to follow the weight loss program. This study will also investigate a cost-effectiveness analysis, which will provide urgently required evidence (29) regarding the value of this additional maintenance program.

The primary aim of this study is to investigate whether a weight loss maintenance program tailored specifically for men significantly improves maintenance of lost weight and other health outcomes 12 months after an initial weight loss program, in a community sample of overweight and obese men. It is hypothesised that the SHED-IT weight loss maintenance group will achieve significantly greater maintenance of (i) weight loss and (ii) other secondary health outcome improvements at 6- and 12-months after a weight loss program, compared to a SHED-IT weight loss-only (self-help) control group. A secondary hypothesis is that the *SHED-IT Weight Loss Maintenance Program* will be more cost-effective than the SHED-IT weight loss-only (self-help) control option. To the authors' knowledge, this will be the first study internationally to test the effectiveness and cost-effectiveness of a weight loss maintenance intervention designed specifically for men.

5.2 Methods

5.2.1 Study design

The study design is a two-phase, assessor-blinded, parallel-group RCT (Figure 5.1). The study has been approved by the University of Newcastle Human Research Ethics Committee and is prospectively registered with the Australian New Zealand Clinical Trials Registry (ACTRN12612000749808). The design, conduct, and reporting of this study will adhere to the Consolidated Standards of Reporting Trials (CONSORT) guidelines (95).

5.2.2 Participants

Overweight or obese (BMI 25-40kg/m^2) men aged 18 to 65 years were recruited in July/August 2012 from the local community of the Hunter Region, New South Wales, Australia. Participants were recruited through current waiting lists, workplace-based emails and notices, and a University media release (radio, newspapers, University website).

5.2.3 Eligibility

To determine eligibility, interested men were directed to an online questionnaire containing two sections: (i) Eligibility criteria questions (Table 5.1) and (ii) Stage 1 of the Adult Pre-exercise Screening Tool (238). The eligibility criteria were designed to ensure that participants could safely complete and engage with all aspects of the SHED-IT programs and to rule out potential confounds of treatment effects. To improve the generalisability of the findings, the study did not exclude men for taking medications that may have interacted with weight loss, provided that it was safe for them to do so. This was determined by one of the study chief investigators (RC), who is an exercise physiologist and registered pharmacist. In some circumstances, men taking medications were required to provide a medical clearance from their general practitioner to participate. Men also needed a medical clearance if health concerns were identified in the pre-exercise screener (e.g., previous heart attack or stroke). All men were required to provide written consent prior to enrolment.

Figure 5.1. CONSORT flowchart for primary outcome and study design for the SHED-IT Weight Loss Maintenance (WLM) trial.

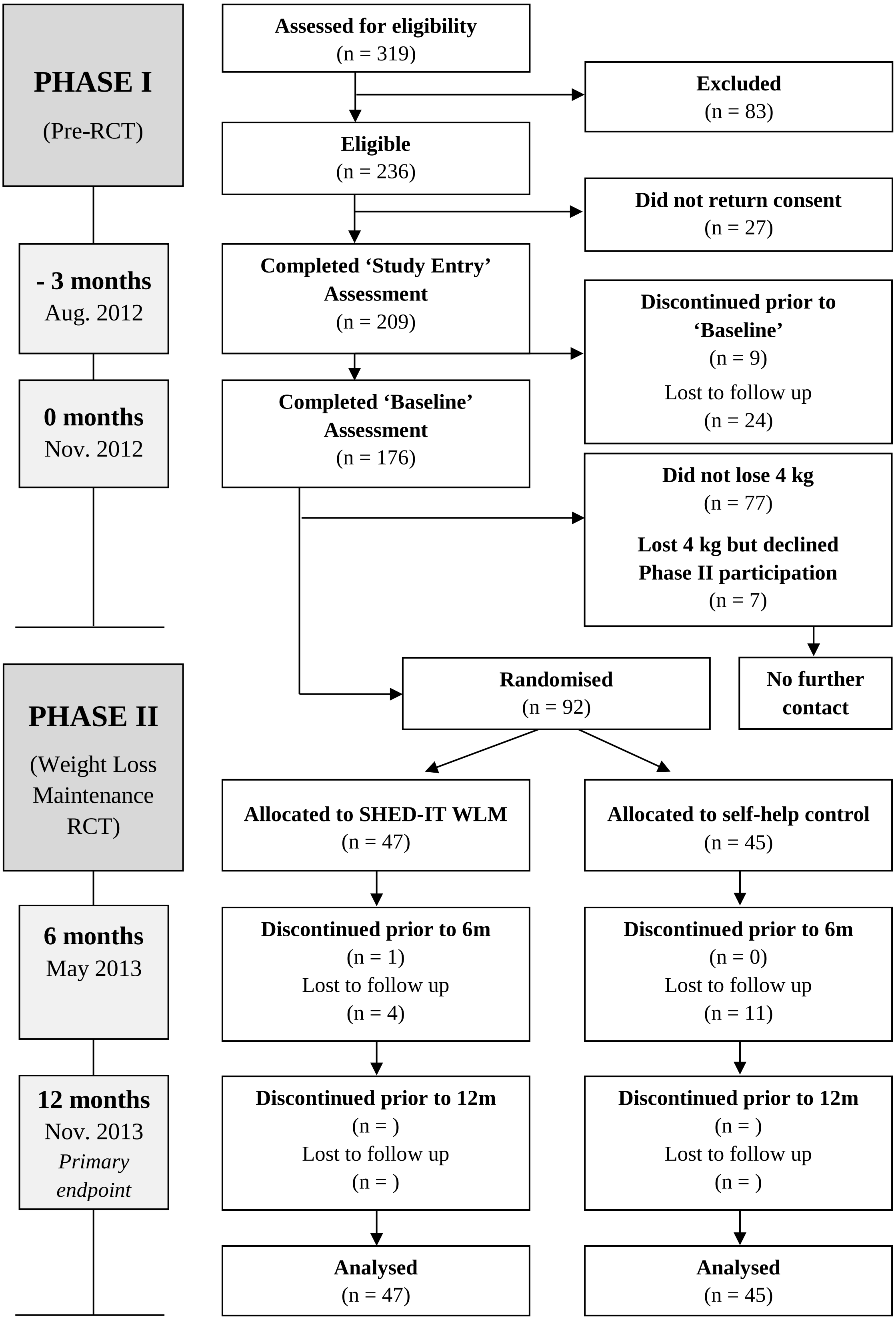

Table 5.1. Eligibility criteria for the SHED-IT Weight Loss Maintenance Trial.

Inclusion criteria

- Male
- Aged 18 – 65 years
- BMI between 25.0 and 40.0 kg/m^2

Exclusion criteria

- Not available for assessment sessions
- No readily available internet access
- Does not own a mobile/cell phone
- Currently participating in an alternative weight loss program
- Intention to participate in other weight loss program during study period
- Currently taking medication to lose or gain weight
- Diabetes requiring insulin treatment
- Experienced weight loss of 5% or more in the previous 6 months

5.2.4 Background to SHED-IT interventions

This research project builds on the extensive development and refinement of the *SHED-IT Weight Loss Program* for men. In brief, in a pilot RCT (79, 80, 83, 84), 65 overweight or obese male university staff and students were randomly assigned to either an Internet-based group (SHED-IT Online) or an Information-only control group (SHED-IT Resources). At 6 months, significant weight loss was observed in both groups, with no significant difference detected between groups. This demonstrated that two versions of a gender-tailored weight loss program could facilitate weight loss in a sample of male university staff and students. However, the scalability of the interventions was limited by the inclusion of a face-to-face information session and the generalisability was reduced by use of a convenience sample.

To address this, the SHED-IT community RCT was conducted in 2010 (77, 81, 82). To move the interventions towards dissemination, all face-to-face contact within the interventions was removed and replaced with a DVD. Two versions of the SHED-IT program (online and paper-based) were tested in a representative community sample against a true, no-intervention control group. Importantly, after 6 months, significant intervention effects were observed for weight and a range of secondary health indicators in both groups compared to the control group. These RCTs established the efficacy and effectiveness of the SHED-IT program and achieved results that were comparable to those in other, more intensive, male-only weight loss programs (217). This may have been due to factoring in gender differences in the program design, which may have increased male engagement with the program and strengthened the results (239).

5.2.5 Phase I: Initial weight loss

In total, 209 eligible men provided consent to participate and completed the 'study entry' assessment in August 2012 (Figure 5.1). After this assessment, they received the latest version of the *SHED-IT Weight Loss Program*. As detailed above, this program has been developed and successfully tested in previous research and many of the intervention components have been described extensively elsewhere (81, 82). Briefly, the program included: (i) The 'SHED-IT Weight Loss DVD for Blokes', (ii) The 'SHED-IT Weight Loss Handbook for Blokes', (iii) The 'SHED-IT Weight Loss Logbook for Blokes', and (iv) weight loss tools including a pedometer, a tape measure and kilojoule (kJ) counter book. All resources were specifically designed to appeal to men and informed by qualitative (86) and quantitative (84) process evaluations, and the men's health literature (e.g., (40, 240)). Men were also encouraged to self-monitor their food intake and physical activity, using either the CalorieKing™ website or MyFitnessPal™ mobile phone app, to create a 2000 kJ deficit on most days.

For the purposes of this study, the SHED-IT program was revised and improved in a few key ways, based on the pilot and community RCT. To improve the scalability of the intervention, participants did not receive any personalised e-feedback from the research team, as was provided in the previous versions. However, the men still had access to the feedback services automatically generated by the website or app, including graphs of daily energy targets and macro- and micro-nutrient intakes. In addition, an automated weekly text message component was introduced during the weight loss phase. These texts reinforced the nine SHED-IT weight loss messages and targeted the hypothesised cognitive and behavioural mediators of behaviour change outlined in Bandura's Social Cognitive Theory (SCT) (69) (e.g., self-efficacy, social support), while remaining light-hearted in nature with sensitive use of humour. This component also served as a low-cost way to maintain the frequency of contact with participants during the weight loss phase. This was an important consideration given that a recent systematic review showed that increased frequency of contact was a key factor associated with success in male-only weight loss studies (217).

5.2.6 Phase II: Weight loss maintenance randomised controlled trial

The 'baseline' assessments for this weight loss maintenance study were conducted in November 2012 (Figure 5.1). This was the first assessment of Phase II and represented the start of the weight loss maintenance RCT. In total, 176 men attended these assessments, representing an 84% retention of Phase I participants. At these assessments, all men who lost at least 4 kg during Phase I (n = 92) were randomised to either (i) a weight loss maintenance group who received the newly developed *SHED-IT Weight Loss Maintenance Program* (n = 47), or (ii) a self-help control group who did not receive any additional resources (n = 45) Men who had not lost at least 4 kg were not eligible for Phase II of this study (n = 77) and their involvement in the trial ceased at this point. Seven men lost 4 kg but declined participation in Phase II. See section 2.10 for additional detail on the randomisation process.

5.2.6.1 The SHED-IT Weight Loss Maintenance Program

The *SHED-IT Weight Loss Maintenance Program* was designed to provide men with the knowledge and skills required to maintain their weight loss over time. As in the weight loss program, the weight loss maintenance resources were developed to appeal to men and to present standard information in ways that make the messages more meaningful for men (81-83). This tailoring included both surface- and deep-structure components, as described in Reniscow et al.'s cultural tailoring framework (241). The surface structure components included the use of male-specific research findings, images and anecdotes in the intervention materials. The deep structure components, which address men's preferences and values, included the use of a frank and realistic approach (242), a focus on the scientific-basis of the recommendations, and encouragement of an autonomous approach to eating and exercise (86). Given that men generally do not engage with weight management programs that significantly disrupt their lifestyle (86, 243), the resources focused on teaching men how to balance their energy intake in a sustainable way while still being able to enjoy occasional luxuries, such as a beer or glass of wine. Sensitive humour was also used throughout the resources to deliver key messages, which is valued by men (242) and perceived as a central facet of masculinity (244). In addition, the intervention materials have been informed by a series of important resources including: (i) the developing evidence base for successful weight loss maintenance strategies (e.g., (52)), (ii) Bandura's SCT of health behaviour (69), (iii) recent systematic reviews of male-only weight management programs (217), web-based weight control programs (33), and weight loss maintenance interventions (245), (iv) the National Health and Medical Research Council Clinical Practice Guidelines for the Management of Obesity in Adults, Adolescents and Children in Australia (8), and (v) the men's health literature (e.g., (40, 86, 91, 240)).

The *SHED-IT Weight Loss Maintenance Program* includes: (i) the 'SHED-IT Weight Loss Maintenance Handbook for Blokes', (ii) the 'SHED-IT Weight Loss Maintenance Logbook for Blokes' (to complete key social cognitive and behavioural tasks), (iii) weekly 'SHED-IT Weight Loss Maintenance emails' (including video messages delivered by PJM and MDY), (iv) bi-weekly text messages, (v) the 'SHED-IT Resistance Training Handbook for Blokes', and (vi) a digiwalker SW200 pedometer and a gymstick^{TM}, which is a portable exercise tool that uses elastic resistance bands. Participants were advised to continue self-monitoring their diet using CalorieKing^{TM} or MyFitnessPal^{TM} for at least 2 days per week or as needed. For additional detail on the program components see Table 5.2.

5.2.7 Theoretical framework of the SHED-IT Programs

Both the *SHED-IT Weight Loss Program* and the *SHED-IT Weight Loss Maintenance Program* were informed by the behaviour change principles outlined in Bandura's SCT (69). The central theme of SCT is that behaviour is influenced by the dynamic interplay between the environment, the person, and the behaviour itself. This interaction is referred to as 'reciprocal determinism'. SCT also contains a causal framework of determinants that are hypothesised to influence the adoption and maintenance of behaviour (71). Within SCT, the most important of these determinants is perceived self-efficacy, which is purported to have a direct influence on behaviour. Self-efficacy is also hypothesised to indirectly affect behaviour through its influence on the other constructs in the model. These constructs are outcome expectations (the perceived consequences of performing the behaviour), self-regulation (e.g., goal setting and planning) and perceived socio-structural factors, such as social support and the perceived environment.

Importantly, in addition to specifying these constructs, SCT also provides guidance on how best to target these constructs to bring about positive and sustained behaviour changes. For example, Bandura outlines several key sources of information that can help to build self-efficacy, including (i) building a sense of mastery, (ii) verbal persuasion, and (iii) modelling from a relatable role model. For additional detail on how SCT was operationalised within the *SHED-IT Weight Loss Maintenance Program* components, see Table 5.2.

Table 5.2. *SHED-IT Weight Loss Maintenance* intervention components, behaviour change techniques and SCT mapping.

Intervention Component	**Additional detail**	**Behaviour Change Techniques (246)**	**Social Cognitive Constructs Targeted**
SHED-IT WLM Handbook for Blokes	• What is weight loss maintenance? • Embracing the plateau • Setting achievable goals • Finding energy balance • The 9 Best WLM Tips for Men • Dealing with setbacks	• Provide information about the consequences of behaviour (in general) • Provide information about the consequences of behaviour (to the individual) • Barrier identification • Prompt self-talk • Relapse prevention/coping planning • Time management • Prompting focus on past successes • Action planning	• Building ***self-efficacy*** (verbal persuasion, mastery) 1. Overcoming ***barriers/impediments*** 2. Encouraging ***self-regulation*** (goal setting and planning) ***3.*** Providing information to generating positive ***outcome expectations***

SHED-IT WLM Logbook for Blokes	• Recalculating energy requirements
	• Weight maintenance chart
	• Goal setting
	• Physical activity monitoring
	  • *Steps*
	  • *Weekly minutes*
	• Strategies to engage family and friends
	• SHED-IT resistance training program
		• Set graded tasks
		• Goal setting (behaviour & outcome)
		• Plan social support
		• Prompt self-monitoring (behaviour and outcome)
		• Provide rewards contingent on successful behaviour
			4. Building ***self-efficacy*** (mastery)
			5. Encouraging ***self-regulation*** (goal setting)
			6. Engaging ***social support*** networks

SHED-IT WLM Emails + Video messages (weekly)	• Weekly HTML emails will be sent to reinforce key messages from the WLM Handbook, to prompt participants to complete key sections of Logbook and to keep participants engaged with the program. • Each email will also include a video message from two of the researchers (PJM & MDY). Each video will support the written content in	• Model/demonstrate the behaviour • Provide information about the consequences of behaviour in general • Provide information on consequences of behaviour to the individual • Provide instruction on how to perform the behaviour • Barrier identification/problem solving	7. Building ***self-efficacy*** (modelling & verbal persuasion) 8. Providing ***social support*** to participants 9. Engaging ***social support*** networks 10. ***Self-regulation*** (planning)

Intervention Component	Additional detail	Behaviour Change Techniques (246)	Social Cognitive Constructs Targeted
	the email and the presenters will cover practical tips and strategies using light-hearted examples to promote weight loss maintenance.	• Action planning • Environmental restructuring • Prompt self-talk	
SHED-IT Resistance Training Handbook	• Introduction to resistance training • Benefits of resistance training • Exercising safely • Instructions on how to perform exercises (with beginner and advanced levels)	• Model/demonstrate the behaviour • Set graded tasks • Prompt self-monitoring of behaviour	11. Building ***self-efficacy*** (modelling) 12. Overcoming ***barriers/impediments***
Text messages (bi-weekly)	• Light-hearted prompts for the nine SHED-IT weight loss messages • Will also target the hypothesised mediators of behaviour change in Bandura's SCT (69)	• Barrier identification • Environmental restructuring • Plan social support • Use of follow-up prompts • Prompt review of behavioural goals • Prompt review of outcome goals	13. Providing ***social support*** to participants 14. Building ***self-efficacy*** (verbal persuasion) 15. Encouraging ***self-regulation*** (goal setting and planning) 16. Engaging ***social support*** networks
Study website / app	• Participants will be advised to continue self-monitoring their diet and exercise at least 2 days a week or as needed. • Participants advised to switch their kJ allowance to weight loss maintenance mode.	• Prompt self-monitoring (behaviour and outcome) • Goal setting (behaviour & outcome)	17. Encouraging ***self-regulation*** (self-monitoring, goal setting)
WLM Tools	• Yamax SW200 pedometer to self-monitor step counts • Gymstick^{TM} (gold) to complete above SHED-IT Resistance Training Program	• Prompt self-monitoring of behaviour • Environmental restructuring	18. Encouraging ***self-regulation*** of behaviour (self-monitoring)

Note: WLM, Weight Loss Maintenance.

5.2.8 Outcome measures

All assessments for this study are being taken in the Human Performance Laboratory at the University of Newcastle, Australia with the same instruments at each time point. Assessors are trained to follow standardised measurement protocols and will be blinded to group allocation at all assessments. To date, measures have been obtained from participants at study entry (August 2012), baseline (November 2012) and 6-months (May 2013) and will be taken at 12 months (November 2013, primary endpoint).

5.2.8.1 Physiological measures

Weight is measured in light clothing, without shoes on a digital scale to 0.01 kg (CH-150kp, A&D Mercury Pty Ltd, Australia). Weight is measured twice, with accepted values within 0.1kg. If measurements are outside the acceptable range, a third measure is taken. The average of the two acceptable measures will be reported. The primary outcome for this study is weight change (kg) in Phase II (i.e., weight change from randomisation to the 12-month assessment).

BMI is calculated using the standard equation (weight [kg]/height[m]^2). Height was measured, at study entry only (i.e., beginning of Phase I), to 0.1 cm using the stretch stature method on a stadiometer (Veeder-Root (VR) High Speed Counter, Harpenden/Holtain, Mentone Education Centre, Morrabin, Victoria). Height was measured twice, with accepted values within 0.3 cm. A third measure was taken if measurements were outside the acceptable range. The average of the two acceptable measures will be reported.

Waist circumference is measured at two points: (i) level with the umbilicus, and (ii) at the narrowest circumference between the lower costal border and the umbilicus. Two measures are taken at each site, with accepted values within 0.5 cm. Further measures are taken if measurements are outside the acceptable range. The average of the two acceptable measures will be reported. To improve reliability, each measurement is recorded with a non-extensible steel tape (KDSF10-02, KDS Corporation, Osaka, Japan) by an assessor with Level 1 Anthropometry qualifications from the International Society for the Advancement of Kinanthropometry.

Blood pressure and resting heart rate are measured three times using NISSEI/DS-105E digital electronic blood pressure monitors (Nihon Seimitsu Sokki Co. Ltd., Gunma, Japan) under standardised procedures. Participants are seated for five minutes before the first blood pressure measurement with a two-minute rest between subsequent measures. Further measurements are taken if the blood pressure or resting heart rate values fall outside of the acceptable ranges (i.e., systolic within 10 mmHg, diastolic within 5 mmHg and resting heart rate within 5 beats per minute). The mean of the two closest systolic pressures and the corresponding diastolic pressure be reported. The mean of the two lowest resting pulse pressures will be used.

Body composition is assessed using the InBody720 (Biospace Co., Ltd, Seoul, Korea), a multi-frequency bioimpedance device featuring an eight-point tactile electrode system. This device has been shown to be a valid and reliable device for body composition assessment (247). Measures of body composition reported will include body fat percentage, visceral fat area (cm^2) and skeletal muscle mass.

Sexual function is assessed using the International Index of Erectile Function-5 (IIEF-5) questionnaire, which is a validated measure of erectile function (248). Improved erectile function was a key outcome observed in the SHED-IT weight loss community trial (78, 81) and the current study will investigate the sustainability of these effects during weight loss maintenance.

5.2.8.2 Physical activity and sedentary behaviour measures

Step counts are objectively measured using Yamax SW200 pedometers (Yamax Corporation, Kumamoto City, Japan), which are both reliable (249) and valid (250) physical activity measures for adults. The pedometers are provided at each assessment session and participants are instructed on how to attach the pedometers (at the waist on the right hand side) and asked to remove the pedometers only when sleeping, when the pedometer might get wet (e.g., swimming, showering) or during contact sports. Participants are asked to wear the pedometers for seven consecutive days and keep to their normal routine. At the end of each day participants are instructed to record their steps on a pedometer record sheet and reset their pedometers to zero. Participants are instructed to note down if they did an activity like cycling, swimming, contact sports or another activity that does not involve stepping and include details (type of activity and duration), or if they forget to wear their pedometer. Step counts will be averaged to create a mean steps per day measure and participants will be included in the analyses if they complete at least four days of pedometer monitoring. The average of existing days will be imputed for participants who have three or less days of missing data.

Light, moderate and vigorous physical activity are measured with a modified version (251) of the validated Godin Leisure-Time Exercise Questionnaire (252). This questionnaire contains three sections where participants indicate how many times in the past month they engaged in light-, moderate-, and vigorous-intensity physical activity in bouts of at least 10 minutes. Participants also estimate the average session duration for each category. These 'frequency' and 'duration' responses are then multiplied within each category to provide a measure of minutes of light, moderate and vigorous physical activity in the previous month.

Sedentary behaviour is assessed using the Sitting Questionnaire, which has been shown to be both a valid and reliable measure of sitting time in various domains (226).

5.2.8.3 Dietary measures

Dietary intake is assessed using the Australian Eating Survey (AES). The AES is a 120-item semi-quantitative Food Frequency Questionnaire (FFQ), which has been validated in both adult males and females (227). Portion sizes for individual food items will be generated by the Australian Bureau of Statistics (ABS) (253) and unpublished data from the 1995 Australian National Nutrition Survey; or the "natural" serving size for common items such as a slice of bread. Participants are asked about frequency of their consumption over the previous six months with frequency options ranging from 'Never' up to '4 or more times per day' but varying depending on the food item. Twenty-one questions directly relate to the intake of vegetables and 11 questions relate to fruit, with seasonality of some fruits addressed in the nutrient analysis.

Nutrient intakes from the AES will be computed using the Australian AusNut 1999 database (All Foods) Revision 17 and AusFoods (Brands) Revision 5 (Australian Government Publishing Service, Canberra) to generate individual mean daily macro-and micro-nutrient intakes. The AES also includes questions to assess the total number of daily serves of fruit, vegetables, bread, dairy products, eggs, fat spreads, sweetened beverages and snack foods, as well as the type of bread, dairy products and fat spreads used. In addition, 12 questions investigate food-related behaviours, including items on frequency of take-away food consumption and eating while watching television.

Portion size is assessed using portion size photographs from the Dietary Questionnaire for Epidemiological Studies Version 2 (DQES v2), FFQ from the Cancer Council Victoria (228). These photos are used to calculate a single portion size factor (PSF) to indicate whether on average a person eats median size serves (PSF=1), more than the median (PSF > 1), or less than the median (PSF < 1) serve sizes for main meals. The DQES was developed specifically for use in Australian adults by the Cancer Council of Victoria as an update of a FFQ used in a cohort of Australian volunteers aged 40–69 years. Both the development of the questionnaire and its validation have been reported previously (254).

Risky alcohol consumption is measured using an adaptation of the Australian Government Department of Veteran Affairs, Alcohol Use Disorders Identification Test (AUDIT) 2009, which is a valid and reliable measurement tool in determining alcohol use, alcohol disorders and alcohol misuse (255).

Weekly breakfast consumption is measured with a single item developed for this study where participants indicate the number of days per week that they usually eat breakfast, with response options ranging from 0 days per week to 7 days per week.

5.2.8.4 Psychological measures

Quality of life and general health are assessed using the validated UK short form 12 (SF-12) questionnaire (256).

Depressive symptoms are measured with the Patient Health Questionnaire eight item depression scale (PHQ-8), which has established validity as a diagnostic measure of depressive disorders in both clinical and community samples (257).

Cognitive restraint is measured with the Cognitive Restraint Subscale from the 3-Factor Eating Questionnaire (258) as identified by Karlsson et al (259).

Weight loss expectations are measured with Part II of the validated Goals and Relative Weights Questionnaire (GRWQ) (260).

5.2.8.5 Social cognitive measures

The hypothesised behavioural mediators outlined in Bandura's SCT (69) are measured with validated scales relating to (i) physical activity and (i) energy-dense, nutrient-poor discretionary choices, referred to 'junk food'. Physical activity intention, from the Theory of Planned Behaviour (137), and autonomous motivation, from Self-determination Theory (261), are also measured to allow investigation of integrated theories, which has been recommended in the literature (74). The construct validity, content validity and two week test-retest reliability of these scales was assessed in a separate, representative sample (n = 22) of overweight and obese Australian men (mean (SD) age 39.7 (14.8) years; BMI 29.1 (5.1) kg/m^2). The internal consistency [Cronbach's α] and reliability (intra-class correlation coefficient [ICC]) of each scale from this pilot-testing phase are detailed in Tables 5.3 and 5.4.

Physical activity cognitions: Prior to completing the physical activity cognitions, participants are asked to read a definition of 'regular physical activity'. For the purposes of this study, 'regular physical activity' is defined as 'at least 60 minutes of physical activity (at a moderate intensity or greater) on 5 or more days each week'. This behavioural referent was chosen as it reflects an overlap in the best available international physical activity recommendations for the minutes of physical activity required for weight loss and weight loss maintenance (64). The description of moderate intensity activity used matches the following definition from the Australian Physical Activity Guidelines for Adults (262):

"Moderate-intensity activity will cause a slight, but noticeable, increase in your breathing and heart rate. A good example of moderate-intensity activity is brisk walking, that is at a pace where you are able to comfortably talk, but not sing. Other examples include mowing the lawn, digging in the garden, or medium-paced swimming or cycling".

To standardise the measures to this referent and reduce potential confusion, the term 'regular physical activity' was used to replace 'regular exercise' or 'exercise' throughout the measures, where possible. See Table 5.3 for addition details on the physical activity scales used.

Energy-dense, nutrient-poor food or 'junk food' cognitions: Most of the 'junk food' social cognitive measures were adapted from measures originally designed to capture low-fat dietary behaviour. The behavioural referent was changed from 'following a low-fat diet' to 'reducing junk food intake' for this study as research shows this is a key problem area for men (77, 79). Further, although following a low-fat diet has been previously linked to weight loss maintenance (50, 52), recent evidence suggests that dietary composition is not as important as overall energy intake (263, 264). While completing this section of the questionnaire, all men are provided with a laminated reference card containing definitions of healthy food and 'junk food' adapted from the Australian Guide to Healthy Eating (265). In addition, this card also contains pictures of the most commonly consumed 'junk foods' reported by men in the SHED-IT community RCT (e.g., bacon, chocolate, potato chips, ice cream and pizza) (81). See Table 5.4 for additional details on the 'junk food' scales used.

Table 5.3. Social-cognitive measures for physical activity with validity and reliability statistics.

Construct	**Source**	**Example**	**Items (Range)**	**Anchors**	**α**	**ICC (95% CI)**
Self-efficacy	(266)	*e.g., I am confident that I can get 'regular physical activity' when I am a little tired*	8 (1-5)	Not at all confident – Completely confident	0.96	0.88 (0.68 to 0.95)
Goal setting [a]	(192)	*e.g., I often set physical activity goals*	10 (1-5)	Strongly disagree – Strongly agree	0.81	0.80 (0.50 to 0.92)
Planning	(267)	*e.g., I make plans concerning when I am going to engage in 'regular physical activity'*	4 (1-7)	Strongly disagree – Strongly agree	0.93	0.70 (0.30 to 0.87)
Positive outcome expectations	(266)	*e.g., 'Regular physical activity' would help me control my weight*	5 (1-5)	Strongly disagree – Strongly agree	0.78	0.74 (0.36 to 0.89)
Perceived barriers [b]	(266)	*e.g., 'Regular physical activity' would take up too much of my time*	3 (1-5)	Strongly disagree – Strongly agree	0.72	0.82 (0.58 to 0.93)
Social support (prospective)	(184)	*e.g., People in my social network are likely to help me get 'regular physical activity'*	2 (1-5)	Strongly disagree – Strongly agree	0.81	0.80 (0.53 to 0.92)
Social support (past month) [c]	(268)	*e.g., During the past month, my family/friends were active with me*	10 (1-5)	Never/does not apply – Very often	*Family* 0.95 *Friends* 0.96	0.96 (0.91 to 0.98) 0.92 (0.80 to 0.97)
Intention [d]	(269)	*e.g., I am motivated/determined to engage in 'regular physical activity*	2 (1-7)	Extremely unmotivated / undetermined – Extremely motivated / determined	0.92	0.92 (0.80 to 0.97)
Autonomous motivation [e]	(270)	*e.g., The reason I would get 'regular physical activity' is because I want to take responsibility for my own health*	6 (1-7)	Not at all true – Very true	0.93	0.92 (0.70 to 0.97)

Note: α = Cronbach's alpha (internal consistency); ICC = intra-class correlation coefficient; CI = confidence interval

[a] Original anchors ("does not describe me" to "describes me completely") were replaced as the pilot sample found them difficult to interpret. [b] Scale adapted from a 5 item measure that demonstrated unacceptable internal consistency in the pilot sample (α = 0.46). [c] Scale measured separately for family and friends. [d] Construct from 'theory of planned behaviour'. [e] Construct from 'self-determination theory'.

Table 5.4. Social-cognitive measures for intake of energy-dense, nutrient-poor foods with validity and reliability statistics.

Construct	Source	Example	Items (Range)	Anchors	α	ICC (95% CI)
Self-efficacy	(271)	*e.g., How tempted would you be to eat your favourite junk food while having a good time with friends at a party*	12 (1-5)	Not at all tempted – Extremely tempted	0.86	0.76 (0.42 to 0.90)
Positive outcome expectations	(162)	*e.g., if I eat less junk food I expect I will lose weight*	8 (1-5)	Strongly disagree – Strongly agree	0.84	0.77 (0.45 to 0.91)
Barriers	(162)	*e.g., if I eat less junk food I expect I will be bored with what I have to eat*	12 (1-5)	Strongly disagree – Strongly agree	0.87	0.89 (0.74 to 0.96)
Planning	(272)	*e.g., when it comes to eating less junk food, I make detailed plans regarding when I have to pay attention to prevent lapses*	5 (1-4)	Strongly disagree – Strongly agree	0.94	0.89 (0.74 to 0.96)
Behavioural strategies	(273)	*e.g., in the past month I set goals to eat less junk food*	15 (1-5)	Never – Many times	0.86	0.77 (0.47 to 0.91)
Social support (prospective)	(184)	*e.g., People in my social network are likely to help me eat less junk food*	2 (1-5)	Strongly disagree – Strongly agree	0.92	0.80 (0.52 to 0.92)
Social support (past month)	(268)	*e.g., In the past month, my family/friends encouraged me not to eat junk food when I'm tempted to do so*	5 (1-5)	Never – Very often	*Family* 0.88 *Friends* 0.86	0.87 (0.69 to 0.95) 0.91 (0.79 to 0.96)
Social sabotage (past month)	(268)	*e.g., In the past month, my family/friends offered me junk food I'm trying not to eat*	5 (1-5)	Never – Very often	*Family* 0.86 *Friends* 0.69	0.83 (0.58 to 0.93) 0.76 (0.41 to 0.90)
Perceived environment [b]	(274)	*Participants indicate how frequently various junk foods (e.g., chocolate, potato chips) are available in their day-to-day life*	13 (1-4)	Never/rarely-Always	0.75	0.75 (0.39 to 0.90)

Note: α = Cronbach's alpha (internal consistency); ICC = intra-class correlation coefficient; CI = confidence interval

[a] Scale measured separately for family and friends. [b] Items chosen to reflect the most commonly consumed energy-dense, nutrient-poor discretionary choices reported by men in the SHED-IT community RCT (81).

5.2.8.6 Process measures

Logbooks: Adherence to self-monitoring (total number of daily diet entries, daily exercise entries and weekly weigh-ins) will be calculated from the online food and exercise diaries in Phase I and Phase II. In addition, all men were asked to hand in their 'SHED-IT Weight Loss Logbook for Blokes' at the end of Phase I. Similarly, men in the weight loss maintenance intervention group will be asked to hand in their 'SHED-IT Weight Loss Maintenance Logbook for Blokes' at the end of Phase II. These will be photocopied and posted back. Adherence to the following logbook tasks will be documented: (i) calculating kJ output (Phase I only), (ii) completing waist charts (Phase I only) (iii) completing weight charts (iv) goal setting, (v) step count monitoring, (vi) creating social support strategies, (vii) physical activity monitoring (minutes of moderate-to-vigorous physical activity; Phase II only), and (viii) completing the resistance training program (Phase II only).

Program evaluations: Detailed process questionnaires will be administered to examine men's perceptions of the *SHED-IT Weight Loss Program* (n = 28 items) and the *SHED-IT Weight Loss Maintenance Program* (n = 28 items). These questionnaires will include scales, individual items and open-ended questions that require men to describe the strengths and weaknesses of the program along with their suggestions for improvement. The process evaluations will cover issues such as the study feasibility, use and appraisal of intervention components and overall levels of satisfaction. We will also ask how much participants would be willing to pay for the offered interventions. The *SHED-IT Weight Loss Program* evaluation was administered to all participants at the end of Phase I. The *SHED-IT Weight Loss Maintenance Program* evaluation will be administered to participants from this group at the end of Phase II.

5.2.8.7 Costing measures

A variety of measures are used to gauge the various costs and savings participants will incur throughout the study. At each assessment participants self-report how often they accessed various health professionals such as general practitioners, dietitians and physiotherapists in the previous 6 months. Medication usage is self-reported by participants throughout the study. At follow-up time points, participants indicate how much time they spent on the CalorieKing^{TM} website or MyFitnessPal^{TM} app in the previous 6 months. Participants are asked to identify whether they experienced any of a series of potential costs (e.g., joining a gym) and savings (e.g., reduced alcohol expenses) as a result of changes they made after starting the SHED-IT program. To assess travel costs, participants report which mode of transport they used to attend each assessment. In addition to participant costs, implementation costs associated with the program delivery, such as the cost of resources and staff costs, will also be monitored throughout the study. Participants will not receive any incentives or reimbursements for completing assessments or otherwise during the study.

5.2.9 Sample size

The sample size calculation is based on the primary outcome of weight change in Phase II (i.e., weight change from randomisation to the 12-month assessment). Using 12-month follow up data from the SHED-IT pilot study (84), we have assumed this will have a SD of 4kg. Thus, 29 men in each treatment group at the primary endpoint (12-month) will give the study 80% power to detect a difference in weight change between groups of 3kg at the 5% significance level using a two sided test. A between-group difference of 3kg was chosen as this is outside the range of normal weight fluctuation and is sufficient to sustain clinically meaningful health benefits (275).

To ensure adequate power for the RCT in Phase II, 195 men were required to enter Phase I. Following this, 80% of this original sample (n = 156/195) were expected to complete the assessments at the end of Phase I. Of those assessed, 50% (n = 78/156) were expected to have lost the 4 kg necessary to enter the RCT in Phase II. Finally, of those who entered Phase II, we expected to retain 75% at the 12-month follow-up assessments (n = 58/78). These projections were grounded in extensive previous research with men in the SHED-IT studies (81-84) and have been reliable to date (See Figure 5.1). Given the accuracy of these predictions, we expect that the study will be powered with the necessary 29 men in each treatment group at the Phase II 12-month assessment.

5.2.10 Randomisation

Participants were randomised at an individual level by an independent statistician who will not have any contact with participants during the trial. Allocation was stratified by BMI category calculated at the 'baseline' assessment (<30 kg/m^2 and ≥ 30 kg/m^2) and phase I weight loss (4 kg-7.4 kg and ≥ 7.5 kg). These categories were based on the distributions of BMI and initial weight loss in the SHED-IT community RCT (81) and were expected to create four strata of approximately equal size.

The allocation sequence within strata was generated by a computer-based random number-producing algorithm in randomly varied block lengths. Randomisation codes were stored in a restricted computer folder, which was not be accessible by those assessing participants, those involved in allocating participants to groups or those participating in data entry for the study. Complete separation will be achieved between the statistician who generated the randomisation sequence and those who conceal allocation from those involved in implementation of assignments.

5.2.11 Allocation

Information for the two study groups was pre-packed into identical white, opaque envelopes. These envelopes were consecutively numbered within the four stratification categories and ordered according to the randomisation schedule. The packing and sequencing of these envelopes was completed by a research assistant who was not involved in the enrolment, assessment or allocation of participants. Study participants completed all baseline assessments before proceeding to a separate room to meet with a study chief investigator who was not involved with the baseline assessments. The allocation sequence was concealed during this process. Participants' BMI category and Phase I weight loss was calculated using an excel spreadsheet from the baseline measurements and the participant were allocated the next available number in the relevant stratification category. At this point the envelope was opened by the investigator and details of the particular study group were briefly provided to the participant using a standardised protocol. If the participant was randomised into the weight loss maintenance intervention they were then provided with their program resources.

5.2.12 Data management, quality assurance and exclusion of bias

Randomisation was undertaken by study chief investigators and the use of randomly varied block sizes ensured that upcoming assignments could not be known in advance. Measures were taken by trained staff at all times points. In order to ensure accurate and consistent measurements, the study weight scale will be professionally calibrated and the height scale will be checked and recalibrated daily before each assessment session. Assessors will be blinded to treatment allocation at all assessments. When men are contacted (via phone and email) to book in for follow-up assessments they will be asked not to inform the assessors of their group allocation. Data will be entered by research assistants blind to group allocation and a program of plausibility checks will be used to identify unrealistic values. The primary outcome measure (weight) will be double entered to ensure accuracy and a random 20% sample of all other measures will also be double entered.

5.2.13 Statistical methods

Analyses will be performed using IBM SPSS Statistics version 20 or later. All variables will be checked for plausibility and missing values. Data will be presented as mean (SD) for continuous variables and counts (percentages) for categorical variables. Differences between groups at randomisation and characteristics of completers versus dropouts will be tested using independent t tests for continuous variables and chi-squared (χ^2) tests for categorical variables.

5.2.13.1 Primary analyses plan

Linear mixed models will be used to assess weight and other secondary outcomes for the impact of treatment (weight loss maintenance intervention vs. control), time (treated as categorical with levels at baseline, 6 and 12 months) and the treatment-by-time interaction, with these three terms forming the base model. This will ensure that the outcomes for participants who drop out of the program at 6 or 12-months are retained in the analyses, consistent with an intention-to-treat approach. Age, socio-economic status, phase 1 weight loss and BMI will be examined to determine whether they contribute significantly to the models (276). If a covariate is significant, a term will be added to the model to adjust for the effects and two-way interactions with time and treatment will also be examined. If these interactions are also significant they will be similarly adjusted for in the model.

5.2.13.2 Secondary analyses plan - Mediation analysis

Hypothesised psychological and behavioural mediators of the weight loss maintenance intervention effect will be examined in SPSS using the INDIRECT macro, developed by Preacher and Hayes (229). This macro generates regression coefficients to reflect (i) the effect of the intervention on the hypothesised mediator, (ii) the association between the hypothesised mediator and the outcome, controlling for treatment condition, and (iii) the total, direct and indirect intervention effects. The macro also generates bias-corrected 95% CIs around the indirect effect and mediation will be established if these confidence intervals do not include zero. The sample size required for the RCT will provide adequate power for this analysis to detect medium sized mediation effects (225).

5.2.13.3 Cost effectiveness analysis plan

The SHED-IT Weight Loss Maintenance intervention will be evaluated using the ACE Obesity approach, consistent with the ACE-Prevention methodology. These methods are international best-practice for cost-effective analyses and include (i) the adoption of a health care perspective, (ii) transparent and scientific methods to identify, measure and value both costs and outcomes from the trial, (iii) modelling and uncertainty testing of epidemiological and costing input parameters, and (iv) interpretation of results within a broader decision-making framework (277, 278). Costing information will be collected from participants throughout the trial and a multi-state life table Markov model will be used to calculate health outcomes resulting from a reduction in weight due to the interventions. Effectiveness will be measured by changes in BMI over time that lowers the risk of weight-related diseases. The model explicitly simulates nine obesity-related diseases including stroke, ischemic heart disease and type 2 diabetes mellitus. Estimates of disease incidence, prevalence and mortality are based on the Australian Burden of Disease 2003 study, updated where appropriate. The model summarises the disease-specific changes in the number of years lived adjusted for disability from the explicitly modelled diseases and average age- and sex-specific disability levels from all other causes.

The analysis will model all costs and population health outcomes over the lifetime of the Australian population, discounting future costs and health outcomes at a rate of 3% per year. The costs and health outcomes are summed over the lifetime to determine the incremental cost-effectiveness ratio, in dollars per disability adjusted life year averted, for each intervention. Monte Carlo analysis is used to derive 95% uncertainty intervals for all outcomes and to determine the probability of intervention cost-effectiveness against a cost-effectiveness threshold of $50,000 per disability adjusted life year. The incremental cost-effectiveness ratio results are displayed on a cost-effectiveness plane with affordability issues addressed in an acceptability curve. The results of the cost-effective analysis will be considered in the context of other decision making criteria including: strength of evidence; capacity of the intervention to reduce inequity; acceptability to stakeholders; feasibility; sustainability; and, potential for other consequences.

5.3 Discussion

Internationally, Australia has one of the highest rates of obesity in men (3) and developing strategies to decrease obesity in this target population is a national and international health priority. There is limited evidence to guide the design of effective and sustainable male-targeted obesity programs that engage men (38, 217), particularly for programs that focus on weight loss maintenance (217). The current study will contribute key information to the evidence base by testing the usefulness of a long-term, gender-tailored weight loss maintenance program that aims to educate men on how to maintain their weight loss through the difficult post-intervention period, where treatment effects are known to regress (50).

Currently, research regarding male-only weight loss maintenance interventions is limited. Borg et al. (112) conducted an RCT with 90 men to test the effectiveness of two exercise programs (walking vs. resistance training) for weight loss maintenance compared to a control. Although both programs included weekly meetings, dietary advice and exercise training sessions three times per week, neither intervention group demonstrated significantly different weight regain to the control group at post-test (6 months) or long-term follow-up (29 months). However, the intervention components in this study were not specifically tailored to men and the initial weight loss was achieved by following a very-low energy diet, which may not be a sustainable approach for long term weight loss (8, 279). Only one other male-only weight loss maintenance RCT has been conducted to date (120), however it published over 15 years ago, did not use intention-to-treat analysis or report a power calculation, and tested the effectiveness of continuing a standardised exercise regime from the weight loss phase against a group who did not continue the exercise regime. There was no significant difference between the groups at 12-month follow up.

To date, the effects of other weight loss maintenance programs have also been modest (245). In the STOP Regain trial (62), participants in a face-to-face maintenance intervention regained 2.4 kg less than a control group after 18 months. Similarly, in the U.S. Weight Loss Maintenance trial (280), participants who received a monthly personal contact maintenance intervention regained approximately 1.5 kg less than a minimal intervention control group after two and half years. Both trials also tested an online maintenance intervention, which performed poorer than the face-to-face arm over the course of the study. Although these modest weight losses could bring about clinically important health benefits (8), the face-to-face interventions would be difficult to implement on a large scale. Although the online maintenance intervention in the Weight Loss Maintenance trial would be a more scalable approach, the weight loss phase still involved 20 group-sessions over 6 months with a trained interventionist. These factors could reduce the scalability of the interventions and decrease cost-effectiveness.

The low-intensity nature of the SHED-IT interventions is a considerable strength of this research, as this would likely increase cost-effectiveness and scalability. Sustainability and affordability are major challenges for weight loss treatments, even those with proven effectiveness (4), and many current approaches are not good ‘value for money’ (8, 281). Current pharmacological treatments are limited and only moderately effective relative to cost (281). Bariatric surgery is expensive, applicable to only those most obese, and not widely available (8). Other options, including intensive behavioural treatments requiring multiple in-person contacts are not viable as they require substantial resources, making them too expensive for widespread use relative to effectiveness (50). To date, cost-effectiveness research into weight loss maintenance programs is lacking (29). This research is essential, as even modestly effective weight loss interventions would likely be cost-effective for healthcare systems at the population level, provided the losses are maintained (29). This study will investigate the cost-effectiveness of the SHED-IT weight loss and weight loss maintenance interventions, which may be more viable and cost-effective alternatives to currently available options, as they involve no face-to-face contact or individually-tailored intervention components.

To date, the strength of evidence from weight loss maintenance trials has been limited by multiple methodological concerns (245), which will be addressed in the current study. Strengths of this study protocol include an RCT design with a no-maintenance intervention control group, extensive detail of rigorous and transparent randomisation procedures, a detailed statistical analysis plan that will follow intention-to-treat principles, and an extended assessment timeline that includes a 6-month passive follow-up to assess the maintenance of treatment outcomes after the intervention has ceased. In addition to measuring weight and other physiological outcomes, we will assess a comprehensive range of secondary outcomes to capture the physiological, behavioural, psychological, social and economic impacts of the program.

This study will build upon a considerable body of research into the *SHED-IT Weight Loss Program* to specifically address the problem of weight regain after weight loss. To the authors' knowledge, this will be the first study internationally to test the effectiveness and cost-effectiveness of a weight loss maintenance intervention designed specifically for men.

CHAPTER 6

A TEST OF SOCIAL COGNITIVE THEORY TO EXPLAIN MEN'S PHYSICAL ACTIVITY CHANGES DURING A GENDER-TAILORED WEIGHT LOSS PROGRAM

Preface:

This chapter presents the results of a structural equation modelling analysis, which I conducted to investigate *Secondary Aim 4* of this thesis (i.e., to examine the utility of Social Cognitive Theory as a theoretical framework to explain the physical activity changes of men during weight loss).

At the time this thesis was submitted, the contents of this chapter were under review in the *American Journal of Men's Health*.

Citation:

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Abstract

Background: Physical inactivity and obesity are leading contributors to the burden of disease in men. Social-cognitive theories may improve physical activity and weight loss interventions by identifying which variables to target to maximise intervention impact. The objective of this study was to test the utility of Bandura's Social Cognitive Theory (SCT) to explain the physical activity changes of men during a weight loss program.

Methods: Participants were 204 overweight/obese men (mean (SD) age: 46.6 (11.3) years; BMI: 33.1 (3.5) kg/m^2). All men received the 3-month *SHED-IT Weight Loss Program,* which is a self-administered, SCT-based program specifically designed for men. A longitudinal, latent variable structural equation model tested the associations between SCT constructs (i.e., self-efficacy, outcome expectations, intention, & social support) and self-reported moderate-to-vigorous physical activity (MVPA) and examined the total variance in MVPA explained by SCT.

Results: The model fit the data well (χ^2 = 59.3, *df* = 24, *p* <0.001; Normed χ^2 = 2.47; CFI>0.95; SRMR<0.06) and explained 61% of the variance in MVPA changes during the intervention. Changes in self-efficacy demonstrated the largest direct and total effects on MVPA change (β_{direct} = 0.44, *p*<0.01; β_{total} = 0.64, *p*<0.01). A practically meaningful effect was also observed from intention to MVPA, but not from outcome expectations or social support.

Conclusions: This study provides some evidence supporting the tenets of SCT when examining MVPA behaviour change in overweight men attempting weight loss. Future physical activity and weight loss interventions for men may benefit by targeting self-efficacy and intention, but the utility of targeting social support and outcome expectations requires further examination.

6.1 Introduction

Almost one third of adults worldwide are considered inactive (131), which increases their risk of heart disease, diabetes, some cancers and premature death (130). Decreasing physical activity levels have also contributed to rising global obesity levels, which have doubled in the past 30 years (3). Although the obesity epidemic has affected both men and women, the burden of disease falls disproportionally on men as they are more likely to store fat abdominally, which is a risk factor for many chronic diseases (23). Although physical activity is a powerful protective factor against the health risks of obesity (282), obese men perform considerably less exercise than their healthy weight counterparts. For example, in Australia, obese men are significantly less likely than healthy weight men to: (i) exercise at moderate-to-vigorous levels (27% vs 34%), (ii) exercise for three or more days per week (33% vs 42%), or (iii) meet physical activity guidelines (30% vs 37%) (283). As such, identifying effective strategies to assist overweight and obese men to increase their physical activity levels is an urgent public health priority (284).

Increasing physical activity levels is a vital strategy for achieving weight loss (64). However, evidence suggests that physical activity interventions are only moderately effective for adults and this effect is not often maintained (285). When reviewing the effectiveness of physical activity interventions for men, George and colleagues reported that only 14 of 23 studies have demonstrated a significant impact on physical activity (284). In addition, the authors noted that as men are considerably under-represented in physical activity research, there is little evidence to illuminate which intervention components are most commonly associated with success in men or which psychological, behavioural, or social factors are most important to target when designing physical activity interventions for men.

Bandura's *Social Cognitive Theory* (SCT) (69, 71, 73) is a prominent behaviour change theory that has been widely applied in the development and evaluation of physical activity interventions (72). In Bandura's most recent conceptualisation of the model (71), he proposed a causal framework with four major constructs that is hypothesised to explain people's participation (or non-participation) in all health behaviours (Figure

1.1). The most important construct in this SCT model is *self-efficacy*, which Bandura defines as the '*beliefs in one's capabilities to organise and execute the courses of action required to produce given attainments*' (73). In other words, self-efficacy represents the confidence people have in their ability to exercise control over their own health habits (71). Self-efficacy is the pivotal construct in SCT and is hypothesised to exhibit a direct effect on behaviour and indirect effects through all other model constructs. *Outcome expectations* are the second SCT construct and represent one's judgements of the likely consequences that will occur as a result of performing, or not performing, a particular behaviour. As noted in Figure 1.1, outcome expectations are suggested to affect behaviour directly and indirectly by influencing goals.

The third construct in this conceptualisation of SCT is *socio-structural factors* (71), which encapsulates the various barriers or facilitators one perceives in relation to achieving their goals. Although this construct is considerably difficult to operationalise in a single model (72), previous SCT models have represented this construct with measures of social support, perceived barriers, functional limitations or perceptions of the built environment (286). In SCT, Bandura also suggests that socio-structural factors indirectly affect health behaviour via *goals*, which are the final model construct (71). For example, people who perceive more social and structural supports for physical activity in their environment should be more likely to set a stronger physical activity goal than those who perceive less support. These goals can be distal, to serve as a general guide, or proximal, to inform current actions (72). According to Bandura, proximal goals share a conceptual overlap with intentions from the Theory of Planned Behaviour (137) and are more likely to promote behaviour changes than distal goals. Given their close proximity to behaviour in the model, goals are hypothesised to: (i) influence behaviour directly; (ii) partially mediate the effect of self-efficacy and outcome expectations on behaviour; and (iii) completely mediate the effect of socio-structural factors on behaviour. Thus, people with greater self-efficacy for physical activity, who expect more favourable outcomes from physical activity, and perceive fewer social and structural impediments to achieving physical activity are hypothesised to set stronger goals and participate in greater levels of physical activity.

Although SCT is a widely researched social cognition model (72), a recent systematic review concluded that the overall quality of SCT models of physical activity was lacking, with few high-quality tests of the theory identified in children, adolescent or adult samples (286). Common methodological flaws included a lack of adjustment for past behaviour, small sample sizes and insufficient evidence of measurement reliability. Theoretical weaknesses were also noted, with only 40% of models including all core SCT constructs and many of the models testing SCT with multiple regression models, which do not allow for simultaneous analyses of all hypothesised pathways. An additional limitation noted was the clear underrepresentation of men in the SCT studies. Indeed, 78% of the SCT models of physical activity in the review used predominantly female samples and no models investigated the utility of SCT in men only (286). As such, the majority of research into the utility of SCT to explain physical activity to date may not apply to men. Given the noted methodological and theoretical limitations evident in SCT research to date, and the urgent need for evidence-based strategies to increase physical activity levels in men, a methodologically rigorous and appropriately specified test of SCT to explain physical activity in men is justified.

Thus, the aim of the current study was to investigate the utility of SCT to explain changes in moderate-to-vigorous physical activity (MVPA) in a sample of overweight and obese men participating in a male-only, weight loss trial. As this was a confirmatory analysis of Bandura's SCT structure (71) (Figure 1.1), the following five hypotheses were tested:

1. The proposed SCT structure would represent a good fit to the data and would explain a significant proportion of the variance in MVPA change.
2. Changes in self-efficacy would demonstrate a direct effect on MVPA change in addition to an indirect effect through changes in outcome expectations, goals, and social support.
3. Changes in outcome expectations would demonstrate a direct effect on MVPA change in addition to an indirect effect through changes in goals.
4. Changes in social support would demonstrate an indirect effect on MVPA change through changes in goals.
5. Changes in goals would demonstrate a direct effect on MVPA change.

6.2 Methods

6.2.1 Study design

This study used data from the *SHED-IT Weight Loss Maintenance Study*, which is described in detail elsewhere (287). In brief, a community sample of 209 overweight and obese men was recruited from the Hunter Region of New South Wales, Australia. To be eligible for participation, men were required to be between 18-65 years of age with a body mass index between 25-40 kg/m^2. Men were excluded if: they were not available for all assessments, did not have internet or mobile phone access, were participating in any other weight loss intervention, were taking medication to lose or gain weight, or had experienced weight loss of 5% of more in the previous 6 months (287). The data in this study were drawn from Phase I of the trial, which used a pre-post design. In this phase, all participants were assessed before and after receiving the 3-month *SHED-IT Weight Loss Program*, which is a gender-tailored program that has been successfully tested in previous research (81, 83). The study was approved by the University of Newcastle's Human Research Ethics Committee and was prospectively registered with the Australia New Zealand Clinical Trials Registry (ACTRN12612000749808).

6.2.2 The SHED-IT Weight Loss Program

The *SHED-IT Weight Loss Program* used in this study was a standardised package that did not include any face-to-face, phone consultation, or email contact and no individualised intervention components. The program included: (i) the SHED-IT Weight Loss Handbook for Men; (ii) the SHED-IT Weight Loss Logbook for Men (which included key SCT-based activities to complete); (iii) the SHED-IT Weight Loss DVD for Men; (iv) access to a study website to document physical activity and energy intake; and (v) self-monitoring tools including a pedometer and tape measure. The resources were specifically designed to appeal to men with attention given to both surface-structure components to engage men (e.g., use of male-specific research findings, pictures and anecdotes) and deep-structure components to address men's values (e.g., a frank approach, a focus on scientific rigour and encouragement of autonomy and choice) (241).

To increase the likelihood of sustained behaviour changes, the program targeted the core constructs of Bandura's SCT. Initially, the program provided education on the physical, social, and self-evaluative (i.e., personal) benefits of weight loss through increased physical activity. To increase men's physical activity self-efficacy, the program also targeted Bandura's three key sources of information (73): (i) mastery (e.g., teaching men to set achievable goals in order to experience repeated successes), (ii) vicarious experience (e.g., use of an identifiable role model in the DVD who experienced successes after implementing the recommended behavioural strategies), and (iii) verbal persuasion (e.g., all resources reflected an encouraging and positive tone). Participants were also taught important self-regulatory skills needed to sustain their physical activity changes over time and in the face of potential barriers, such as goal setting, self-monitoring and reward provision (73). Finally, the resources encouraged men to engage their social networks to help them achieve their weight loss and physical activity goals (69). More extensive details of the *SHED-IT Weight Loss Program* used in this trial can be found elsewhere (287).

6.2.3 Measures

Data were collected in August 2012 (Time 1) and November 2012 (Time 2). At both assessments men completed a questionnaire containing validated scales for self-efficacy (266), outcome expectations (266), social support (268), and intention (as a proximal goal) (267). As noted previously, a measure of intention was deemed appropriate to represent the goal construct given the considerable conceptual overlap between the two constructs (71).

The behavioural referent of the scales was standardised across the scales. This referent referred to 'achieving regular physical activity', defined as 'at least 60 minutes of physical activity (at a moderate intensity or greater) on 5 or more days per week' (i.e., at least 300 minutes per week). Although the new Australian physical activity guidelines for adults recommend achieving between 150-300 minutes of MVPA per week (288), the American College of Sports Medicine have suggested that the full 300 minutes may be required for long-term weight loss maintenance (64). The description of moderate physical activity used matched the following definition from the *Australian Physical Activity Guidelines for Adults* (262): *"Moderate-intensity activity will cause a slight,* *but noticeable, increase in your breathing and heart rate. A good example of moderate-intensity activity is brisk walking, that is at a pace where you are able to comfortably talk, but not sing. Other examples include mowing the lawn, digging in the garden, or medium-paced swimming or cycling".*

Prior to completing the cognitions, men were asked to read an information page which included the above definition of 'regular physical activity'. In addition, to standardise the measures and reduce potential confusion, the term 'regular physical activity' was used to replace 'regular exercise' or 'exercise' in the social cognitive measures. The scales were previously tested in a sample of overweight and obese Australian men (n = 22, mean (SD) age 39.7 (14.8) years; BMI 29.1 (5.1) kg/m^2) (287). The internal consistency (α) and test-retest reliability (ICC) values for each scale are reported in the next section.

6.2.3.1 Physical activity

The primary outcome of the current SCT model of physical activity was leisure time MVPA, which was measured with a modified version of the validated Godin Leisure-Time Exercise Questionnaire (GLTEQ) (252). In the original GLETQ, participants are asked to indicate how many times in the past month they engaged in moderate intensity physical activity (e.g., not exhausting, light perspiration) and vigorous intensity physical activity (e.g., heart beats rapidly, sweating) in bouts of at least 10 minutes. In the current study this was modified so that participants also estimated the average session duration for each category. Duration and frequency responses were then multiplied for both categories and summed to provide a measure of minutes spent in MVPA in the past month. This approach has been validated in previous research (251).

6.2.3.2 Self-efficacy

Self-efficacy was measured with a validated 8-item scale (α = 0.96; ICC = 0.88) (266) that has been used extensively in previous research (286). This scale measured participant's confidence to achieve regular physical activity in the following 3 months when faced with a series of barriers (e.g., when they have competing demands). Response options ranged from 1 (not at all confident) to 5 (completely confident).

6.2.3.3 Outcome expectations

Outcome expectations were measured with the validated 5-item exercise pros subscale (α = 0.78; ICC = 0.74) (266). This scale measured the degree to which participants expected that participating in regular physical activity in the following 3 months would decrease stress, help control weight, improve sleep, improve their outlook and make them feel more confident about their health. Response options ranged from 1 (strongly disagree) to 5 (strongly agree).

6.2.3.4 Socio-structural factors

Socio-structural factors were represented with a validated 10-item measure of family social support for physical activity (α = 0.95; ICC = 0.96) (268). Social support was chosen for this model as it: (i) features prominently in the SCT literature (69); (ii) has been noted as an important correlate of physical activity in adults (289); and (iii) was a specified intervention target in the *SHED-IT Weight Loss Program* (287). The scale measures how often participants received various types of support for physical activity from their family in the previous month (e.g., encouragement to stick to physical activity program, reminders to be active, co-participation in physical activity). Response options ranged from 1 (never) to 5 (always). Of note, the original measure also included a 'friend' social support scale, but this was not used in the current study as the distribution was highly skewed, with 56% of men reporting average scores of rare or non-existent support for physical activity from their friends.

6.2.3.5 Goal

Physical activity goal was assessed with a two item scale (α = 0.92; ICC = 0.92), which captured intention to achieve regular physical activity in the following three months (267). Following the recommendations of Rhodes et al.'s recommendations, intention was measured without the use of the word 'intend', given its conceptual overlap with the 'planning' construct (269). Response options ranged from 1 (extremely unmotivated/undetermined) to 7 (extremely motivated/determined.

6.2.3.6 Anthropometrics and demographics

Weight was measured in light clothing, without shoes on a digital scale to 0.01 kg (CH-150kp, A&D Mercury Pty Ltd., Australia). Height was measured to 0.1 cm using the stretch stature method on a calibrated stadiometer (Veeder-Root (VR) High Speed Counter, Harpenden/Holtain, Mentone Education). Body Mass Index was calculated using the standard equation (weight [kg]/height$[m]^2$). Socio-demographic variables were collected by questionnaire including age, employment, country of birth, marital status, education, and socio-economic status (290). These variables are not included in the analysis, but are reported to provide additional information on the study sample.

6.2.4 Data treatment and analysis

Data were analysed in SPSS 21 (SPSS Inc., Chicago, IL, USA) and AMOS Graphics 21. A structural equation model using maximum likelihood estimation and single indicator latent variables was created to test the hypothesised model structure. Given the sample size, this analysis method was deemed to be most appropriate as it minimises model parameters, while still allowing all hypothesised pathways to be assessed simultaneously and all constructs to be assessed free of measurement error (291). As Bollen recommends, the error variances were fixed to one minus the reliability of the measure multiplied by the variance (i.e., $(1 - \alpha) \times SD^2$) in order to estimate the model (291). As modelled in recent theory tests (292), physical activity was also treated as an unobserved variable to account for the inherent measurement error in the self-report measure, with the test-retest reliability of the measure used in place of the internal consistency when fixing the error variance. To examine how changes in the cognitions were associated with changes in physical activity over the 3 months, a cross-lagged model structure was employed where cognitions and behaviour at 3 months (Time 2) were controlled for baseline values (Time 1). These time-lagged pathways were only estimated between the same variable at each time point (e.g., self-efficacy at baseline to self-efficacy at follow-up), with the other time-lagged pathways fixed to zero. This analysis is in line with recent theory-tests which have tested the assumptions of SCT in the physical activity domain (210).

Model fit was assessed with several indices. As recommended for all structural equation models, the χ^2 test was used to test absolute model fit. As this test is highly sensitive to sample size, we also examined the normed χ^2 index of model parsimony, which divides the χ^2 test statistic by the degrees of freedom to adjust for model complexity (acceptable fit: $1 < \chi^2/df < 3$) (293). Model fit was also assessed with the Comparative Fit Index (CFI; acceptable fit: > 0.95) and the Standardised Root Mean Residual (SRMR; acceptable fit: < 0.06) (294). According to Hu and Bentler, these incremental fit indices are preferred for evaluating latent structural models as they resulted in the smallest sum of Type I and Type II errors when tested against other combinations of fit indices (294).

As the assessors were instructed to check completed questionnaires for missed items, complete data were recorded for all measures at baseline. As a result of loss to follow up, 22% of the data for all measures were missing at the 3-month assessment. When the missing data were examined, Little's MCAR test failed to reject the assumption that the data were missing completely at random ($\chi^2 = 33.5$, $df = 32$, $p = 0.40$), and no significant baseline differences were observed between completers and drop-outs for (i) physical activity outcomes, (ii) social-cognitive measures or (iii) any of the measured socio-demographic characteristics (all $p > 0.05$). As such, the missing data were imputed using the expectation maximisation procedure in SPSS.

Initial analyses in SPSS indicated skewness in the MVPA outcome measure at Time 1. As data transformations are not recommended for structural equation modelling, we reduced skewness by retracting univariate outliers to within 3.29 standard deviations of the mean (295). Finally, inspection of the Mahalanobis distance statistic for each participant indicated the presence of five multivariate outliers. To improve the multivariate normality of the data, which is an assumption of maximum likelihood estimation, these participants were removed leaving a final sample of 204 participants (i.e., 98% of the total study sample). To further improve the robustness of the analysis against univariate and multivariate skewness, the bootstrapping procedure was employed in AMOS and bias-corrected regression coefficients are reported. Following Ferguson's recommendations, beta coefficients were interpreted as 0.5 (moderate) and 0.8 (large). The minimum effect required to represent 'practical' significance was set at 0.2 (296).

6.3 Results

6.3.1 Descriptive statistics and bivariate correlations

Baseline characteristics for the 204 men included in the final analysis are reported in Table 6.1. The mean age of the sample was 46.6 years (range = 18-65) and mean weight was 105.7 kg (range = 75.6-144.9). Overall, 79% of the men were obese, 88% were employed and 85% were born in Australia. Mean scores and inter-correlations for all models components are detailed in Table 6.2. Briefly, MVPA significantly increased (p <0.001) between Time 1 (mean = 90 min, SD = 113) and Time 2 (mean = 191 min, SD = 129). Although social support increased, intention and outcome expectations decreased and self-efficacy did not change during the program. At Time 2, significant associations were observed between all socio-cognitive measures and behaviour, ranging from r = 0.20 (social support / MVPA) to r = 0.58 (self-efficacy / MVPA).

Table 6.1. Baseline demographic and anthropometric characteristics of study sample (n = 204).

Characteristic	Mean	SD
Age (years)	46.6	11.3
Height (cm)	178.5	6.8
Weight (kg)	105.7	14.1
BMI (kg/m^2)	33.1	3.5
	n	**%**
BMI category [a]		
Overweight	42	21
Obese I	100	49
Obese II	62	30
Socio-economic status [b]		
1-2	11	5
3-4	23	11
5-6	84	41
7-8	62	30
9-10	24	12
Born in Australia	174	85
English spoken at home	199	98
Currently employed	180	88
Currently studying	31	15
Married	154	76
Obtained post-school qualifications	166	81

Note: BMI, body-mass index; SD, standard deviation
[a] Overweight (25 – 29.9 kg/m^2); Obese I (30.0 – 34.9 kg/m^2); Obese II (35.0 – 39.9 kg/m^2). [b] Socio-economic status by population decile for SEIFA Index of Relative Socio-economic Advantage and Disadvantage.

Table 6.2. Descriptive statistics and correlations among model constructs

	Time 1 (0 months)					Time 2 (3 months)				
	1. MVPA	2. SE	3. OE	4. Goal	5. SS	6. MVPA	7. SE	8. OE	9. Goal	10. SS
Time 1 (0 months)										
1. MVPA	1.00									
2. Self-efficacy (SE)	0.24**	1.00								
3. Outcome expectations (OE)	0.04	0.06	1.00							
4. Goal	0.19*	0.61**	0.28**	1.00						
5. Social Support (SS)	0.15*	0.18*	0.14	0.23**	1.00					
Time 2 (3 months)										
6. MVPA	0.34**	0.22**	0.15*	0.23**	0.04	1.00				
7. Self-efficacy (SE)	0.20**	0.57**	0.18**	0.38**	0.09	0.58**	1.00			
8. Outcome expectations (OE)	0.15*	0.25*	0.62**	0.39**	0.16*	0.35**	0.48**	1.00		
9. Goal	0.25**	0.42**	0.23**	0.41**	0.20**	0.52**	0.70**	0.53**	1.00	
10. Social Support (SS)	0.04	0.27**	0.18*	0.20**	0.62**	0.20**	0.33**	0.28**	0.44**	1.00
Mean	89.8	3.06	4.32	5.88	2.29	190.6	3.05	4.25	5.44	2.62
SD	112.7	0.71	0.48	0.74	0.89	129.7	0.82	0.46	1.11	0.96

Note: MVPA, moderate-to-vigorous physical activity; SD = standard deviation.
* $p < 0.05$; ** $p < 0.01$, *** $p < 0.001$

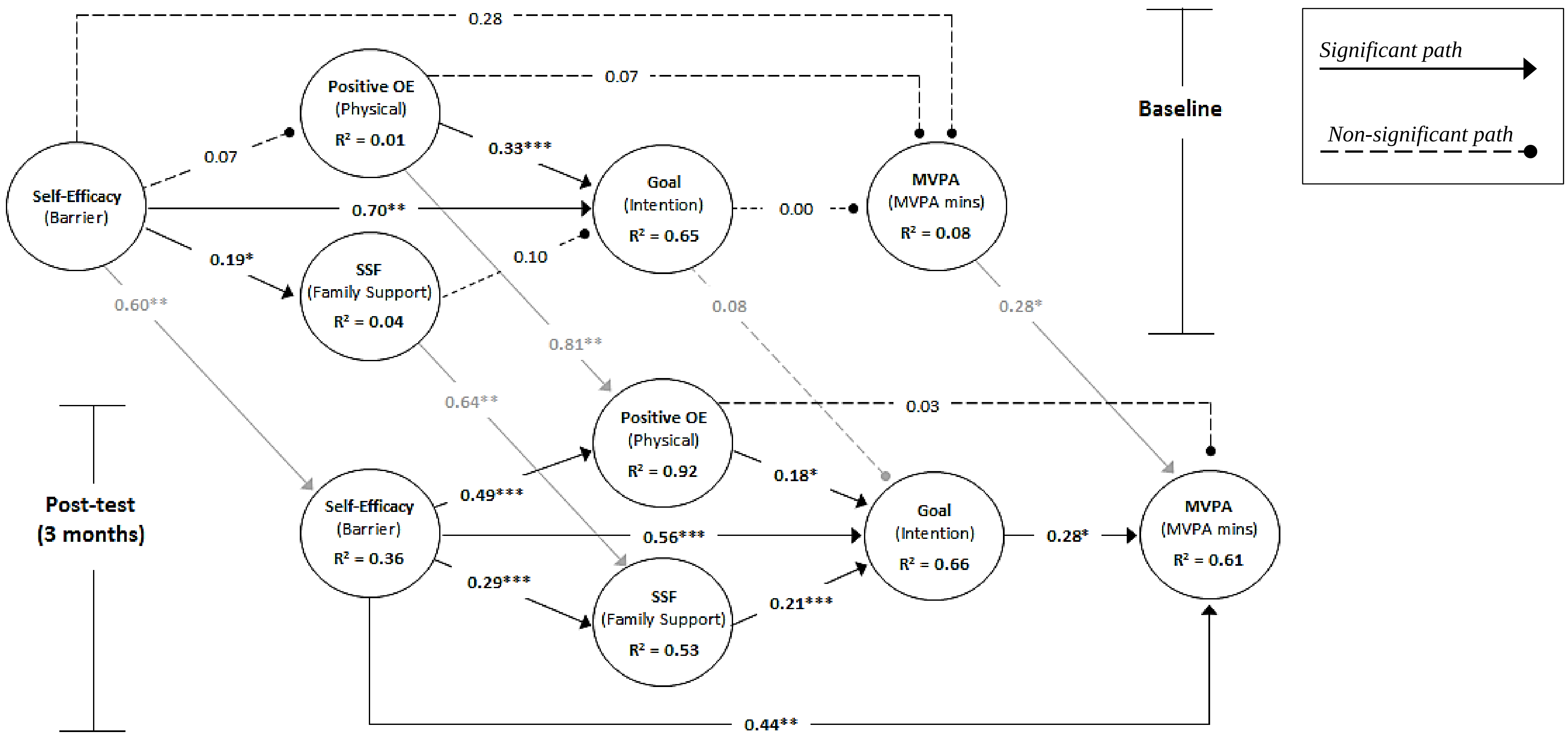
6.3.2 Model results

The fit indices indicated that the proposed model provided a good fit to the data (χ^2 = 59.3, *df* = 24, *p* <0.001; Normed χ^2 = 2.47; CFI >0.95; SRMR <0.06). As such, no further modifications were made. Overall, the model explained 61% of the variance in MVPA change (*p*<0.001) over the 3-month intervention period (Hypothesis 1).

As seen in Figure 6.1, changes in self-efficacy demonstrated a significant direct effect on changes in MVPA (β_{direct} = 0.44, *p* <0.01) as well as a significant indirect effect ($\beta_{indirect}$ = 0.20, *p* <0.05) through its influences on changes in outcome expectations (β = 0.49, *p* <0.001), intention (β = 0.56, *p* <0.001) and social support (β = 0.29, *p* <0.001) (Hypothesis 2). Of all SCT constructs, changes in self-efficacy demonstrated the largest total effect on MVPA change (β_{total} = 0.64, *p* <0.01).

Contrary to expectations, changes in outcome expectations did not exhibit a direct influence on change in MVPA (β_{direct} = 0.03, p = 0.79) (Hypothesis 3). A significant indirect effect was observed from changes in outcome expectations to changes in MVPA ($\beta_{indirect}$ = 0.05, p <0.05), via its influence on intention (β = 0.18, p <0.05), but this pathway did not reach the criteria for practical significance. Similarly, social support changes demonstrated significant, but non-practical indirect effect on MVPA changes ($\beta_{indirect}$ = 0.06, p <0.05) via an influence on changes in intention (β = 0.21, p <0.001) (Hypothesis 4). A small, but significant direct effect was observed from changes in intention to changes in MVPA (β_{direct} = 0.28, p <0.05) (Hypothesis 5). For additional information on all model pathways, see Table 6.3.

Figure 6.1. Longitudinal Social Cognitive Theory model of moderate-to-vigorous physical activity in overweight and obese men.



Note: OE = outcome expectations; SSF = socio-structural factors; MVPA = moderate-to-vigorous physical activity. To improve clar stability coefficients have been greyed and indicator variables and error terms are not displayed.

Table 6.3. Direct effects, total indirect effects, and total effects among SCT constructs and MVPA.

Latent variable	Effect [a]	Baseline (0m)					Post-test (3m)				
		1. SE	2. OE	3. SS	4. Goal	5. MVPA	6. SE	7. OE	8. SS	9. Goal	10. MVPA
Baseline											
1. Self-efficacy (SE)	Direct	n/a	0.07 ns	0.19*	0.70**	0.28 ns	0.60**	-	-	-	-
	Indirect	n/a	-	-	0.04 ns	0.00 ns	-	0.36***	0.30***	0.52**	0.49***
	Total	n/a	0.07 ns	0.19*	0.74**	0.28**	0.60**	0.36***	0.30***	0.52**	0.49***
2. Outcome Expectations (OE)	Direct	-	n/a	-	0.33***	0.07 ns	-	0.81**	-	-	-
	Indirect	-	n/a	-	-	0.00 ns	-	-	-	0.17**	0.09 ns
	Total	-	n/a	-	0.33***	0.07 ns	-	0.81**	-	0.17**	0.09 ns
3. Social Support (SS)	Direct	-	-	n/a	0.10 ns	-	-	-	0.64**	-	-
	Indirect	-	-	n/a	-	0.00 ns	-	-	-	0.14***	0.04 ns
	Total	-	-	n/a	0.10 ns	0.00 ns	-	-	0.64**	0.14***	0.04 ns
4. Goal	Direct	-	-	-	n/a	0.00 ns	-	-	-	0.08 ns	-
	Indirect	-	-	-	n/a	-	-	-	-	-	0.02 ns
	Total	-	-	-	n/a	0.00 ns	-	-	-	0.08 ns	0.02 ns
5. MVPA	Direct	-	-	-	-	n/a	-	-	-	-	0.28*
	Indirect	-	-	-	-	n/a	-	-	-	-	-
	Total	-	-	-	-	n/a	-	-	-	-	0.28*

Latent variable	Effect [a]	Baseline (0m)					Post-test (3m)				
		1. SE	2. OE	3. SS	4. Goal	5. MVPA	6. SE	7. OE	8. SS	9. Goal	10. MVPA
3 months											
6. Self-efficacy (SE)	Direct	-	-	-	-	-	n/a	0.49***	0.29***	0.56***	0.44**
	Indirect	-	-	-	-	-	n/a	-	-	0.15**	0.20*
	Total	-	-	-	-	-	n/a	0.49***	0.29***	0.71***	0.64**
7. Outcome Expectations (OE)	Direct	-	-	-	-	-	-	n/a	-	0.18*	0.03 ^{ns}
	Indirect	-	-	-	-	-	-	n/a	-	-	0.05*
	Total	-	-	-	-	-	-	n/a	-	0.18*	0.08 ^{ns}
8. Social Support (SS)	Direct	-	-	-	-	-	-	-	n/a	0.21***	-
	Indirect	-	-	-	-	-	-	-	n/a	-	0.06*
	Total	-	-	-	-	-	-	-	n/a	0.21***	0.06*
9. Goal	Direct	-	-	-	-	-	-	-	-	n/a	0.28*
	Indirect	-	-	-	-	-	-	-	-	n/a	-
	Total	-	-	-	-	-	-	-	-	n/a	0.28*
10. MVPA	Direct	-	-	-	-	-	-	-	-	-	n/a
	Indirect	-	-	-	-	-	-	-	-	-	n/a
	Total	-	-	-	-	-	-	-	-	-	n/a

Note: n/a, not applicable; - (dash), not estimated.

[a] Direct effect = the unique effect the variable has on the outcome (i.e., the effect that is unmediated by any other variable in the model). Indirect effect = the total effect of a construct on physical activity via its influence on other constructs in the model (i.e., sum of mediated effects to physical activity in model). Total effect = the sum of the direct effects plus indirect effects (i.e., the total effect of the variable on the outcome, directly and through other constructs).

* p <0.05, ** p < 0.01, *** p < 0.001

6.4 Discussion

The aim of this study was to investigate the utility of SCT to explain changes in MVPA in a sample of overweight and obese men participating in a male-only, weight loss trial. The fit indices indicated that the model provided a good fit to the data and the explained 61% of the variance in MVPA changes during the three-month study period. Changes in self-efficacy demonstrated the largest direct and total effects on MVPA change (β_{direct}=0.44, p<0.01; β_{total}=0.64, p<0.01). A practically meaningful effect was also observed from intention to MVPA (β_{direct} = 0.28, p <0.05), but not from outcome expectations or social support.

In support of our first set of hypotheses, SCT provided a good fit to the data and explained a large proportion of the variance in the MVPA changes of the 204 overweight and obese men during the *SHED-IT Weight Loss Program* (Hypothesis 1). In a recent meta-analytic review of SCT models of physical activity, Young and colleagues reported that, overall, the SCT models accounted for 31% of the variance in physical activity (286), which was less than half of the R^2 for MVPA found in the current paper. This difference may be explained by the methodological strengths of the current study which have clearly addressed many of the limitations of previous studies, including use of a longitudinal design, high retention rates, an appropriate sample size, use of valid and reliable measures of physical activity and SCT cognitions, use of structural equation modelling, and adjustment for past behaviour. Indeed, Young et al also found that study quality significantly moderated the meta-analysed effect size for physical activity, with higher quality studies explaining more variance than lower quality studies (286).

The results also supported the second hypothesis regarding self-efficacy. As anticipated, changes in self-efficacy demonstrated a small-to-moderate direct effect on MVPA and a small indirect effect, which combined to form a moderate-to-large total effect. Thus, men who increased their self-efficacy for MVPA during the study showed the largest improvements in MVPA behaviour. This is in line with an established body of evidence indicating that self-efficacy is an important contributor to physical activity behaviour (75). This study also identified that changes in self-efficacy exhibited a significant total indirect effect on changes in MVPA via an influence on changes in outcome expectations, intentions and perceived socio-structural factors. In line with the tenets of SCT, men who increased self-efficacy for MVPA also increased their positive expectations of the benefits of MVPA, strengthened their intention to achieve regular MVPA and reported more social support for MVPA from their family. This is an important finding, as the indirect effect of self-efficacy on physical activity has been under-investigated in SCT research.

To date, the majority of studies have either tested SCT with multiple regression models, which cannot determine indirect effects, or have not reported the indirect effect of self-efficacy in the results. When reported, evidence for the effect has been mixed. For example, some studies have reported a significant indirect effect of self-efficacy on physical activity (e.g., (162)), but others reported a non-significant effect (e.g., (161)). Although self-efficacy consistently demonstrates a significant direct effect on physical activity behaviour, this study also supports Bandura's assertion that self-efficacy exhibits an indirect effect on PA through an influence on all other model components (71, 73). However, given the mixed findings in the literature to date, this pathway requires further validation in future research.

Hypothesis 3 regarding the role of outcome expectations within the SCT model was not supported as changes in outcome expectations did not exhibit a direct effect on MVPA changes. Further, although a significant effect was observed from outcome expectations to MVPA via intention, this effect was deemed too small to be practically meaningful (296). These results are consistent with two recent reviews, which reported that outcome expectations have demonstrated a mixed effect (141) or null effect (286) on physical activity. Bandura has previously addressed this issue in relation to behaviours where outcomes are inextricably linked to performance, such as physical activity, by suggesting that '*when differences in efficacy beliefs are controlled, the outcomes expected for given performances make little or no independent contribution to prediction of behaviour*' (73). The current model supports this assertion, given that the significant association between outcome expectations in the correlational analyses no longer existed when the construct was situated in the complete SCT model. This suggests that the role of outcome expectations in the SCT model, when specifically predicting physical activity, may need to be re-evaluated. However, it is important to acknowledge that the current model used a general measure of outcome expectations rather than measuring the three major classes delineated in SCT (i.e., physical, social and self-evaluative), which may have affected the results.

This study did not support Hypothesis 4 regarding the hypothesised indirect effect of social support on MVPA, via intentions. Similar to outcome expectations, although the indirect pathway reached statistical significance, the strength of the association was too small to be considered practically significant. Of interest, while social support is a key indicator of SCT's 'socio-structural barriers and facilitators' construct, sociological research in men's health shows that men prefer to complete lifestyle programs independently (40). Indeed, previous weight loss programs with men have reported poor compliance to social support related tasks (85). Thus, future research should consider whether other socio-structural factors (e.g., perceptions of the built environment, access to training facilitates) are more important to target in male-only studies. Alternatively, it is important to acknowledge that the location of social support within SCT models has varied. For example, Anderson and colleagues have reported on a number of equally well-fitting SCT models where social support operates on physical activity indirectly through constructs including self-efficacy (161, 162). Indeed, in contrast to his recent work, Bandura has previously proposed that social support may operate on behaviour through self-efficacy (73). As such, it is apparent that further research is required to establish the importance of the social support construct within SCT, particularly in relation to men.

Hypothesis 5 regarding the direct effect of intention on MVPA was supported. Men who increased their intention to achieve regular MVPA also increased their MVPA levels through the study period. Although the effect was small, it was consistent with the broader research of the link between goals/intentions and physical activity (142). However, it is of interest that the model did not identify a cross-sectional association between MVPA intention and MVPA at Time 1 or between MVPA intention measures over time. These results may be a by-product of recruiting a highly motivated group of overweight men with strong intentions to increase their MVPA levels during the intervention, without much knowledge of what this experience would involve.

As previously noted, this study addressed many of the weaknesses of the previous studies examining SCT models of physical activity (286), including use of a longitudinal design, high retention rates, a relatively large sample size, use of a valid and reliable measures of physical activity and SCT cognitions, use of structural equation modelling and adjustment for past behaviour and cognitions. In addition, this was one of the very few studies to assess all major SCT constructs according to Bandura's most recent model conceptualisation (71). This study also provides unique information into the utility of SCT to explain MVPA behaviour in men, who are notably underrepresented in theoretical research (286), physical activity research (284), and weight loss research (217). There are also some limitations to acknowledge. First, the current model reports on a self-report measure of MVPA only. Although this was a validated tool (252), self-reported measures are subject to common methods bias, where associations between SCT constructs and physical activity are inflated due to the shared measurement method (211). Although a recent review noted that method of behaviour assessment did not significantly moderate the effectiveness of SCT models of physical activity (286), the SCT evidence-base would benefit from more studies that validate the current model with objectively measured physical activity. Further, this study did not include any follow-up after the post-test assessment to measure maintenance of study effects. Finally, for model parsimony we limited the socio-structural factors construct to family social support only. With a larger sample size this construct could be expanded to include other factors such as perceived environmental variables or perceived barriers.

In summary, Bandura's SCT explained a large proportion of the MVPA changes of men participating in a weight loss program. To the authors' knowledge, this is the first study to apply structural equation modelling to test the assumptions of SCT when explaining MVPA in an entirely male sample. Although these results provide some evidence to support the tenets of Bandura's SCT when examining MVPA behaviour in men, further research is required to replicate the results with objective measures of MVPA and with longer follow-up to establish the maintenance of effects. Future physical activity and weight loss interventions for men may benefit by including explicit strategies to optimise men's self-efficacy and intention to perform physical activity. Conversely, this study suggests that social support and outcome expectations may not be as important to target in male-only populations, although this hypothesis requires further validation.

CHAPTER 7

EFFICACY OF A SCALABLE, GENDER-TAILORED INTERVENTION TO PREVENT WEIGHT REGAIN IN MEN: THE SHED-IT WEIGHT LOSS MAINTENANCE RANDOMISED CONTROLLED TRIAL

Preface:

This chapter presents the primary outcome paper of the *SHED-IT Weight Loss Maintenance Trial*, which I co-authored. The results of this study align with *Secondary Aim 5* of this thesis (i.e., to evaluate the effect of the *SHED-IT Weight Loss Maintenance Program* on men's weight and other health outcomes, 12 months after successfully completing the *SHED-IT Weight Loss Program*).

At the time this thesis was submitted, the contents of this chapter were under review in the *International Journal of Obesity*.

Citation:

Morgan, P.J., **Young, M.D.,** Collins, C.E., Plotnikoff, R.C., & Callister, R. (under review). Efficacy of a scalable, gender-tailored intervention to prevent weight regain in men: The SHED-IT Weight Loss Maintenance randomised controlled trial. *International Journal of Obesity*.

Abstract

Background/Objectives: Weight regain after weight loss is common. Weight loss maintenance (WLM) programs can reduce regain, but many are too intensive for realistic dissemination and none have been tailored for men. This study examined whether a gender-tailored, scalable WLM program could reduce weight regain after weight loss in men.

Subjects/Methods: The study was a prospective, two-phase, parallel-group randomised controlled trial (RCT). Ninety-two overweight/obese men (BMI 25-40 kg/m^2, Age 18-65 years) who lost at least 4kg after completing the 3-month *SHED-IT Weight Loss Program* (Phase I) were randomised to receive: (i) the 6-month *SHED-IT WLM Program* (n = 47) or (ii) no additional resources (self-directed control; n = 45) (Phase II). The *SHED-IT WLM Program* was a self-administered, gender-tailored program that included written materials (handbook, log book), pre-programmed bi-weekly text messages and weekly video emails, and other resources (website, pedometer, resistance training device). The primary outcome was weight change (kg) during Phase II (i.e., from randomisation to the 12-month assessment).

Results: Mean (SD) entry weight was 105.6 (14.1) kg. Mean (SD) Phase I weight loss was 7.3 (2.5) kg. Phase II retention was 83% at 6- and 12 months (primary endpoint). Intention-to-treat linear mixed models showed no significant difference in weight regain between groups at 12 months (-1.5 kg, 95% CI, -3.7 to 0.7, p=0.19). Both groups demonstrated important maintenance of initial weight loss, with the intervention and control groups regaining only 8% (0.6 kg; 95% CI -0.9 to 2.2) and 28% (2.1 kg; 95% CI 0.5 to 3.7) of lost weight, respectively.

Conclusions: Provision of a scalable, gender-tailored WLM program did not facilitate improved maintenance of lost weight among men who participated in a gender-tailored weight loss program. The within-group results highlight the utility of gender-tailored, theory-based programs to help men maintain modest weight loss.

7.1 Introduction

Obesity is a global public health concern associated with many adverse physical and psychological health consequences (1). To address the international escalation of obesity prevalence (2, 3), researchers have extensively tested behavioural weight loss interventions to help people reduce their risk of morbidity and mortality (297). Although these interventions have shown good efficacy to generate clinically meaningful, albeit modest, weight loss in the short-term (90), long term success rates are poor. Indeed, systematic reviews indicate that close to 50% of initial losses are regained in the first year after treatment alone (46, 47).

To address this seemingly intractable problem, researchers are now evaluating additional weight loss maintenance (WLM) interventions (49, 245). These interventions have been informed by cross-sectional and cohort studies, such as the *U.S. National Weight Control Registry* (50), which indicate that successful maintenance may require different skills and behaviours to those used during weight loss. This approach has shown initial promise, with a recent meta-analysis of WLM RCTs (n = 2949) demonstrating that participants who received an additional WLM program regained 1.6 kg less than self-help controls in the 12 months after weight loss (49). However, the WLM evidence base is currently in its early stages (90) and has been hampered by a lack of practical, scalable interventions and low numbers of men.

Similar to weight loss research (38), WLM studies have been characterised by a distinct lack of male participants, who represent only 27% of randomised controlled trial (RCT) participants on average (49). Further, the evidence base for male-only weight control programs is limited in quality as well as quantity[12] and few programs have been 'gender tailored' to account for the psychological, sociological and biological differences between men and women (26). As such, men perceive weight loss to be a 'feminised realm' (26) and are less likely than women to attempt weight loss (298), despite being susceptible to greater health risk from their obesity (299). Men are also less likely than women to realise they are overweight or feel dissatisfied with their weight (298) and men who attempt weight loss are less likely to experience long term success (28). This is greatly concerning as 36.9% men worldwide are now overweight or obese (2) and the international prevalence of obesity in men has doubled to 9.8% in the past 30 years (3).

The WLM research base is also limited by a lack of practical, scalable interventions that could realistically be implemented at a population level (49). To date, most programs have included substantial face-to-face contact, which inherently decreases scalability and increases costs. In their recent review, Dombrowski and colleagues described an urgent need for novel WLM programs with realistic potential for widespread dissemination (49). The authors also noted that most previous WLM RCTs have been characterised by a high risk of bias and few have been conducted with men (49, 245). As such, high quality evaluations of WLM programs that are scalable and appealing to men are urgently needed.

Thus, the primary aim of this study was to investigate whether a gender-tailored, scalable WLM program for men would significantly improve men's maintenance of lost weight and other health outcomes 12 months after initial weight loss. It was hypothesised that the men who received the *SHED-IT Weight Loss Program* plus the *SHED-IT WLM Program* would achieve significantly greater WLM at 12 months, compared to a self-help control group who received the *SHED-IT Weight Loss Program* alone.

7.2 Subjects and Methods

7.2.1 Participants

The detailed methods of the trial have been published elsewhere (287). Overweight or obese (BMI 25-40kg/m^2) men aged 18 to 65 years were recruited in July-August 2012 from the Hunter Region of New South Wales, Australia. The primary recruitment strategy was a University media release. Men were excluded from entering Phase I (and therefore the study) if they were unable to attend assessments, had no internet or mobile phone, had insulin-dependent diabetes, had experienced recent weight loss (5% or more in the previous 6 months), or intended to participate in an alternative weight loss program during the study.

7.2.2 Study design

This study included two phases (Figure 7.1). In Phase I (3-month weight loss phase), all men were provided with the *SHED-IT Weight Loss Program*, which has been extensively evaluated in previous efficacy (83, 84, 86) and effectiveness RCTs (77, 78, 81, 85, 300). To enter Phase II (12-month parallel-group, assessor-blinded RCT), a 4 kg weight loss was required during Phase I. This cut-off was chosen as 4 kg represents sufficient weight loss to confer clinically meaningful health benefits (67, 68) and aligns with the design of a seminal WLM study (280). In Phase II, men were randomly allocated (1:1 ratio) to receive: i) the 6-month *SHED-IT WLM Program*, which was developed for this study, or ii) no additional resources (self-help control). As seen in Figure 7.1, assessments were conducted at 'study entry' (prior to Phase I; August 2012), 'WLM Baseline' (end of Phase I; randomisation into WLM RCT (Phase II); November 2012), 6 months from randomisation (WLM post-test; May 2013) and 12 months from randomisation (6-month WLM follow up; primary endpoint; November 2013). The study received ethics approval from the University of Newcastle's Human Research Ethics Committee and was prospectively registered with the Australia New Zealand Clinical Trials Registry (ACTRN12612000749808).

7.2.3 The SHED-IT Weight Loss Program (Phase I)

The *SHED-IT Weight Loss Program* is described extensively elsewhere (82). However, the program was improved in several key areas after the community effectiveness RCT (81). These modifications included the provision of weekly Social Cognitive Theory (SCT)-based (69) motivational text messages and the removal of personalised e-feedback to increase scalability (81). In addition, the program included: (i) a DVD (presented by PJM), which emphasised nine SHED-IT weight loss strategies for men; (ii) a Handbook and Log Book (to complete SCT tasks); and (iii) a pedometer and tape measure. Men were encouraged to self-monitor their diet and physical activity with the CalorieKing™ website (www.calorieking.com.au) or MyFitnessPal™ app to create a 2000 kJ deficit on most days.

7.2.4 The SHED-IT Weight Loss Maintenance Program (Phase II)

The 6-month *SHED-IT WLM Program* was designed to provide men with new knowledge and skills regarding key behaviours associated with successful WLM. These messages included eating breakfast regularly (52, 56), eating more fruits and vegetables (52, 54, 55), watching less than 2 hours of TV/day (60, 61), increasing moderate-to-vigorous physical activity to ≥300min of activity/week (64, 65), and reducing intake of energy-dense, nutrient-poor discretionary foods (50, 235). Cognitive-behavioural techniques including cognitive reframing to challenge negative thinking were also included. Although the WLM program did not advocate further weight loss, men were advised to continue weighing themselves weekly and to revert to weight loss strategies if they gained 2.5 kg or more from randomisation (52, 63).

The resources included: (i) a Handbook and Log Book (to complete SCT tasks) (85); (ii) weekly emails (including video messages from chief investigators PJM and MDY); (iii) bi-weekly SCT-based text messages; and (iv) a Gymstick^{TM} (portable resistance training tool). Participants were advised to continue self-monitoring using CalorieKing^{TM} or MyFitnessPal^{TM} for at least 2 days per week.

7.2.5 Theoretical framework and gender tailoring

While there was a clear distinction between the strategies and advice provided in each phase, the *SHED-IT Weight Loss Program* and *SHED-IT WLM Program* had a shared focus on the need for gradual and sustainable lifestyle change. Further, both programs targeted the core SCT behaviour change constructs (i.e., self-efficacy, outcome expectations, goals, socio-structural barriers and facilitators) (69) and were 'gender tailored' (241) to ensure the messages were engaging and meaningful to men (81-83). This tailoring included surface-structure components, (e.g., male-specific research findings, images and anecdotes) and deep structure components (e.g., a frank and realistic approach, a focus on the science, an autonomous approach to eating and exercise) (86, 242). Given that men generally do not engage with programs that significantly disrupt their lifestyle (86, 243), the programs taught men to balance their energy without eliminating 'luxury' foods (e.g., the occasional beer). Humour was incorporated through all resources given its strong ties to traditional masculinity (244).

7.2.6 Data collection and measures

Assessments were conducted at the University of Newcastle by trained, blinded assessors. Before entering the laboratory, all participants were greeted by a member of the research team who answered any questions and reminded them not to reveal any information about their group assignment to the assessors.

7.2.6.1 Primary outcome

Weight change (kg) during Phase II (i.e., from randomisation). Weight was measured twice (without shoes, light clothing), on a digital scale (CH-150kp, A&D Mercury Pty Ltd, Australia).

7.2.6.2 Secondary outcomes

BMI was calculated with the standard equation¸ with height measured at the first study assessment with a calibrated stadiometer (Veeder-Root (VR) High Speed Counter, Harpenden/Holtain, Mentone Education Centre, Morrabin, Victoria). *Waist circumference* was measured level with the umbilicus and at the narrowest circumference with a non-extensible steel tape (KDSF10-02; KDS Corporation, Osaka, Japan. *Body composition* was assessed using the valid and reliable InBody720 multi-frequency, bioimpedance device (Biospace Co., Ltd, Seoul, Korea) (247). *Resting blood pressure and heart rate* were measured using NISSEI/DS-105E digital monitors (Nihon Seimitsu Sokki Co. Ltd., Gunma, Japan).

Physical activity was recorded by participants with seven consecutive days of pedometry using reliable (249) and valid (250) Yamax SW200 pedometers (Yamax Corporation, Kumamoto City, Japan). *Sitting time* was assessed with the validated Sitting Questionnaire (226). *Dietary intake* was assessed using the validated 120-item Australian Eating Survey Food Frequency Questionnaire (227). *Portion size* was assessed using a validated portion size measure (228, 254). *Risky alcohol consumption* was measured with the validated short-form of the Alcohol Use Disorders Identification Test (AUDIT) (255). *Weekly breakfast consumption* was captured with a single, frequency-per-week item. Extensive detail on these measures is published elsewhere (287).

7.2.7 Sample size

The sample size calculation was based on the primary outcome of weight change during Phase II (i.e., from randomisation). The standard deviation of weight change was estimated to be 4 kg (84). Thus, 29 men per group were required at 12 months for 80% power to detect a 3 kg between-group difference in weight change ($p<0.05$; two-sided test). A 3 kg difference was chosen as this is outside the range of normal weight fluctuation and is sufficient to sustain clinically meaningful health benefits (67, 68, 275). Recruitment projections were based on data from previous SHED-IT studies (81-84). In total, 195 men were required to enter Phase I, as 20% were expected to drop out during Phase I (n=39) and 40% were expected to complete Phase I without achieving sufficient weight loss to enter the RCT (n=78). Of the remaining 78 men who would enter Phase II (i.e., the RCT), we expected to retain 75% at the 12-month follow-up assessments (n = 58; 29 per group).

7.2.8 Randomisation and allocation

Participants were randomised at an individual level by an independent statistician who had no contact with participants. Allocation was stratified by: (i) BMI at the 'WLM Baseline' assessment (<30 kg/m^2 and ≥ 30 kg/m^2), and (ii) Phase I weight loss (4.0-7.4 kg and ≥ 7.5 kg). Allocation sequences within strata were generated by a computer-based random-number-producing algorithm in randomly varied block lengths. Information for each study arm was pre-packed into identical opaque envelopes and ordered according to the randomisation schedule by a research assistant who was not involved in enrolment, assessment or allocation. After completing all assessments, participants met with a blinded member of the research team who allocated the participant to the next available position in their stratification category before opening the corresponding envelope and providing details of the allocation with a standardised protocol.

7.2.9 Statistical analysis

Data were checked for plausibility and missing values before analyses were performed using IBM SPSS version 22. Data are presented as means (SD or 95% CI) for continuous variables and counts (%) for categorical variables. Differences in key characteristics between attenders and non-attenders were tested with independent samples *t* tests and chi-squared tests.

Linear mixed models assessed all outcomes for the impact of treatment (WLM intervention vs. control), time ('WLM Baseline', 6 and 12 months) and the treatment-by-time interaction. These models are robust to the biases of missing data and model missing responses into the results, consistent with an intention-to-treat approach (301). To align with a seminal WLM trial (280), age, socio-economic status, Phase I weight loss and BMI were examined as potential covariates. Where significant, a term was added to the model to adjust for these effects. Two-way interactions with time and treatment were then examined for significant covariates and adjusted for, where significant.

7.3 Results

In total, 236 of the 319 men who completed online screening were eligible for Phase I (Figure 7.1). Of this group, 209 men provided consent and received the *SHED-IT Weight Loss Program* after completing the study entry assessments (Phase I). After three months, 92 men had lost ≥4 kg and were willing to participate in the WLM RCT (Phase II). The 'WLM Baseline' data for these men are presented in Table 7.1. As the intervention effects during weight loss provide essential context for those observed during WLM (302), Phase I change data are also provided. At randomisation, RCT participants had a mean age of 49.2 years (range, 27-65 years), a mean weight of 98.3 kg (range, 70.9-138.9 kg), and a mean Phase I weight loss of 7.3 kg (range, 4.1-18.3 kg) (Figure 7.2). Phase II retention was 83% at both the 6- and 12-month assessments, with no significant differences in retention between groups (p>0.05). All randomised men were included in the analysis. Non-attenders at 12 months had significantly greater 'WLM Baseline' values for weight and sitting time, and ate breakfast on fewer days per week, compared to those who attended. No harms or unintended effects were reported in either group during the study.

Figure 7.1. CONSORT flowchart and study design for the SHED-IT Weight Loss Maintenance trial.

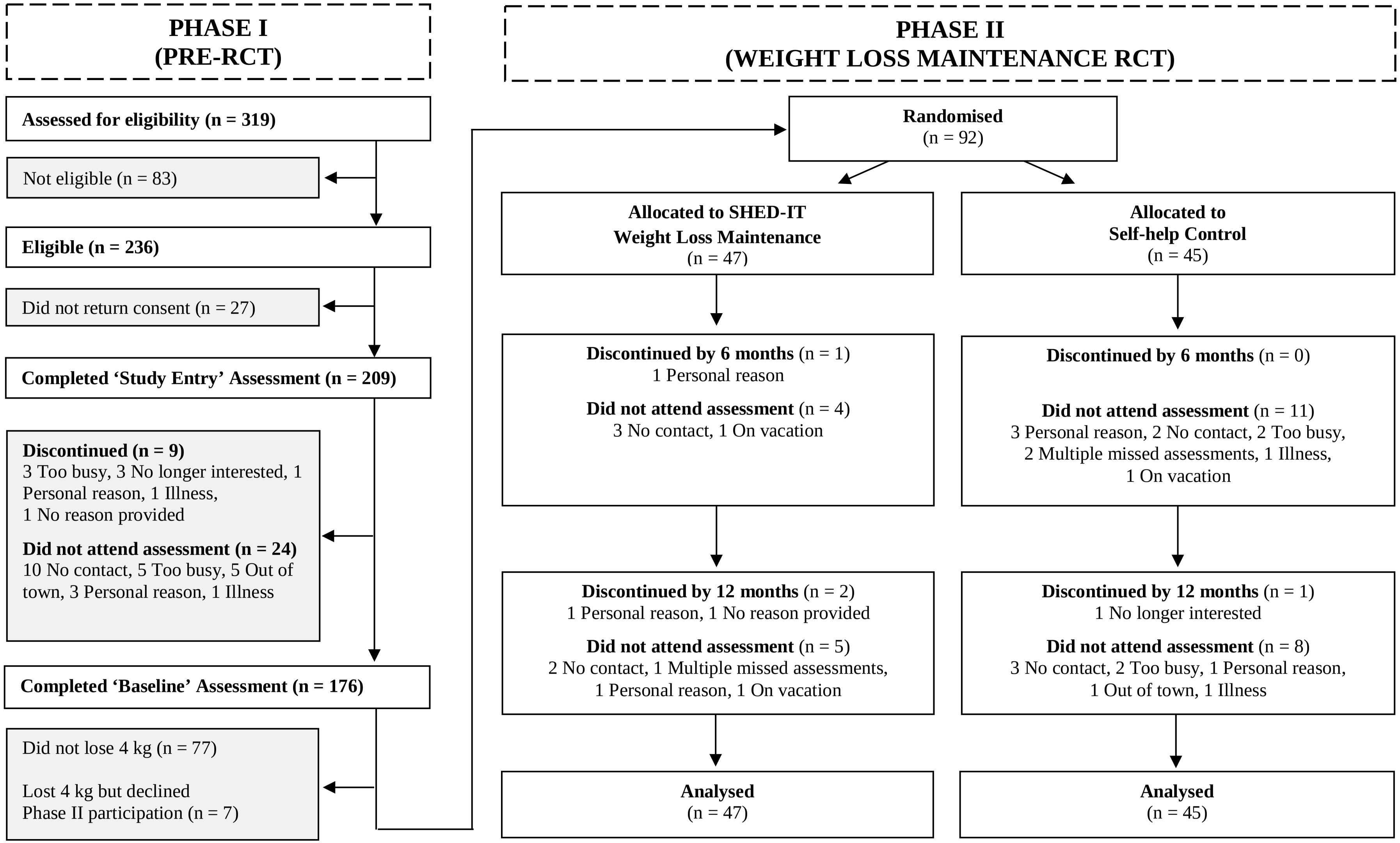


Table 7.1. Phase II baseline characteristics of men randomised to the SHED-IT Weight Loss Maintenance group (n = 47) and the control group (n = 45).

Outcome	Phase I Change (Phase II baseline – study entry)							Phase II baseline					
	WLM		Control		Total			WLM		Control		Total	
	Mean	*SD*	*Mean*	*SD*	*Mean*	*SD*	*p-value*	*Mean*	*SD*	*Mean*	*SD*	*Mean*	*SD*
Age (y)	-	-	-	-	-	-	-	49.5	9.9	49.0	10.4	49.2	10.1
Height (cm)	-	-	-	-	-	-	-	178.2	6.8	179.2	6.4	178.6	6.6
Weight (kg)	-7.3	2.0	-7.4	2.9	-7.3	2.5	<0.001	98.1	14.0	98.5	14.9	98.3	14.3
BMI (kg/m^2)	-2.3	0.7	-2.3	1.0	-2.3	0.9	<0.001	30.8	3.3	30.6	3.4	30.7	3.3
Body Fat (%)	-4.1	2.7	-3.8	5.3	-4.0	4.2	<0.001	29.1	6.0	28.0	6.8	28.6	6.4
Visceral Fat Area (cm^2)	-24.5	10.9	-27.3	25.8	-25.9	19.6	<0.001	154.2	36.8	151.6	37.1	152.9	36.8
Skeletal Muscle Mass (kg)	-0.6	1.1	-1.0	3.5	-0.8	2.6	<0.01	39.2	4.9	40.0	4.8	39.6	4.8
Waist (Umbilicus) (cm)	-6.7	2.7	-6.1	3.7	-6.4	3.2	<0.001	109.3	9.1	109.2	12.3	109.2	10.7
Waist (Narrowest) (cm)	-6.2	2.8	-6.2	4.5	-6.2	3.7	<0.001	104.9	9.3	104.5	12.7	104.7	11.0
Systolic Blood Pressure (mmHg)	-12.3	11.1	-10.0	9.9	-11.1	10.5	<0.001	123.7	11.6	123.9	10.2	123.8	10.9
Diastolic Blood Pressure (mmHg)	-6.0	8.1	-5.9	7.8	-5.9	7.9	<0.001	80.3	9.1	79.1	8.9	79.7	8.9
Resting Heart Rate (bpm)	-7.8	9.2	-4.5	9.4	-6.2	9.5	<0.001	63.3	9.3	69.8	10.7	66.5	10.5
Physical Activity (steps/day) [a]	1274	2957	1851	2119	1559	2578	<0.001	7962	2735	9276	3162	8603	3006
Sitting Time (min/day)[b]	34	188	-13	167	11	179	0.56	640	181	586	216	614	200
Energy Intake (kJ/day)	-2225	2756	-1473	2829	-1857	2802	<0.001	9290	3582	9338	3300	9314	3428
Fruit and Vegetables (servings/day)	0.0	2.4	0.1	1.9	0.1	2.2	0.81	6.4	2.3	6.3	2.6	6.4	2.5
Risky Alcohol Consumption [c]	-0.9	1.3	-0.9	1.3	-0.9	1.3	<0.001	4.6	2.5	4.2	2.6	4.4	2.5
Portion Size [d]	-0.2	0.2	-0.2	0.2	-0.2	0.2	<0.001	1.0	0.2	0.9	0.2	1.0	0.2
Breakfast frequency (days/week)	0.3	1.2	0.7	1.7	0.5	1.5	<0.01	6.3	1.5	6.5	1.2	6.4	1.4

BMI, Body-mass index; bpm, beats per minute. *p*-values indicate significance of Phase I changes for the complete randomized sample.

[a] n = 82. [b] = 86. [c] Maximum possible score = 12; a score of 6 or 7 may indicate a risk of alcohol-related harm and potential harm for groups susceptible to effects of alcohol. [d] A single portion size factor (PSF) indicates whether on average a person eats median size serves (PSF = 1), more than the median (PSF > 1), or less than the median (PSF < 1) serve sizes for main meals.

7.3.1 Change in weight

As reported in Table 7.2, the WLM intervention group had regained 0.6 kg (95% CI -0.9 to 2.2) at 12 months (primary endpoint) and the control group had regained 2.1 kg (0.5, 3.7). This represented an 8% regain of lost weight in the intervention group and a 28% regain in the control group. However, the between group difference was not significant at 6 months (-1.7, 95% CI -3.6 to 0.1) or 12 months (-1.5 kg, 95% CI, -3.7 to 0.7). Overall, 92% of men who attended the 12-month assessment were at or below their entry weight and 53% had achieved a 5% weight loss from study entry.

Figure 7.2. Unadjusted weight change by treatment group (n=92; intention-to-treat analysis). Error bars represent 95% confidence intervals.

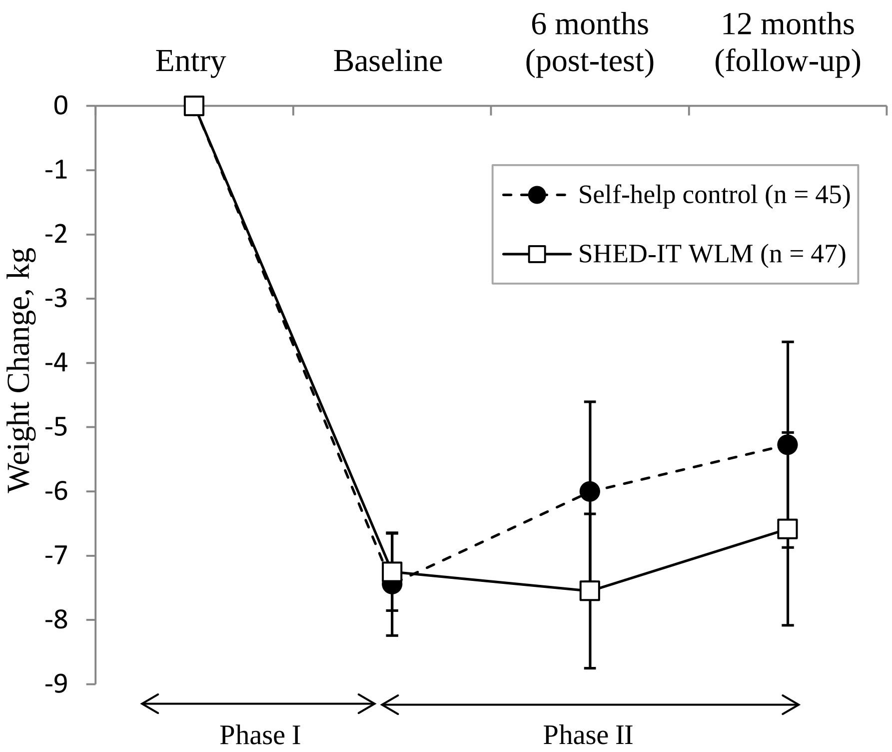


Table 7.2. Estimated mean (95% CI) Phase II changes from 'WLM Baseline' to 6 months and 12 months within each group and the mean difference in change between groups at 6 and 12 months (intention-to-treat analysis) (n = 92).

Outcome	**Time**	**Mean change from randomisation (95% CI)**		**Mean difference between groups (95% CI)**	**Group x time *p*-value**
		SHED-IT WLM	**Control**		
Weight (kg) [a]	6	-0.3 (-1.5, 1.0)	**1.4 (0.1, 2.8)**	-1.7 (-3.6, 0.1)	
	12	0.6 (-0.9, 2.2)	**2.1 (0.5, 3.7)**	-1.5 (-3.7, 0.7)	0.18
BMI (kg/m^2) [a]	6	-0.1 (-0.4, 0.3)	**0.5 (0.0, 0.9)**	-0.5 (-1.1, 0.0)	
	12	0.2 (-0.2, 0.7)	**0.7 (0.2, 1.2)**	-0.4 (-1.1, 0.3)	0.19
Body Fat (%) [a b c]	6	0.1 (-0.6, 0.9)	**1.0 (0.1, 1.8)**	-0.8 (-1.9, 0.3)	
	12	0.5 (-0.5, 1.5)	**1.4 (0.3, 2.4)**	-0.9 (-2.3, 0.6)	0.36
Visceral Fat Area (cm^2) [a c]	6	3.4 (-0.5, 7.3)	**9.1 (4.8, 13.4)**	-5.7 (-11.5, 0.1)	
	12	**5.1 (0.2, 10.0)**	**9.0 (3.7, 14.2)**	-3.8 (-11.0, 3.3)	0.14
Skeletal Muscle Mass (kg) [a c]	6	-0.2 (-0.5, 0.1)	0.0 (-0.4, 0.4)	-0.2 (-0.7, 0.3)	
	12	-0.1 (-0.4, 0.2)	0.1 (-0.3, 0.4)	-0.2 (-0.7, 0.3)	0.68
Waist (umbilicus) (cm) [a b c d]	6	-0.7 (-1.7, 0.4)	0.7 (-0.4, 1.8)	-1.4 (-2.9, 0.1)	
	12	0.3 (-1.0, 1.6)	**1.6 (0.2, 3.0)**	-1.3 (-3.2, 0.7)	0.19
Waist (narrow) (cm) [a b c e f]	6	0.1 (-0.9, 1.2)	**1.3 (0.1, 2.4)**	-1.1 (-2.7, 0.4)	
	12	0.1 (-1.4, 1.6)	1.3 (-0.3, 2.8)	-1.2 (-3.3, 1.0)	0.35
Systolic Blood Pressure (mmHg) [a]	6	**4.1 (0.8, 7.5)**	**4.3 (0.6, 8.0)**	-0.1 (-5.1, 4.8)	
	12	0.8 (-2.4, 4.0)	**5.0 (1.5, 8.4)**	-4.2 (-8.9, 0.5)	0.18
Diastolic Blood Pressure (mmHg)	6	**2.3 (0.6, 4.0)**	**3.5 (1.5, 5.4)**	-1.1 (-3.7, 1.4)	
	12	0.5 (-1.5, 2.5)	**3.2 (1.1, 5.3)**	-2.7 (-5.6, 0.2)	0.19

Outcome	Time	Mean change from randomisation (95% CI)		Mean difference between groups (95% CI)	Group x time *p*-value
		SHED-IT WLM	**Control**		
Resting Heart Rate (bpm) [b g]	6	1.0 (-1.3, 3.2)	-1.1 (-3.6, 1.5)	2.0 (-1.4, 5.5)	
	12	1.4 (-1.7, 4.5)	-0.3 (-3.6, 3.0)	1.7 (-2.8, 6.3)	0.49
Physical activity (steps/day) [b g h]	6	-413 (-1172, 347)	**-930 (-1716, -144)**	517 (-582, 1617)	
	12	-351 (-1214, 512)	-329 (-1228, 570)	-22 (-1273, 1229)	0.63
Sitting time (min/day) [i]	6	**-40 (-75, -5)**	-33 (-71, 5)	-7 (-59, 44)	
	12	-41 (-90, 8)	23 (-29, 75)	-63 (-135, 8)	0.08
Energy intake (kJ/day) [b g]	6	-1 (-459, 457)	57 (-456, 570)	-58 (-750, 635)	
	12	636 (-84, 1356)	712 (-58, 1483)	-76 (-1136, 983)	0.98
Fruit & Vegetables (servings/day) [b g]	6	**0.6 (0.1, 1.1)**	-0.3 (-0.9, 0.3)	**0.9 (0.2, 1.7)**	
	12	**1.1 (0.5, 1.7)**	0.1 (-0.6, 0.7)	**1.1 (0.1, 2.0)**	**<0.05**
Risky alcohol consumption [c j]	6	0.2 (-0.4, 0.8)	**0.6 (0.0, 1.2)**	-0.4 (-1.2, 0.5)	
	12	0.4 (-0.1, 0.9)	0.4 (-0.1, 0.8)	0.0 (-0.6, 0.7)	0.59
Portion size [a b d g j]	6	**0.1 (0.0, 0.1)**	0.0 (-0.0, 0.1)	0.0 (-0.1, 0.1)	
	12	**0.1 (0.0, 0.2)**	0.0 (-0.0, 0.1)	0.1 (-0.0, 0.2)	0.38
Breakfast frequency (days/week)	6	0.0 (-0.3, 0.2)	-0.3 (-0.6, -0.1)	0.3 (-0.0, 0.6)	
	12	0.0 (-0.2, 0.2)	**-0.2 (-0.4, -0.1)**	**0.2 (0.0, 0.5)**	**<0.05**

BMI = Body-mass index; bpm = beats per minute; CI = confidence intervals; ITT = intention-to-treat; WLM = weight loss maintenance. Bold font represents a significant effect.

[a] Adjusted for Study entry BMI. [b] Adjusted for Phase I change. [c] Adjusted for Age. [d] Adjusted for BMI x Treatment. [e] Adjusted for Phase I change x Treatment. [f] Adjusted for Age x Time. [g] Adjusted for Phase I change x Time. [h] n = 81. [i] n = 86. [j] Adjusted for socio-economic status.

7.3.2 Change in secondary outcomes

During Phase I, significant improvements were observed for most secondary outcomes including BMI, % body fat, visceral fat, waist circumference, blood pressure, resting heart rate, physical activity, energy intake, risky alcohol consumption, portion size, and breakfast consumption (Table 7.1). At 12 months post-randomisation, significant between group differences were only observed for daily servings of fruit and vegetables and frequency of breakfast consumption (Table 7.2). For energy intake, men reduced their kJ by approximately 1900kJ during Phase I and by 12 months the daily kJ intake of the sample remained approximately 1200 kJ below study entry, with no between group differences. Although no significant differences were found for physical activity, randomised men increased step counts by approximately 1600 steps/day during Phase I and maintained an increase of 1300 steps/day above study entry at 12 months.

7.4 Discussion

This study investigated whether a gender-tailored, scalable WLM intervention would reduce weight regain over 12 months in a sample of men who had lost weight with a gender-tailored weight loss program. During the weight loss phase, the men lost 7.3 kg on average. Twelve months after randomisation into the WLM phase, the *SHED-IT WLM* group had regained 8% of their initial weight loss compared to 28% in the self-help control group, but this difference was not significant. Significant WLM intervention effects were observed for daily fruit and vegetable intake and frequency of breakfast consumption but not for other secondary outcomes. Over half of the men who completed the study maintained a 5% weight loss or greater from the beginning of Phase I.

The primary hypothesis of this study was not supported. While this may indicate that the *SHED-IT WLM Program* was not effective, it is also important to consider the results in the context of the broader WLM literature. Notably, the 1.5 kg difference in weight regain between groups at 12 months was comparable to the 12-month effect reported in a recent meta-analysis of RCTs testing behavioural WLM programs against controls (i.e., 1.6 kg) (49). This is promising, as many of the meta-analysed interventions included substantial staff-dependent support including multiple face-to-face sessions and telephone consultations (49). In comparison, the *SHED-IT WLM Program* was essentially identical for all participants and included no personal support, providing greater potential for widespread dissemination.

Further, the SHED-IT WLM group demonstrated comparable, if not superior, maintenance effects to other WLM programs in the literature. For example, in the *U.S. WLM Trial* (280), the personal-contact WLM group regained ~25% of the initial 8.5 kg weight loss despite receiving 20 face-to-face sessions during weight loss and 12 face-to-face or phone-based consultations during WLM (49, 280). In contrast, the *SHED-IT WLM* group regained 8% of their initial 7.3 kg weight loss at 12 months despite receiving standardised resource packs in both phases of the trial. However, contrary to expectations, the control group regained only 28% of initial weight loss at 12 months, despite receiving no additional resources after completing the *SHED-IT Weight Loss Program*. To compare, these results are comparable to those observed in the personal-contact intervention group from the *U.S. WLM Trial* who had regained ~25% at 12 months and superior to the control arm who regained ~45% (49, 280).

As the *SHED-IT Weight Loss Program* was originally developed as a stand-alone intervention, it also encouraged men to make sustainable and realistic lifestyle changes. Although the *SHED-IT WLM Program* was informed by research suggesting that successful WLM requires unique skills and behaviours to those implemented during weight loss (55), other researchers have challenged this assumption and contended that a sustainable approach during weight loss is more critical (302). In contrast to the current study, many previous WLM RCTs have used unsustainable weight loss strategies during Phase I (e.g., very low calorie diets) without imparting any cognitive or behavioural strategies (49, 245), which may lead to further barriers during WLM (49, 302). Although there is some uncertainty around whether maintenance-specific skills and behaviours are required (49), we contend that long-term success requires realistic and sustainable changes during weight loss that align with an individual’s lifestyle and preferences. This approach may explain why 89% of the control group were able to stay below their entry weight 15 months post study entry.

The dietary and physical activity findings were mixed. Despite a significant decrease in daily kJ intake during Phase I, each group slightly increased their kJ intake during Phase II, which is consistent with other studies (280). However, significant intervention effects were found for daily servings of fruit and vegetables and frequency of breakfast consumption, which are important findings given: (i) 96% of Australian men are not meeting fruit and vegetable intake recommendations,(6) and (ii) fruit and vegetable intake (52, 54, 55, 235) and regular breakfast consumption (52, 56-58) are associated with long-term WLM. Although no intervention effect for physical activity was observed during the RCT, both groups maintained an increase of ~1300 steps per day above study entry levels. This represents a clinically important finding given that only 20% of Australian men are meeting physical activity recommendations (9) and previous physical activity interventions for men have been characterised by mixed findings, poor study quality, large drop outs, short-term assessments, supervised exercise regimes, and a lack of objective measures (284). Although successful WLM requires further increases in physical activity levels after weight loss (50, 64, 65) the men in the current study may have believed this to be unnecessary as most maintained their weight within the recommended range (± 2.3 kg from randomisation). The *SHED IT WLM Program* also had a focus on resistance training, which is not accurately assessed with pedometry.

This assessor-blinded RCT had several strengths including: use of intention-to-treat analysis, allocation concealment during randomisation, objective assessment of physical activity, and inclusion of a follow-up assessment after the conclusion of the maintenance program. Further, few WLM trials to date have been conducted outside of the USA or Scandinavia and many have recruited participants at high risk for CVD or other health complications, which limits generalisability (49). In contrast, the current trial used relatively minimal selection criteria to maximise the applicability of results to the general population (287). This study also has some limitations to acknowledge. As the RCT only included men who lost at least 4 kg during the weight loss phase, the generalisability of the current findings are limited to men that respond to initial weight loss. However, this is a standard study design feature in WLM research (49) and aligns with the primary aim of the study (i.e., to test the effectiveness of a WLM intervention). In addition, due to funding timelines, the weight loss phase lasted only three months. A longer weight loss intervention phase may have led to more men becoming eligible for

Phase II as they would have had more time to lose the required 4 kg. Finally, although the study was powered for weight, it was not powered for the secondary outcomes.

Achieving long-term weight loss is a considerable challenge for many men. Twelve months after losing at least 4 kg with the *SHED-IT Weight Loss Program*, men in this study had maintained 72% of their weight loss. This maintenance effect increased to 92% among men who also received the *SHED-IT WLM Program*, but the difference between groups was not significant. Given the relative effectiveness of the *SHED-IT Weight Loss Program*, a longer research design may be required in future studies to determine the unique benefit of the additional WLM program. Although the primary study hypothesis was not supported, this study has demonstrated that gender-tailored, theory-based programs can assist men to maintain modest weight loss.

CHAPTER 8

IMPACT OF A MALE-ONLY WEIGHT LOSS MAINTENANCE PROGRAM ON SOCIAL COGNITIVE DETERMINANTS OF PHYSICAL ACTIVITY AND HEALTHY EATING: A RANDOMISED CONTROLLED TRIAL

Preface:

This chapter presents the results of the *SHED-IT Weight Loss Maintenance Trial* for men's cognitions and behaviour in relation to: i) moderate-to-vigorous physical activity (MVPA), and ii) discretionary food intake. The physical activity results of this paper align with the *Primary Aim* of this thesis (i.e., to evaluate the effect of the *SHED-IT Weight Loss Maintenance Program* on men's MVPA cognitions and MVPA behaviour, 12 months after successfully completing the *SHED-IT Weight Loss Program*).

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Abstract

Objectives: To examine the effect of a gender-tailored, Social Cognitive Theory (SCT)-based weight loss maintenance (WLM) intervention on men's physical activity and healthy eating cognitions and behaviours 12 months after completing a weight loss program. **Design**: A two-phase, assessor-blinded, randomised controlled trial.

Methods: Ninety-two overweight/obese men (mean (SD) age: 49.2 years (10.1), BMI: 30.7 (3.3) kg/m^2) who lost at least 4 kg after completing the 3-month SCT-based *SHED-IT Weight Loss Program* were randomly allocated to receive: (i) the SCT-based *SHED-IT WLM Program*, or (ii) no additional resources (self-help control group). The 6-month gender-tailored *SHED-IT WLM Program* was completely self-administered and operationalised SCT behaviour change principles to assist men to increase moderate-to-vigorous physical activity (MVPA) and decrease energy-dense, nutrient-poor (discretionary) food consumption after initial weight loss. After randomisation (baseline), men were re-assessed at 6 months (WLM post-test) and 12 months (6-month WLM follow-up). SCT cognitions (e.g., self-efficacy, goal setting), MVPA, and discretionary food consumption were assessed with validated measures.

Results: Following significant improvements in cognitions, MVPA and discretionary food consumption during the weight loss phase, intention-to-treat, linear mixed models revealed no significant group-by-time differences in cognitions or behaviours during the WLM phase. Initial improvements in MVPA and some cognitions (e.g., goal setting, planning, social support) were largely maintained by both groups at the end of the study. Dietary effects were not as strongly maintained, with the intervention and control groups maintaining 57% and 75% of the Phase I improvements in discretionary food intake, respectively.

Conclusions: An additional SCT-based WLM program did not elicit further improvements over a self-help control in the cognitions or behaviours for MVPA or discretionary food intake of men who had lost weight with a SCT-based weight loss program.

8.1 Introduction

Rising male obesity rates are an international health concern (2). Between 1980 and 2013, the global prevalence of overweight and obesity in adult men increased from 29% to 37% (2). Although men have traditionally been under-represented in experimental weight loss research (38, 217), the field has progressed considerably in recent years with several methodologically rigorous male-only randomised controlled trials (RCTs) providing important insights into how best to engage and assist men to achieve clinically meaningful weight loss (303-305). However, weight regain after weight loss remains a major public health and research challenge. Indeed, systematic reviews show that approximately 50% of lost weight is regained in the first year after treatment alone (45, 46).

To address this problem, researchers are now testing weight loss maintenance (WLM) interventions, where participants are taught additional skills or provided with additional support in an attempt to reduce weight regain. In a recent meta-analytic review, Dombrowski and colleagues determined that participants who received a WLM program regained 1.6 kg less than controls on average in the 12 months after weight loss (49). However, in a review of dietary approaches to WLM, Collins and colleagues reported that only 14/56 studies reported significant intervention effects (245), suggesting the field is still in its infancy. Notably, as men were under-represented in both of these WLM reviews, little is known about how to assist men to achieve long-term success (49, 245). This provides a strong rationale for the development and assessment of WLM programs that specifically target men.

Although genetic and environmental factors are important drivers of weight gain, cognitive and behavioural factors also play a significant role (8). In this sense, health psychology can provide an important contribution to the development of effective weight management interventions (48). For example, systematic examinations of psychological theories have informed researchers on which cognitive, behavioural, social, and environmental factors may be most important to target in health-behaviour interventions (306). Further, the application of health psychology theory may have particular importance for WLM interventions, as people rely on effective cognitive strategies and further behavioural improvements to overcome the powerful physiological responses that influence weight regain (307). For example, research suggests that successful weight loss maintainers perform close to 300 minutes of moderate-to-vigorous physical activity (MVPA) per week (65), which is a considerably greater dose than is recommended for initial weight loss alone (i.e., 150 minutes of moderate-intensity activity per week) (64). However, despite these potential applications, most WLM interventions to date have not been explicitly informed by theory (49). To progress the field, experimental research is needed to: (i) test the assumptions of behaviour change theories during WLM, and (ii) determine which social and cognitive determinants can be effectively targeted to increase the longevity of participants' weight loss and subsequent health outcomes (48).

Bandura's (1986, 2004) *Social Cognitive Theory* (SCT) is one such theory, which has received considerable attention in the literature (72). The pivotal construct in SCT is self-efficacy, which represents the belief that one can exercise control over one's health habits (71). In addition to directly influencing behaviour, self-efficacy is hypothesised to indirectly influence behaviour through interaction with the following constructs: (i) outcome expectations (i.e., the perceived benefits and costs of performing a behaviour), (ii) goals (i.e., intentions and self-regulatory capabilities), and (iii) socio-structural barriers and facilitators (e.g., perceived environment, social support) (69, 71).

Notably, SCT has shown good utility for understanding and predicting physical activity (286) and healthy eating (e.g., (308)), which are the two key behaviours associated with weight management. Indeed, SCT has informed the development of several successful weight loss programs in recent years (e.g., (82, 162)). Although these factors also indicate that SCT may also be a useful theory to inform WLM interventions, this has yet to be confirmed, given the dearth of theory-based research in the field (48). Indeed, to the authors' knowledge, no RCTs in men have tested the effectiveness of a WLM intervention that operationalises the core SCT behaviour change constructs or reported the impact of the intervention on these constructs.

The *SHED-IT Weight Loss Maintenance Trial* was conducted to investigate the utility of a gender-tailored, SCT-based WLM program for men. Although the core focus of the trial was on the maintenance of weight loss, and the anthropometric and physiological outcomes of this RCT are reported elsewhere (309), the aim of the current exploratory analysis was to examine the program's effect on men's physical activity and healthy eating cognitions and behaviours in the 12 months after initial weight loss. Compared to the self-help control group, it was hypothesised that men who received the *SHED-IT WLM Program* would demonstrate: i) significantly greater improvements in cognitions and behaviour relating to MVPA, and ii) significantly greater improvements in cognitions and behaviour relating to energy-dense, nutrient-poor 'discretionary' food during the WLM phase.

8.2 Methods

8.2.1 Study design

This investigation presents a secondary analysis of data from the *SHED-IT Weight Loss Maintenance Trial* (287). The study was a two-phase, parallel group RCT (allocation ratio 1:1) that tested the effectiveness of the *SHED-IT WLM Program* to prevent weight regain in a sample of men who had previously lost weight (Figure 7.1). As noted above, the primary aim of this investigation was to examine the effect of the program on men's MVPA and discretionary food cognitions and behaviours. The study was granted institutional ethics approval, was prospectively registered with the *Australia New Zealand Clinical Trials Registry* (ACTRN12612000749808), and adhered to the guidelines provided in the *Consolidated Statement of Reporting Trials* (CONSORT). Extensive details on the study methods (287) and primary outcomes (309) are reported elsewhere.

8.2.2 Participants

Briefly, 209 overweight and obese men (18-65 years, BMI 25-40 kg/m^2) were recruited from the Hunter Region of New South Wales, Australia. Men were eligible for Phase I (i.e., the weight loss phase) if they: were aged 18-65 years, had a BMI 25-40 kg/m^2, had access to the internet and a mobile phone, were not currently taking medication to lose or gain weight, did not have diabetes requiring insulin treatment, and had not experienced recent weight loss (i.e., 5% of bodyweight in previous 6 months). Men were eligible for Phase II (i.e., the WLM RCT) if they had lost at least 4 kg during Phase I. All men provided written informed consent prior to enrolment (287).

8.2.3 Phase I: Weight loss

In Phase I, 209 overweight and obese men were provided with the 3-month *SHED-IT Weight Loss Program*, which was previously tested in both an efficacy trial (83, 84) and an effectiveness trial (81, 300). Briefly, the program includes: i) The '*SHED-IT Weight Loss DVD for Men*', (ii) The '*SHED-IT Weight Loss Handbook for Men'*, (iii) The '*SHED-IT Weight Loss Log Book for Men*', (iv) weekly SCT-based texts to reinforce program messages, and (v) weight loss tools including a pedometer and a tape measure. Men are also encouraged to self-monitor their food intake and physical activity, using either the CalorieKing™ website or MyFitnessPal™ mobile phone app, to create a 2000kJ deficit on most days.

8.2.4 Phase II: Weight loss maintenance RCT

After 3 months, 92 men who had lost at least 4 kg during Phase I and were willing to participate in Phase II (i.e., the WLM RCT) were randomly allocated to: i) a WLM group, who received the *SHED-IT WLM Program*, or ii) a self-help control group, who received no additional support or resources.

The aim of the *SHED-IT WLM Program* was to provide evidence-based WLM recommendations in a style that was engaging and appealing to men. The program included the following components: (i) the '*SHED-IT WLM Handbook for Men'*, (ii) the *'SHED-IT WLM Log Book for Men'* (iii) weekly SCT-based emails, which included video messages from two study researchers (PJM and MDY), (iv) SCT-based bi-weekly text messages, (v) the '*SHED-IT Resistance Training Handbook for Men*', and (vi) a portable resistance training device (Gymstick™) and a pedometer (Digiwalker SW200). Men were encouraged to continue use the CalorieKing™ website or MyFitnessPal™ app as needed.

8.2.5 Program scalability and theoretical framework

To maximise scalability, neither program included any personal contact (e.g., face-to-face or group support, phone contacts, or exercise sessions) or individually-tailored components. In essence, the programs were identical for each participant and, aside from standardised text messages and emails, the men were not offered any additional support between assessments. This approach is considerably less intensive than previous studies (49) and greatly increases the potential for dissemination. In addition, both programs were explicitly informed by Bandura's SCT, including operationalisation of key SCT constructs, and designed specifically to appeal to men. Extensive detail on the development, intervention components, behaviour change techniques, and theoretical mapping of the programs is available elsewhere (287).

The programs explicitly targeted the core SCT constructs to generate changes in key weight-related behaviours. For example, as noted above, both included a *Log Book* where participants were advised to complete key SCT tasks. With reference to the latest behaviour change technique taxonomy (246), these tasks included setting graded tasks, goal setting (behaviour and outcome), planning social support, prompting self-monitoring (behaviour and outcome), and providing rewards contingent on successful behaviour. Although participants were encouraged to focus on any physical activity or dietary behaviours during the weight loss phase, the *SHED-IT WLM Program* explicitly focused on two recommendations which have been linked to successful WLM in the literature: (i) increasing structured MVPA after weight loss to at least 300 minutes of MVPA per week (65) and (ii) reducing consumption of discretionary foods (50).

The gender tailoring process was guided by the men's health literature (e.g., (240, 242)) and incorporated data from the qualitative (86) and quantitative (85) process evaluations of previous SHED-IT weight loss trials. Consistent with the *SHED-IT Weight Loss Program*, gender-tailoring was applied to both surface-structure components (e.g., pictures of men, male health statistics) and deep-structure components, which appeal to men's health values (e.g., a frank approach, thoughtful use of humour, scientific legitimacy) (241).

8.2.6 Data collection and measures

Trained, blinded assessors conducted all assessments at the University of Newcastle's Human Performance Laboratory. Before entering the laboratory, all participants were greeted by a member of the research team who answered any questions and reminded them not to reveal any information about their group assignment to the assessors. Assessments were held at 'study entry' (i.e., the start of Phase I; Aug. 2012), 'WLM baseline' (i.e., the start of Phase II [WLM RCT]; Nov. 2012), '6 months' (WLM post-test; May 2013) and '12 months' (6-month WLM follow-up; Nov. 2013).

Validated scales were used to assess the behaviour change cognitions described in Bandura's SCT (e.g., self-efficacy). Validation data and references are located in Table 8.1 (physical activity scales) and Table 8.2 (discretionary food scales). Before completing the physical activity scales, men were asked to read the study definition of 'regular physical activity' (i.e., 'at least 60 min of physical activity (at a moderate intensity or greater) on 5 or more days each week'). Similarly, before completing the 'discretionary food' scales, men were provided with a reference card containing definitions of 'healthy foods' and 'discretionary foods' adapted from the Australian Guide to Healthy Eating (265). These cards also contained pictures of commonly consumed discretionary foods reported by Australian men in previous weight loss studies (e.g., pizza, potato chips, ice-cream) (77, 79).

Time spent in *MVPA* was assessed with a slightly modified version of the validated Godin Leisure Time Exercise Questionnaire (GLTEQ) (252). As in the original GLTEQ, men reported the number of times per week they engaged in moderate or vigorous physical activity for at least 10 minutes in the previous month. In the current version, participants also estimated the average session duration for each category. These 'frequency' and 'duration' categories were then multiplied within each category and summed to provide a measure of weekly MVPA minutes (251). This adapted measure has demonstrated good sensitivity to change in previous weight loss research with men (104). Total energy from *discretionary foods* was assessed using the Australian Eating Survey (AES), which is a validated 120-item food frequency questionnaire (227). *Weight* was measured in light clothing, without shoes on a digital scale to 0.01 kg (CH-150kp, A&D Mercury Pty Ltd., Australia).

Table 8.1. SCT measures for physical activity with validity and reliability statistics.

Construct (Source)	Items (Range)	Anchors	Validity and reliability statistics		Example
			α [a]	ICC (95% CI) [b]	
Self-efficacy (266)	8 (1-5)	Not at all confident – Completely confident	0.92	0.88 (0.68 to 0.95)	*e.g., I am confident that I can get 'regular physical activity' when I am a little tired*
Positive outcome expectations (266)	5 (1-5)	Strongly disagree – Strongly agree	0.78	0.74 (0.36 to 0.89)	*e.g., 'Regular physical activity' would help me control my weight*
Perceived barriers (266) [c]	3 (1-5)	Strongly disagree – Strongly agree	0.75	0.82 (0.58 to 0.93)	*e.g., 'Regular physical activity' would take up too much of my time*
Social support (268) [d]	10 (1-5)	Never/does not apply – Very often	*Family:* 0.91 *Friends:* 0.91	0.96 (0.91 to 0.98) 0.92 (0.80 to 0.97)	*e.g., During the past month, my family/friends were active with me*
Behavioural goal (269) [e]	2 (1-7)	Extremely unmotivated / undetermined – Extremely motivated / determined	0.86	0.92 (0.80 to 0.97)	*e.g., I am motivated/determined to engage in 'regular physical activity'*
Goal setting (192) [f]	10 (1-5)	Strongly disagree – Strongly agree	0.85	0.80 (0.50 to 0.92)	*e.g., I often set physical activity goals*
Planning (267)	4 (1-7)	Strongly disagree – Strongly agree	0.93	0.70 (0.30 to 0.87)	*e.g., I make plans concerning when I am going to engage in 'regular physical activity'*

α, Cronbach's alpha (internal consistency); ICC, intra-class correlation coefficient; CI, confidence interval

[a] Internal consistency of the scales in the weight loss maintenance RCT sample at study entry (n = 92). [b] Two-week test-retest reliability of the scales in an independent pilot sample of 22 overweight and obese Australian men (mean(SD) age 39.7 (14.8) years; BMI 29.1 (5.1) kg/m^2). [c] Scale adapted from a 5 item measure that demonstrated unacceptable internal consistency in the pilot sample (α = 0.46). [d] Scale measured separately for family and friends. [e] A validated measure of intention was used to represent the behavioural goal construct, as Bandura (2004) has acknowledged a considerable conceptual overlap between these two variables. [f] Original anchors ("does not describe me" to "describes me completely") were replaced as the pilot sample found them difficult to interpret.

Table 8.2. SCT measures for intake of discretionary foods with validity and reliability statistics.

Construct (Adapted from)	**Items (Range)**	**Anchors**	**Validity and reliability statistics**		**Example**
			α [a]	**ICC (95% CI) [b]**	
Self-efficacy (271)	12 (1-5)	Not at all tempted – Extremely tempted	0.84	0.76 (0.42 to 0.90)	*e.g., How tempted would you be to eat your favourite junk food while having a good time with friends at a party*
Positive outcome expectations (162)	8 (1-5)	Strongly disagree – Strongly agree	0.80	0.77 (0.45 to 0.91)	*e.g., If I eat less junk food I expect I will lose weight*
Perceived barriers (162)	12 (1-5)	Strongly disagree – Strongly agree	0.87	0.89 (0.74 to 0.96)	*e.g., If I eat less junk food I expect I will be bored with what I have to eat*
Social support (268) [c]	5 (1-5)	Never – Very often	*Family:* 0.88 *Friends:* 0.89	0.87 (0.69 to 0.95) 0.91 (0.79 to 0.96)	*e.g., In the past month, my family/friends encouraged me not to eat junk food when I was tempted to do so*
Social sabotage (268) [c]	5 (1-5)	Never – Very often	*Family:* 0.74 *Friends:* 0.75	0.83 (0.58 to 0.93) 0.76 (0.41 to 0.90)	*e.g., In the past month, my family/friends offered me junk food I'm trying not to eat*
Perceived environment (274) [d]	13 (1-4)	Never/rarely – Always	0.88	0.75 (0.39 to 0.90)	*Participants indicate how frequently various junk foods (e.g., chocolate, potato chips) are available in their day-to-day life*
Planning (272)	5 (1-4)	Strongly disagree – Strongly agree	0.92	0.89 (0.74 to 0.96)	*e.g., When it comes to eating less junk food, I make detailed plans regarding when I have to pay attention to prevent lapses*
Behavioural strategies (273)	15 (1-5)	Never – Many times	0.85	0.77 (0.47 to 0.91)	*e.g., In the past month I set goals to eat less junk food*

α, Cronbach's alpha (internal consistency); ICC, intra-class correlation coefficient; CI, confidence interval

[a] Indicates the internal consistency of the scales in the weight loss maintenance RCT sample at study entry (n = 92). [b] Two-week test-retest reliability of the scales in an independent pilot sample of 22 overweight and obese Australian men (mean(SD) age 39.7 (14.8) years; BMI 29.1 (5.1) kg/m^2). [c] Scale measured separately for family and friends. [d] Items chosen to reflect the most commonly consumed discretionary foods reported by men in the SHED-IT Community RCT (81).

8.2.7 Statistical analysis

Phase I changes were assessed using paired-samples t-tests. For the WLM RCT data, linear mixed models were used to assess MVPA, discretionary food consumption and all SCT cognitions for the impact of treatment (i.e., WLM intervention vs. self-help control), time (i.e., 'WLM baseline', '6 months', and '12 months'), and the treatment by time interaction. Linear mixed models are recommended for analysing experimental data as they are robust to the biases of missing data and model missing responses in the results, consistent with an intention-to-treat approach (301). Age, socio-economic status, BMI, and Phase I change score were examined as covariates and adjusted for where significant. If a covariate was significant, two-way interactions with treatment and time also examined and significant effects were also added to the model. For the RCT results, a Bonferroni correction was applied to adjust for the multiple comparisons. Cohen's *d* effect sizes were calculated as the mean difference between groups divided by the pooled standard deviation of the outcome at baseline (d = $M_1–M_2/SD_{pooled}$). Effect sizes were interpreted as small (0.2-0.4), medium (0.5-0.7) and large (>0.8) (310).

8.2.8. Sample size

The primary WLM study (309) was powered to detect a between-group difference of 3 kg (SD 4 kg) in weight regain during the RCT (i.e., Phase II). Assuming a 25% attrition rate during Phase II, the study required 39 men to be randomised into each group for 80% power to detect a 3 kg difference in weight regain at 12 months (p=0.05, two-sided).

8.2.9. Randomisation and allocation

Participants were randomised at an individual level by an independent statistician who had no contact with participants during the study. The allocation sequence was generated by a computer-based random number-producing algorithm in randomly varied block lengths (stratified by BMI and Phase I weight loss). Information for the two study groups was pre-packed into identical opaque envelopes and ordered according to the randomisation schedule by a research assistant who was not involved in enrolment, assessment or allocation. Study participants completed all assessments before meeting with a member of the research team who was not involved in assessments. The researcher allocated the participant to the next available position in their stratification category before opening the corresponding envelope and providing details of the allocated group using a standardised protocol.

8.3 Results

As seen in Table 8.3, randomised men had a mean age of 49.2 years (range, 27-65 years) and a mean weight of 98.3 kg (range, 70.9-138.9). At baseline (i.e., at the conclusion of Phase I), the men were performing an average of 207 minutes/week of MVPA (SD 147) and consuming an average of 3215 kJs/day of discretionary food (SD 1981). Phase II retention for the cognitive and behavioural outcomes was 76% at 6 months and 78% at 12 months. No significant differences in retention were observed between the intervention and control groups at 6 months (χ^2=1.20, *df*=1, *p*=0.27) or 12 months (χ^2=0.01, *df*=1, *p*=0.91). As reported elsewhere, intention-to-treat linear mixed models revealed a 1.5 kg mean between-group difference in weight regain at 12 months (95%CI -0.7, 3.7, *p*=0.18), with the intervention group regaining 0.6 kg (95%CI -0.9, 2.2) (92% maintenance of Phase I reduction) and the control group regaining 2.1 kg (95%CI 0.5, 3.7) (72% maintenance of Phase I reduction) (309). Tables 8.4 and 8.5 present the social cognitive and behavioural results of the trial for MVPA and discretionary food intake, respectively.

Overall, the *SHED-IT WLM Program* was well received by the men. At post-test, 93% acknowledged that the program increased their knowledge and skills regarding WLM, 95% reported having a better understanding of what is required for WLM and 85% believed it was a helpful addition to the Phase I *SHED-IT Weight Loss Program*.

Table 8.3. Baseline characteristics of men randomised into the SHED-IT Weight Loss Maintenance RCT (n = 92).

Outcome	**Mean (SD) Phase I change [a]**			**WLM baseline mean (SD) [b]**		
	SHED-IT WLM	**Self-help Control**	**Total [Cohen's d]**	**SHED-IT WLM**	**Control**	**Total**
Age (years)	-	-	-	49.5 (9.9)	49.0 (10.4)	49.2 (10.1)
Weight (kg)	-7.3 (2.0)	-7.4 (2.9)	-7.3 (2.5) [0.51]	98.1 (14.0)	98.5 (14.9)	98.3 (14.3)
BMI (kg/m^2)	-2.3 (0.7)	-2.3 (1.0)	-2.3 (0.9) [0.70]	30.8 (3.3)	30.6 (3.4)	30.7 (3.3)
MVPA (minutes/week)	126.6 (146.7)	133.4 (155.7)	129.9 (150.4) [1.53]	207.9 (135.6)	205.9 (159.3)	206.9 (147.3)
Discretionary foods (kJ/day) [c]	-2026.5 (2036.2)	-1492.5 (1620.8)	-1765.3 (1854.2) [0.74]	3180.3 (2114.1)	3250.5 (1817.9)	3214.7 (1980.7)
Physical activity cognitions [possible range]						
Self-efficacy [1-5]	0.1 (0.7)	0.1 (0.8)	0.1 (0.7) [0.16]	3.2 (0.9)	3.2 (0.8)	3.2 (0.9)
Positive outcome expectations [1-5]	-0.1 (0.5)	0.0 (0.6)	-0.0 (0.6) [0.05]	4.3 (0.5)	4.2 (0.5)	4.3 (0.5)
Barriers [1-5] [d]	-0.1 (0.7)	-0.1 (0.7)	-0.1 (0.7) [0.16]	2.4 (0.8)	2.4 (0.8)	2.4 (0.8)
Social support (family) [1-5]	0.6 (0.8)	0.4 (0.8)	0.5 (0.8) [0.60]	2.8 (1.0)	2.7 (1.0)	2.8 (1.0)
Social support (friends) [1-5]	0.3 (0.9)	0.2 (0.7)	0.3 (0.8) [0.36]	1.9 (1.0)	1.9 (1.0)	1.9 (1.0)
Behavioural goal [1-7]	-0.2 (0.8)	-0.4 (1.5)	-0.3 (1.2) [0.39]	5.8 (1.1)	5.4 (1.3)	5.6 (1.2)
Goal setting [1-5]	0.6 (0.7)	0.5 (0.8)	0.6 (0.7) [0.93]	3.1 (0.8)	3.1 (0.7)	3.1 (0.7)
Planning [1-7]	1.0 (1.5)	0.4 (1.7)	0.7 (1.6) [0.46]	5.7 (1.2)	5.5 (1.3)	5.6 (1.3)
Discretionary food cognitions [possible range]						
Self-efficacy [1-5]	0.3 (0.5)	0.5 (0.6)	0.4 (0.6) [0.66]	3.1 (0.8)	3.2 (0.7)	3.1 (0.7)
Positive outcome expectations [1-5]	-0.2 (0.5)	0.0 (0.6)	-0.1 (0.5) [0.13]	4.0 (0.6)	4.1 (0.5)	4.1 (0.5)
Barriers [1-5] [d]	-0.3 (0.6)	-0.4 (0.5)	-0.4 (0.6) [0.65]	2.3 (0.7)	2.3 (0.5)	2.3 (0.6)
Perceived environment [1-4] [d]	-0.2 (0.6)	-0.3 (0.6)	-0.2 (0.6) [0.39]	2.0 (0.6)	2.0 (0.6)	2.0 (0.6)
Social support (family) [1-5]	0.5 (1.1)	0.7 (0.9)	0.6 (1.0) [0.56]	2.9 (1.1)	3.1 (1.0)	3.0 (1.1)
Social support (friends) [1-5]	0.5 (0.8)	0.5 (0.9)	0.5 (0.8) [0.90]	1.9 (1.0)	1.8 (1.0)	1.9 (1.0)
Social sabotage (family) [1-5] [d]	-0.1 (0.7)	0.0 (0.6)	-0.0 (0.7) [0.03]	2.1 (1.0)	2.1 (0.8)	2.1 (0.9)
Social sabotage (friends) [1-5] [d]	-0.1 (0.6)	0.1 (0.8)	0.0 (0.7) [0.03]	1.8 (0.9)	2.0 (0.8)	1.9 (0.9)
Planning [1-4]	0.1 (0.6)	0.3 (0.7)	0.2 (0.7) [0.32]	2.5 (0.5)	2.6 (0.5)	2.6 (0.5)
Behavioural strategies [1-5]	0.6 (0.6)	0.8 (0.5)	0.7 (0.6) [1.30]	3.0 (0.7)	3.0 (0.6)	3.0 (0.7)

Note. BMI = body-mass index; WLM = Weight Loss Maintenance.
[a] Calculated as score at 'baseline' (i.e., start of Phase II, randomisation into the WLM RCT) minus score at 'study entry' (i.e., the start of Phase I; weight loss). [b] 'Baseline' for this study was measured at randomisation into the WLM RCT (i.e., start of Phase II). [c] Energy-dense, nutrient poor, discretionary choices. [d] A reduction in the mean score for this variable represents a favourable treatment effect.

Table 8.4. Intention-to-treat changes in MVPA cognitions and weekly MVPA during the SHED-IT Weight Loss Maintenance RCT (i.e., Phase II) (n = 92).

Outcome	Time	Mean change from randomisation (95% CI)		Mean difference between groups (95% CI) [Cohen's D]	Group x time *p*-value [a]
		SHED-IT WLM (n = 47)	Self-help Control (n = 45)		
MVPA cognitions					
Self-efficacy [b c]	6	-0.1 (-0.4, 0.1)	-0.4 (-0.6, -0.1)	0.2 (-0.1, 0.6) [0.26]	0.18
	12	-0.2 (-0.4, 0.1)	-0.2 (-0.4, 0.0)	0.0 (-0.3, 0.3) [0.03]	0.30
Positive outcome expectations [b c d e]	6	-0.0 (-0.2, 0.1)	-0.1 (-0.3, 0.0)	0.1 (-0.1, 0.3) [0.21]	0.34
	12	0.1 (-0.1, 0.2)	-0.1 (-0.2, 0.1)	0.1 (-0.1, 0.3) [0.17]	0.26
Barriers [b c d]	6	0.1 (-0.1, 0.3)	0.2 (-0.0, 0.4)	-0.1 (-0.4, 0.2) [0.14]	0.47
	12	-0.1 (-0.3, 0.1)	0.2 (-0.0, 0.4)	-0.2 (-0.5, 0.0) [0.30]	0.08
Social support (family) [b c d f]	6	-0.3 (-0.6, -0.1)	-0.3 (-0.6, -0.0)	-0.0 (-0.4, 0.3) [0.02]	0.91
	12	-0.2 (-0.5, 0.1)	-0.2 (-0.5, 0.1)	-0.0 (-0.4, 0.4) [0.01]	0.97
Social support (friends) [b c d e g]	6	-0.1 (-0.3, 0.1)	-0.3 (-0.5, -0.1)	0.2 (-0.1, 0.5) [0.22]	0.17
	12	0.0 (-0.2, 0.2)	-0.0 (-0.3, 0.2)	0.0 (-0.3, 0.4) [0.01]	0.94
Behavioural goal [b c h]	6	-0.2 (-0.5, 0.1)	-0.3 (-0.7, 0.0)	0.1 (-0.3, 0.6) [0.11]	0.58
	12	-0.4 (-0.7, -0.1)	-0.2 (-0.5, 0.2)	-0.3 (-0.7, 0.2) [0.21]	0.26
Goal setting [b c h]	6	-0.1 (-0.3, 0.0)	-0.0 (-0.2, 0.2)	-0.1 (-0.3, 0.1) [0.14]	0.42
	12	-0.1 (-0.2, 0.1)	-0.1 (-0.3, 0.0)	0.1 (-0.2, 0.3) [0.09]	0.55
Planning [b c h]	6	-0.3 (-0.8, 0.2)	0.1 (-0.4, 0.6)	-0.4 (-1.1, 0.3) [0.32]	0.26
	12	-0.2 (-0.7, 0.2)	-0.1 (-0.5, 0.4)	-0.1 (-0.8, 0.5) [0.11]	0.65
MVPA (minutes/week) [b c]	6	1.6 (-43.4, 46.7)	-25.8 (-74.7, 23.1)	27.4 (-39.1, 93.9) [0.19]	0.41
	12	-16.1 (-68.5, 36.3)	8.8 (-45.3, 62.9)	-24.9 (-100.2, 50.4) [0.17]	0.43

Note. MVPA = moderate-to-vigorous physical activity.
[a] Bonferroni adjusted significance level set to $p < 0.00125$. [b] Adjusted for phase I change. [c] Adjusted for phase I change x time. [d] Adjusted for age. [e] Adjusted for age x time. [f] Adjusted for socio-economic status. [g] Adjusted for age x group. [h] Adjusted for phase I change x group.

Table 8.5. Intention-to-treat changes in discretionary food cognitions and consumption during the SHED-IT Weight Loss Maintenance RCT (i.e., Phase II) (n = 92).

Outcome	Time	Mean change from randomisation (95% CI)		Mean difference between groups (95% CI) [Cohen's D]	Group x time *p*-value [a]
		SHED-IT WLM (n = 47)	Self-help Control (n = 45)		
Discretionary food cognitions					
Self-efficacy [b c d]	6	-0.1 (-0.3, 0.0)	-0.2 (-0.4, -0.1)	0.1 (-0.1, 0.3) [0.10]	0.46
	12	-0.3 (-0.5, -0.2)	-0.1 (-0.3, 0.0)	-0.2 (-0.4, 0.0) [0.29]	0.03
Positive outcome expectations [b c]	6	0.0 (-0.1, 0.2)	0.1 (-0.1, 0.2)	-0.1 (-0.3, 0.2) [0.09]	0.65
	12	0.1 (-0.0, 0.2)	0.0 (-0.1, 0.1)	0.1 (-0.1, 0.2) [0.15]	0.29
Barriers [b c]	6	0.0 (-0.1, 0.2)	0.1 (-0.0, 0.3)	-0.1 (-0.3, 0.1) [0.17]	0.32
	12	0.1 (-0.1, 0.2)	0.1 (-0.2, 0.3)	-0.0 (-0.3, 0.2) [0.07]	0.59
Perceived environment [b c d]	6	0.0 (-0.1, 0.1)	-0.0 (-0.2, 0.1)	0.1 (-0.1, 0.2) [0.13]	0.35
	12	0.0 (-0.1, 0.1)	-0.1 (-0.2, 0.1)	0.1 (-0.1, 0.3) [0.13]	0.58
Social support (family) [b c d e]	6	-0.3 (-0.5, -0.1)	-0.3 (-0.5, -0.1)	-0.0 (-0.3, 0.3) [0.01]	0.94
	12	-0.5 (-0.8, -0.2)	-0.4 (-0.7, -0.1)	-0.0 (-0.4, 0.4) [0.04]	0.98
Social support (friends) [b c d f]	6	-0.2 (-0.4, 0.1)	-0.1 (-0.4, 0.1)	-0.1 (-0.4, 0.3) [0.05]	0.78
	12	-0.2 (-0.4, -0.1)	-0.3 (-0.4, -0.1)	0.1 (-0.1, 0.3) [0.07]	0.64
Social sabotage (family) [b c d]	6	0.2 (-0.0, 0.3)	-0.0 (-0.2, 0.2)	0.2 (-0.1, 0.4) [0.20]	0.15
	12	0.1 (-0.1, 0.2)	0.1 (-0.1, 0.2)	0.0 (-0.2, 0.3) [0.02]	0.29
Social sabotage (friends) [b c d]	6	0.1 (-0.2, 0.3)	0.0 (-0.3, 0.3)	0.1 (-0.3, 0.5) [0.07]	0.75
	12	0.2 (-0.0, 0.4)	0.1 (-0.1, 0.3)	0.1 (-0.2, 0.4) [0.09]	0.83
Planning [b c]	6	-0.1 (-0.3, 0.1)	-0.1 (-0.3, 0.1)	0.0 (-0.3, 0.3) [0.04]	0.90
	12	0.0 (-0.2, 0.2)	-0.1 (-0.3, 0.0)	0.1 (-0.1, 0.4) [0.27]	0.26
Behavioural strategies [b c g]	6	-0.3 (-0.5, -0.1)	-0.2 (-0.4, -0.0)	-0.1 (-0.3, 0.2) [0.12]	0.56
	12	-0.3 (-0.5, -0.2)	-0.4 (-0.5, -0.2)	0.0 (-0.2, 0.3) [0.03]	0.76
Discretionary food (kJ/day)	6	315.0 (-13.6, 643.5)	200.3 (-164.6, 565.1)	114.7 (-376.3, 605.7) [0.06]	0.64
	12	867.9 (461.1, 1274.6)	368.7 (-67.5, 804.8)	499.2 (-97.2, 1095.5) [0.25]	0.25

[a] Bonferroni adjusted significance level set to $p < 0.00125$. [b] Adjusted for *phase I change*. [c] Adjusted for phase I change x time. [d] Adjusted for age. [e] Adjusted for socio-economic status. [f] Adjusted for age x time. [g] Adjusted for phase I change x group.

8.3.1 MVPA outcomes

8.3.1.1 Phase I changes for MVPA variables

In Phase I, randomised men reported a large increase in goal setting (*d*=0.93), and a medium increase in perceived family support (*d*=0.60). Small increases were also observed in social support from friends (*d*=0.36) and planning (*d*=0.46), but no changes were reported in self-efficacy, outcome expectations, or barriers. A small decrease was identified for behavioural goal (*d*=0.39). In addition to these cognition effects, the sample reported a significant, large mean increase in MVPA of 129.9 minutes/week (p<0.001; d=1.53).

8.3.1.2 Phase II changes for MVPA variables

No significant group-by-time effects were observed for any MVPA cognitions during the RCT (Table 8.4). Similarly, the group-by-time effects for MVPA were not significant at post-test (+27.4 mins/week; 95%CI -39.1, 93.9) or follow-up (-24.9 mins/week; -100.2, 50.4).

8.3.1.3 Maintenance of Phase I effects for MVPA variables

Table 8.6 presents a summary of the MVPA cognition effects for both groups from study entry to baseline (i.e., the start of the RCT; 3 months total) and from study entry to the 12 month assessment (i.e., the end of the RCT; 15 months total). At 12 months, both the intervention and control groups had maintained medium-to-large increases in physical activity goal setting and small-to-medium increases in planning and social support. Conversely, both study groups reported medium-to-large decreases in behavioural goal from study entry to 12 months. Aside from a small reduction in perceived barriers for the intervention group, no clear effects were observed for self-efficacy, outcome expectations, or barriers from study entry to 12 months. Phase I increases in MVPA were largely maintained by both groups at 12 months. During Phase II, the intervention group reduced MVPA by 16.1 minutes/week from WLM baseline (87% maintenance of Phase I effect) and the control group increased by 8.8 minutes/week (107% maintenance of Phase I effect).

8.3.2 Discretionary food outcomes

8.3.2.1 Phase I changes for discretionary food variables

During Phase I, randomised men reported large increases in the use of behavioural strategies (e.g., goal setting, d=1.30) and social support from friends (d=0.90). In addition, medium positive effects were observed for self-efficacy (d=0.66), perceived barriers (d=0.65), and family social support (d=0.56) and small positive effects were observed for perceived environment and planning. No clear changes were reported for outcome expectations or social sabotage. In addition, the sample reported a significant, medium-sized mean decrease in discretionary food intake of 1765 kJ/day (p<0.001; d=0.74).

8.3.2.2 Phase II changes for discretionary food variables

As seen in Table 8.5, no significant group-by-time effects were observed for any discretionary food cognitions during the RCT. Similarly, the group-by-time effects for discretionary food consumption were not significant at post-test (+115 kJ/day; 95%CI -376, 606) or follow-up (499 kJ/day; 95% CI -97, 1096).

8.3.2.3 Maintenance of Phase I effects for discretionary food variables

At 12 months, the intervention and control groups had maintained a number of favourable effects from study entry, including medium-to-large effects for behavioural strategies, medium effects for barriers, and small-to-medium effects for planning and perceived environment (Table 8.6). Although no improvements were maintained for outcome expectations, family support or family sabotage, the groups reported overall small-to-medium increases in friend support. Initial increases in self-efficacy were maintained in the control group, but not the intervention group (Table 8.6). During Phase II, the intervention group reported a mean increase in discretionary food consumption of 868 kJ/day (57% maintenance of Phase I effect) and the control group reported a 369 kJ/day increase (75% maintenance of Phase I effect).

Table 8.6. Overall effects for Phase I (from study entry to baseline i.e., the start of the RCT) and for study duration (from study entry to 12 months i.e., the end of the RCT) for the *SHED-IT Weight Loss Maintenance* group and the *SHED-IT Weight Loss*-only self-help control group.

Outcome	SHED-IT WLM (n =47)		Self-help Control (n = 45)	
	Entry to Baseline [a]	Entry to 12 months [b]	Entry to Baseline [a]	Entry to 12 months [b]
Physical activity cognitions				
Self-efficacy	-	-	✓	-
Outcome expectations	-	-	-	-
Barriers [c]	-	✓	✓	-
Social support (family)	✓✓	✓	✓✓	✓
Social support (friends)	✓✓	✓✓	✓	✓
Behavioural goal	×	×××	××	××
Goal setting	✓✓✓	✓✓✓	✓✓✓	✓✓
Planning	✓✓	✓✓	✓	✓
Discretionary food cognitions				
Self-efficacy	✓✓	-	✓✓✓	✓✓
Outcome expectations	×	×	-	-
Barriers [c]	✓✓	✓✓	✓✓✓	✓✓
Perceived environment [c]	✓	✓	✓✓	✓✓
Social support (family)	✓✓	-	✓✓	✓
Social support (friends)	✓✓✓	✓✓	✓✓✓	✓
Social sabotage (family) [c]	-	-	-	-
Social sabotage (friends) [c]	-	×	-	×
Planning	✓	✓	✓✓	✓
Behavioural strategies	✓✓✓	✓✓	✓✓✓	✓✓✓

Note. WLM = weight loss maintenance; ✓ = small favourable effect (d = 0.2-0.4); ✓✓ = medium favourable effect (d = 0.5-0.7); ✓✓✓ = large favourable effect ($d \geq 0.8$); × = small unfavourable effect (d = 0.2-0.4); ×× = medium unfavourable effect (d = 0.5-0.7); ××× = large unfavourable effect ($d \geq 0.8$); - (dash) = no effect ($d < 0.2$).

[a] Change from 'study entry' (i.e., start of Phase I, weight loss) to 'baseline' (i.e., start of Phase II, weight loss maintenance RCT, 3 months total). [b] Change from 'study entry' (i.e., start of Phase I, weight loss) to '12 months' (i.e., end of Phase II, weight loss maintenance RCT, 15 months total). [c] Favourable effect = decrease.

8.4 Discussion

The aim of this study was to examine the effect of a gender-tailored, theory-based WLM intervention on men's SCT cognitions, MVPA, and discretionary food consumption, 6 and 12 months after successfully losing weight. Initial improvements in MVPA and some cognitions (e.g., goal setting, planning, social support) were largely maintained by both groups at the end of the study. Dietary effects were not as strongly maintained, with the intervention and control groups maintaining 57% and 75% of the Phase I improvements in discretionary food intake, respectively. The study hypotheses were not supported as no significant group-by-time effects were observed for cognitions or behaviours during the RCT. This study demonstrated that, for men who lost weight with the gender-tailored, theory-based *SHED-IT Weight Loss Program*, the *SHED-IT WLM Program* did not provide a significant additional benefit for MVPA, discretionary food intake, or the SCT cognitions in the 12 months post-weight loss.

In Phase I, men reported a number of improvements in key SCT cognitions for MVPA including goal setting, planning and social support. Although self-efficacy, outcome expectations and perceived barriers were unchanged, participants reported a large mean increase in self-reported MVPA by the conclusion of the weight loss phase (+130 minutes/week). Similarly, men reported a number of favourable effects for discretionary food cognitions, including increases in self-efficacy, planning, use of behavioural strategies, and perceived social support. Decreases were also observed in perceived barriers and the availability of various discretionary foods in their environment. Although the intervention WLM group received an additional program that targeted these cognitions and behaviours further, this was no more effective than receiving the initial *SHED-IT Weight Loss Program* alone. These findings may be due to a number of reasons including: (i) study design and the weight loss program in Phase 1, (ii) choice of behavioural referent and measurement issues, and (iii) operationalisation of SCT constructs and program adherence.

First, the null findings may be related to the weight loss program used in this trial. During Phase I, all men were provided with the *SHED-IT Weight Loss Program*, which was originally designed as a stand-alone program for men. As such, this program was also explicitly informed by the behaviour change principles outlined in SCT and focused on sustainable behaviour change, which may have obscured the effect of the maintenance program. For example, during Phase I men were encouraged to self-monitor their physical activity and energy intake, set goals for physical activity and healthy eating, and engage their family and friends in their weight loss efforts. Of note, a process evaluation from a previous trial revealed the participants' success in the *SHED-IT Weight Loss Program* was linked to engagement with key SCT tasks during the study (i.e., goal setting and self-monitoring) (85). As such, it is feasible that the control group may have continued to use these strategies throughout the WLM phase.

This may explain why both groups maintained medium-to-large intervention effects for MVPA and discretionary food and small-to-medium effects for most SCT cognitions. Further, this may also explain why the self-help control group in this study, who received no additional resources after the 3-month *SHED-IT Weight Loss Program,* only regained 2.1 kg by 12 months, which was comparable to other WLM intervention groups in the literature (49)

The men's responses may also have been affected by the behavioural referents chosen. For example, given the men were only performing 77 minutes of MVPA per week at study entry, the physical activity referent in this study (regular physical activity = 300 minutes of MVPA/week) may have been too ambitious. Although the average MVPA of the men increased to 208 minutes/week by WLM baseline (i.e., a 270% increase), the men were still considerably short of the 300 minute target. If the participants felt this goal was unattainable, then it would have been much harder to elicit meaningful changes in the associated cognitions, particularly self-efficacy. However, this referent was chosen to reflect the best available recommendations for the required dose of physical activity to maintain weight loss (64, 65). Thus, the challenge for future researchers is to educate men about the importance of reaching this important target, without negatively affecting their self-efficacy.

Further, although the dietary measures assessed cognitions for 'discretionary food intake', the majority of the scales were adapted from measures assessing cognitions regarding adherence to a low-fat diet (Table 8.2). The decision to switch this behavioural referent was both practical, given the lack of published scales assessing cognitions for discretionary food intake, and theoretical, given that discretionary food intake is a globally recognised dietary problem area for men (77, 224) and research shows that dietary composition is not as important as overall energy intake for long-term WLM (263). While all scales demonstrated adequate psychometrics in the current sample and an appropriate pilot sample (287), it is unclear how changing the referents from the original scales may have affected the results. Further, the men's answers may have been affected by response fatigue given that a large number of scales were required to capture the SCT cognitions for each behaviour. The act of measuring these cognitions may also have served as motivational prompts for the control group.

Finally, although every effort was made to ensure the *SHED-IT WLM Program* adequately targeted the key SCT constructs (287), it is possible the men did not engage with the program components enough to receive the required dose. Notably, a process evaluation from a previous investigation of the *SHED-IT Weight Loss Program* revealed that, despite initial engagement, most men did not fully comply with the SCT tasks during weight loss, and engagement with reward setting and social support strategies was particularly poor (85). As men in the intervention group received the *SHED-IT WLM Program* after completing the *SHED-IT Weight Loss Program*, it is feasible that fatigue from Phase I may have resulted in reduced intervention compliance during Phase II, but this was not explored in the current study.

This investigation contained several strengths including use of data from a methodologically rigorous RCT and the use of valid and reliable measures for the SCT cognitions that were pilot tested in a representative sample of overweight and obese Australian men. The study had high retention, measurements were taken by blinded assessors, and linear mixed models were used for the analyses consistent with an intention-to-treat approach. In addition, the scalable interventions targeted an under-represented group and clear detail is available regarding the theoretical mapping of the program. The study also had some limitations. Although the RCT was powered to detect changes in weight, it was not powered a-priori to detect meaningful changes in the secondary outcomes presented in this paper. As such, the results of this isolated trial should be interpreted with caution. Further, although the study used validated measures, the key WLM behaviours (i.e., MVPA and discretionary food intake) were assessed via self-report, which may be associated with more measurement error than objective measures. Finally, although the study measured a wide range of cognitions, not all SCT cognitions were captured for each behaviour.

This study revealed that provision of a gender-tailored, SCT-based WLM intervention provided no additional benefit for men who had already received a SCT-based program for initial weight loss. Future research could explore the impact of this potential confounder by initially randomising men to a series of different weight loss interventions (e.g., *SHED-IT Weight Loss Program* vs. very-low energy diet), and then re-randomising successful participants to either receive the *SHED-IT WLM Program* or no additional resources. Indeed, the application of sequential research designs to examine WLM interventions has recently been recommended (48). Second, to adequately assess men's cognitions for physical activity and specific dietary behaviours (e.g., discretionary food intake) there is a need for more psychometric scale development in this under-studied group. Third, future research should examine: i) whether compliance to the SCT program tasks was associated with successful WLM, and ii) which particular behaviour change techniques are the most important to feature in future WLM programs.

In conclusion, this study revealed that men who only received the 3-month SCT-based *SHED-IT Weight Loss Program* demonstrated statistically comparable maintenance of key behaviours and cognitions over 12 months to men who also received the SCT-based *SHED-IT WLM Program*. More research is required to determine whether the program would provide some benefit to men who achieved initial weight loss with less sustainable approaches involving no cognitive-behavioural training, such as very-low energy diets or supervised exercise programs. Although WLM may require further improvements in physical activity and dietary behaviours after initial weight loss, this study suggests this may be too difficult for participants to implement in a short time frame. Future studies could consider including a 'behaviour stabilisation' phase, where participants are supported to maintain their initial changes before challenging themselves further. Although SCT has shown good utility to elicit health behaviour initiation, researchers could consider drawing on knowledge from theories such as the 'Health Action Process Approach' for future interventions (311), which explicitly examine social cognitive predictors of behaviour maintenance including maintenance self-efficacy and recovery self-efficacy.

CHAPTER 9

THESIS DISCUSSION

9.1 Overview

This thesis examined the utility of Social Cognitive Theory (SCT) to explain physical activity behaviour and reported on the development and evaluation of the SCT-based *SHED-IT (Self-help, Exercise and Diet using Information Technology) Weight Loss Maintenance Program* for men. Given the importance of increasing physical activity to prevent weight regain after weight loss, the primary aim of the thesis was:

1. To examine the effect of the *SHED-IT Weight Loss Maintenance Program* on the moderate-to-vigorous physical activity (MVPA) cognitions and MVPA behaviour of men, 12 months after successfully completing the *SHED-IT Weight Loss Program*.

The secondary aims for this thesis were:

1. To synthesise the current evidence base for male-only weight control interventions;
2. To systematically review the utility of SCT to explain physical activity;
3. To identify behavioural mediators of sustained weight loss in a previous male-only weight loss study;
4. To examine the utility of SCT to explain men's physical activity changes during weight loss; and,
5. To examine the effect of the *SHED-IT Weight Loss Maintenance Program* on men's weight and other health outcomes.

As this thesis was presented as a series of publications, the key findings for each of these aims have been comprehensively discussed, and compared and contextualised with the existing literature in the preceding chapters. Thus, the purpose of this chapter is to synthesise these findings and present a series of evidence-based recommendations, as well as acknowledging the strengths and limitations of this body of work. The discussion is structured in three major sections:

1. Previous weight control programs for men;
2. SCT and physical activity; and,
3. The *SHED-IT Weight Loss Maintenance Trial*.

9.2 Previous Weight Control Interventions for Men

A key component of this thesis pertained to the effectiveness of previous male-only weight loss and weight loss maintenance interventions. This component, which informed the *SHED-IT Weight Loss Maintenance Trial*, included the following secondary thesis aims: (i) to synthesise the current evidence base for male-only weight control interventions (Chapter 2), and (ii) to identify behavioural mediators of sustained weight loss in a previous male-only weight loss study (Chapter 4).

9.2.1 Review of male-only weight control interventions

Chapter aim: To synthesise the current evidence base for male-only weight control interventions (Secondary Aim 1)

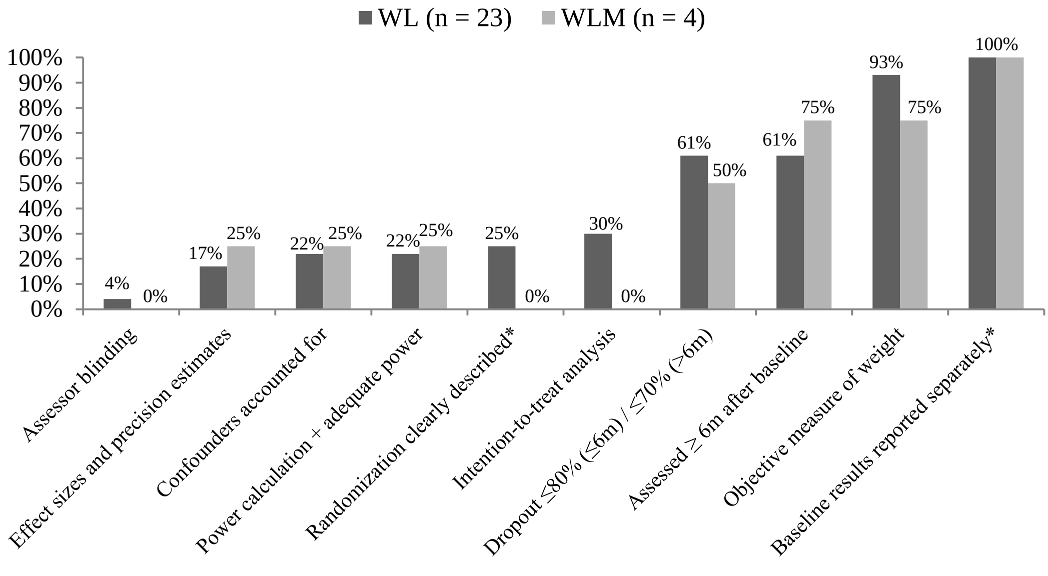
Chapter 2 presented a systematic review of weight control interventions that recruited men only. Results from these studies, and a fixed-effects meta-analysis of randomised controlled trials (RCTs), showed strong evidence for the effectiveness of male-only weight loss programs (weighted mean difference at the end of weight loss: -5.7 kg, 95% CI -6.4, -5.0). These treatment effects are similar to other meta-analysed effects for behavioural weight loss programs in the literature (34), and would be sufficient to generate clinically meaningful health benefits including reduced blood pressure and cholesterol (35, 67) and reduced risk of developing type II diabetes (68). Although the review also aimed to investigate the effectiveness of male-only weight loss maintenance interventions, this could not be determined as only two RCTs were identified (112, 120) that tested the effectiveness of physical activity programs that were not gender tailored and had no clear theoretical framework. In both studies, the weight loss maintenance programs were largely unsuccessful, with significant and comparable weight regain observed in the intervention groups and control groups at the end of the weight loss maintenance period.

This review also identified three intervention components that were associated with effectiveness in male-only weight loss programs. First, 89% of interventions that included a *prescribed energy restriction* were effective, compared to 46% that did not. This provided good evidence that men require a daily kilojoule (kJ) target in addition to general advice around key lifestyle behaviours. Although the *SHED-IT Weight Loss*

Program already included this strategy (81), this informed the recommendation for men to continue self-monitoring their energy balance during the *SHED-IT Weight Loss Maintenance Program* (287). The review also noted that *increased frequency of contact* was associated with effectiveness during the weight loss phase. In response to this, the *SHED-IT Weight Loss Program* was updated to include a weekly text message component in the current study and bi-weekly text messages were built into the design of the *SHED-IT Weight Loss Maintenance Program* (287). Although the review found that inclusion of *group face-to face support* was associated with effectiveness, this was not introduced into the programs to preserve their low-intensity, scalable format.

Finally, it is important to acknowledge that the overall quality of male-only weight loss and weight loss maintenance trials was poor, which may indicate a high risk-of-bias (see Figure 9.1 for a summary). Thus, the review provided a strong rationale for high-quality and rigorously designed weight loss and weight loss maintenance trials specifically targeting men.

Figure 9.1. Proportion of the 23 male-only weight loss (WL) studies and 4 male-only weight loss maintenance (WLM) studies that included each methodological quality characteristic (for further information, see Table 2.2).



* Calculated only for trials where this was applicable.

9.2.2 Behavioural mediators of weight loss

Chapter aim: To identify behavioural mediators of sustained weight loss in a previous male-only weight loss study (Secondary Aim 3)

As noted in Chapter 2, men are under-represented in weight loss research (23, 38) and the evidence base for male-only weight loss programs is limited in both the quality and quantity of studies. As such, relatively little is known about the behavioural strategies to target in weight loss programs for men. Thus, Chapter 4 presented a secondary analysis of data from the *SHED-IT Weight Loss Community Trial* (81), which investigated whether improvements in targeted weight loss behaviours significantly mediated the *SHED-IT Weight Loss Program's* effect on weight at follow-up.

In the intention-to-treat, multiple-mediator model, 47% of the intervention's effect at 6 months was attributed to changes in hypothesised mediators during the first 3 months. Consistent with previous mediation analyses (221, 232), the largest mediation effect was through increases in physical activity (steps/day), which mediated 0.6 kg (or 17%) of the *SHED-IT Weight Loss Program's* effect on weight. In addition, positive intervention effects on kJs from take-away meals and portion size in the first 3 months were responsible for 15% and 14% of the intervention effect on weight at 6 months, respectively. This study provided novel evidence of key behavioural strategies that could be targeted in future weight loss research with men.

9.2.3 Strengths and limitations

These investigations included a number of key strengths. A notable strength of the systematic review was the comprehensive search strategy employed, which covered eight electronic databases with no date restrictions to maximise sensitivity. In addition, the conduct and reporting of the review followed the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) statement (93), which ensured that all recommendations were generated through a rigorous and transparent process. After comprehensive examination of the methodological quality of the current evidence, the review concluded that the current evidence base for male-only weight control trials was limited.

As such, the subsequent mediation analysis of a methodologically-rigorous, male-only RCT (81, 82) addressed an important gap in the literature. Notably, confidence in the mediation effects was increased through use of an appropriate temporal sequence where behaviour change during the intervention mediated weight loss at follow-up. Although this time-lagged sequence is strongly encouraged in the literature (218), many previous mediation analyses have used cross-sectional designs, which cannot investigate causal effects. Further strengths of the mediation analysis included use of a multiple-mediator, intention-to-treat model with adjustment for baseline values, blinded assessors, and validated measures for all model components.

These investigations also had some limitations to acknowledge. The main limitations of the systematic review were the focus of the review on weight outcomes at the expense of other important health markers (e.g., waist circumference) and the absence of non-English studies. In the mediation analysis, although the *SHED-IT Weight Loss Program* targeted nine weight loss behaviours, three were not measured during the study. As such, the influence of '*keeping a healthy lifestyle diary*', '*reading food labels*' and '*surfing the urge*' (i.e., resisting unnecessary snacking') could not be established. Further, although the dietary mediators were measured with a validated questionnaire (227), they may have included more measurement error than the objective physical activity measure. Consequently, the model may have implicitly favoured physical activity in the results.

9.2.4 Implications

9.2.4.1 For research

1. Currently, the evidence base for male-only weight loss and weight loss maintenance trials is limited in both quality and quantity. To progress the field, more evidence is required from high-quality, methodologically-rigorous RCTs that are informed by the CONSORT guidelines and include long-term follow up.

2. It is encouraging to see that the use of a male-only approach in weight control and physical activity interventions has gained momentum in recent years. Although no publication-date restrictions were imposed on the systematic

review, only 23 behavioural male-only weight control interventions were initially retrieved. However, in the 2-3 years since the review was conducted and published, a number of additional high-quality, innovative male-only studies have been published (81, 303-305, 312, 313). As such, an update of the review in the future may provide additional insights to inform future weight control studies with men.

3. To minimise potential risk of bias, future studies should include assessor blinding and ensure that the randomisation procedures are adequately described and appropriately conducted. Researchers should also ensure that their trials are adequately powered a-priori, that potential confounders are adjusted for in the results, and that effect sizes and precision estimates are included with all data to facilitate accurate interpretation and inclusion of studies in future meta-analyses.

4. In addition to methodologically rigorous RCTs, the evidence base would greatly benefit from more published mediation analyses. Currently, there is a dearth of knowledge regarding which weight loss strategies are particularly effective with men. In addition to determining overall effectiveness, mediation analyses of high-quality RCTs can provide powerful insights into *how* an intervention has, or has not, worked. Such insights would be invaluable in future intervention work with men.

5. Although this body of work demonstrates that a male-only approach is effective, it was unable to determine whether men who receive gender-tailored resources demonstrate greater treatment outcomes compared to men who receive gender-neutral programs (in male-only or mixed-sex studies). This is an important question for future research to investigate.

9.2.4.2 For practice

This thesis has provided sound evidence that male-only behavioural programs can assist men to achieve clinically meaningful weight loss. Although the evidence base was limited, the systematic review revealed that weight loss interventions for men may be more successful if they include a prescribed energy restriction, group face-to-face support, and three or more contacts per month on average. In addition to this, the mediation analysis provided strong evidence that male-only programs would likely benefit by specifically targeting and ensuring a considerable focus on men's physical activity, portion size, and take away food consumption. Currently there is little evidence to inform future weight loss maintenance programs for men. However, evidence from two RCTs (112, 120) indicates that successful maintenance may require more than the provision of a supervised exercise program.

9.3 Social Cognitive Theory and Physical Activity

The second major component of this thesis considered the utility of SCT to explain physical activity. This component included investigations into the following secondary thesis aims: i) to systematically review the explanatory power of SCT models of physical activity (Chapter 3), and ii) to determine the utility of SCT to explain men's physical activity changes during weight loss (Chapter 6).

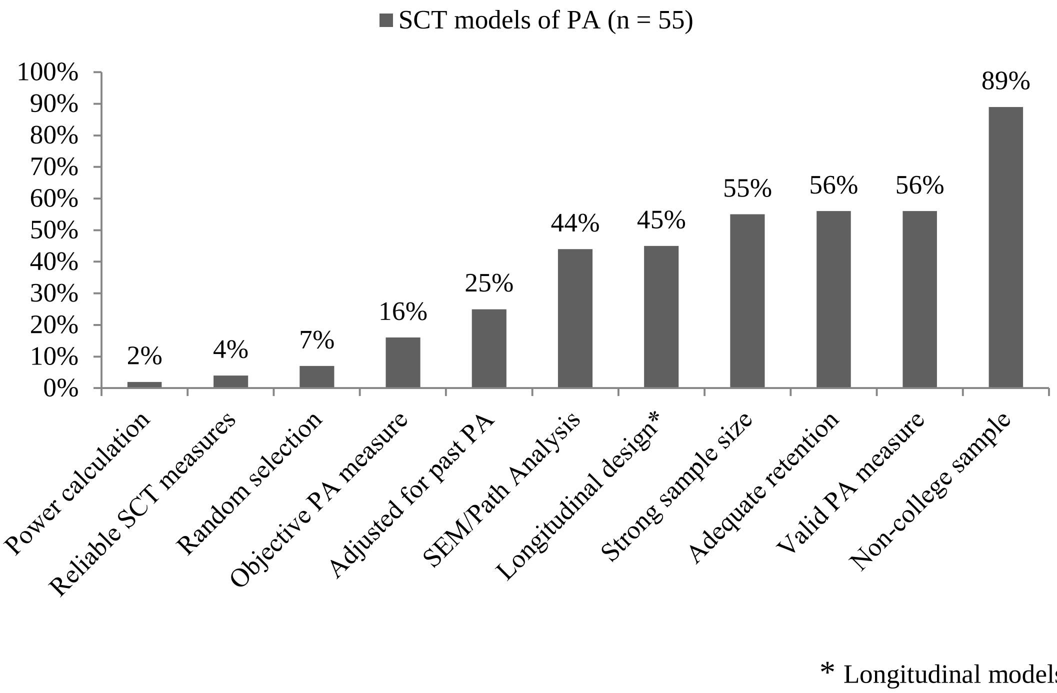
9.3.1 Review of Social Cognitive Theory models of physical activity

Chapter aim: To systematically review the utility of SCT to explain physical activity (Secondary Aim 2)

Chapter 3 presented a meta-analytic review of SCT models of physical activity. The review searched 10 electronic databases and retrieved 55 distinct models of physical activity. When combined in a random-effects meta-analysis, these models accounted for 31% of the variance in physical activity. Following the recommendations of a seminal study in the literature (134), this was sufficient to determine that SCT has good utility to explain physical activity. In addition, a planned moderator analysis identified a significant, positive association between the variance explained and: (i) mean age of the sample, and (ii) total methodological quality score, but not for sex, study design, physical activity measure, or adjustment for past behaviour.

However, the evidence base was limited in a number of key areas. Of note, men were considerably under-represented in the SCT models, representing only 32% of the 13,358 participants in the meta-analysis. As many of the models were secondary analyses of data from behaviour-change interventions, this sex imbalance likely reflects the broader concern of male disengagement with health behaviour research (23, 38, 49, 284). In addition, although methodological quality significantly moderated the effectiveness of SCT to explain physical activity, the overall quality of the models was poor in many areas (see Figure 9.2 for a summary). As such, the true utility of SCT may have been underestimated due to the number of poor quality theory tests in the literature. This review highlighted the clear need for more high-quality SCT tests in the physical activity domain, particularly with men.

Figure 9.2. Proportion of the 55 SCT models of physical activity (PA) that included each methodological quality characteristic (for additional information, see Tables 3.1 and 3.3).



* Longitudinal models only

9.3.2 A Social Cognitive Theory model of men's physical activity

Chapter aim: To examine the utility of SCT as a theoretical framework to explain the physical activity changes of men during weight loss (Secondary Aim 4)

Further to the systematic review, which revealed that men were underrepresented in SCT models of physical activity, the aim of Chapter 6 was to investigate the utility of SCT to explain the physical activity changes of a sample of overweight and obese men during weight loss. Using Phase I data from the *SHED-IT Weight Loss Maintenance Trial*, the fit indices revealed that SCT provided a good fit to the observed data and explained 61% of the variance in men's physical activity changes during the 3-month *SHED-IT Weight Loss Program*. All of the direct and indirect pathways delineated within SCT were supported by significant pathways within the model except the direct effect of outcome expectations on physical activity. However, it is important to note that the direct effect on MVPA from family social support and the indirect effect from outcome expectations did not reach the criteria for practical significance.

In line with Bandura's hypotheses (71, 73), the study demonstrated that men who increased their self-efficacy for physical activity during the intervention were more likely to: (i) see more potential benefits of participating in physical activity, (ii) observe more social support from their family for physical activity, (iii) report more intention to participate in regular physical activity, and (iv) increase their physical activity levels during the intervention. As such, this longitudinal analysis provided preliminary evidence that targeting the behaviour change constructs outlined in Bandura's SCT may be a useful strategy to increase the physical activity levels of men.

9.3.3 Strengths and limitations

These investigations into SCT models of physical activity included several strengths. To ensure that all relevant SCT tests were retrieved in the systematic review, a high-sensitivity search strategy was employed. Key strategies included searching 10 electronic databases with no date or sample-based restrictions, hand-searching the reference lists of all includes articles and 26 relevant reviews, and performing a citation search for a seminal SCT article (71). Further review strengths included extensive data extraction from all studies and high levels of inter-rater agreement for the methodological quality assessments. To ensure that the results of the review could be extrapolated to the wider population, the meta-analysis followed a random-effects approach, as recommended in the literature (155). This review also provided key insights which informed the subsequent investigation into the utility of SCT to explain physical activity in men, who are an understudied population.

To improve on previous research, the male-only investigation tested SCT with a longitudinal, intention-to-treat, structural equation model that adjusted for past behaviour and cognitions. In addition, the sample size was sufficient for the analysis and all measures had adequate validity and reliability in the sample of interest. As summarised in Figure 9.2, these characteristics were missing from many previous SCT models of physical activity.

These investigations also had some limitations to acknowledge. First, as the review only considered studies that were published and written in the English language, it is possible that some ethnic groups were under-represented in the analysis. Also, due to the considerable variation in the conceptualisation and measurement of the SCT constructs, the review was unable to meta-analyse the unique contributions of each construct to physical activity behaviour. The primary limitation of the subsequent male-only SCT test was that physical activity was measured with a self-report measure. Although this was a validated tool, the variance explained in self-reported physical activity is generally inflated due to common methods bias (211). In addition, the sample was not randomly selected and was likely to be behaviourally motivated, which somewhat limits the generalisability of the findings.

9.3.4 Implications

9.3.4.1 For research

Although Bandura's SCT is one of the most widely applied psychological theories to explain health behaviour (306), this thesis provided the first quantitative synthesis of its utility to explain physical activity. While preliminary evidence confirmed that SCT is a useful framework to further the understanding of physical activity, few high-quality theory tests were identified. Future research into SCT and physical activity could significantly improve the evidence base by:

1. *Testing SCT with a rigorous study design*: Within SCT, Bandura specifies a causal network of social-cognitive factors, which are purported to exhibit both direct and indirect effects on behaviour. However, the majority of previous studies have used cross-sectional designs, which preclude causal inference, and multiple regression analysis, which cannot investigate indirect effects. To

provide valid tests of SCT in future research, researchers need to analyse longitudinal, structural equation models, which adjust for the effects of past behaviour and cognitions. In addition to direct effects, researchers should ensure that indirect and total effects for all SCT constructs are also reported.

2. *Improving the measurement of behaviour and cognitions*: Researchers should ensure that all social-cognitive measures have adequate psychometric properties in the sample under investigation. At a minimum, future studies should report the internal consistency and test-retest reliability for all cognitions. To date, authors have relied on self-report measures of physical activity and more studies are required to validate the SCT model of physical activity with objective measures such as accelerometry.

3. *Including all core SCT constructs*: Notably, only 40% of SCT models included in the systematic review included all of the four major constructs (i.e., self-efficacy, outcome expectations, goals, and socio-structural factors). Further, only a small number of these models ordered the four constructs according to Bandura's hypothesised sequence (see Figure 1.1). It is also important to note that a large number of models which claimed to test SCT were deemed ineligible for the review as they did not include any constructs other than self-efficacy. In order to generate more valid data regarding the utility of SCT to explain physical activity, it is crucial that future studies include measures for all of the key SCT constructs and order these in the appropriate structural sequence.

4. *Generating cumulative knowledge across theories*: Currently, many of the core constructs from competing theories share considerable conceptual overlap. For example, self-efficacy and goals from SCT are similar to perceived behavioural control and intention from the Theory of Planned Behaviour. To improve understanding of physical activity behaviour, future research should conduct novel, integrative theoretical research to examine whether these variables do indeed represent the same constructs and, if so, how the evidence from competing theories can be best synthesised.

5. *Ecological models*: Although this thesis focused on social-cognitive determinants of physical activity, it is important to acknowledge that psychological variables alone cannot provide a complete explanation of human behaviour (134). Thus, it is important to examine how social-cognitive explanations of behaviour can be situated within broader ecological models, which consider the effect of the environment in combination with individual and social factors. Given the established influence of institutional, built environment and policy factors on physical activity levels (314), testing comprehensive models that combine both approaches is an important goal for future research.

9.3.4.2 For practice

Despite the methodological limitations, this thesis provides good evidence to support the application of SCT principles in behavioural physical activity or weight loss programs. In the systematic review, self-efficacy, intention and self-regulation were most consistently associated with physical activity across all populations. In addition, the current theory-test with overweight and obese men revealed that increases in self-efficacy, outcome expectations, intentions, and family social support were significantly associated, directly or indirectly, with increased physical activity during the weight loss. Future programs for men may benefit from explicitly targeting these important socio-cognitive variables, particularly for self-efficacy and intentions, which represented the largest practically meaningful effects.

9.4 The SHED-IT Weight Loss Maintenance Trial

The final component of this thesis described the development, implementation and evaluation of the *SHED-IT Weight Loss Maintenance Trial*. In addition to the study protocol for the trial (Chapter 5), this component included investigations into the following two thesis aims: i) to examine the effect of the *SHED-IT Weight Loss Maintenance Program* on men’s weight and other health outcomes, 12 months after successfully completing the *SHED-IT Weight Loss Program* (Chapter 7), and ii) to examine the effect of the *SHED-IT Weight Loss Maintenance Program* on men’s MVPA cognitions and MVPA behaviour (*primary aim of thesis*; Chapter 8).

9.4.1 Study outcomes for weight

Chapter aim: To examine the effect of the SHED-IT Weight Loss Maintenance Program on men's weight and other health outcomes, 12 months after successfully completing the SHED-IT Weight Loss Program (Secondary Aim 5)

Chapter 7 presented the primary outcome paper of the *SHED-IT Weight Loss Maintenance Trial*, which was conducted in response to the urgent need for scalable and effective weight loss maintenance programs that engage men (217). In total, 92 overweight/obese men who lost at least 4 kg after receiving the 3-month *SHED-IT Weight Loss Program* (Phase I) were randomised into Phase II to receive: i) the 6-month *SHED-IT Weight Loss Maintenance Program*, or ii) no additional resources (self-help control) (Phase II). Notably, both SHED-IT Programs were gender-tailored and neither included any personal contact or individualised intervention components. Both programs also operationalised Bandura's SCT to target key behaviours associated with weight loss and weight loss maintenance. After randomisation (i.e., weight loss maintenance baseline), the men were re-assessed at 6 months (post-test) and 12 months (6-month follow-up). During Phase I, randomised men demonstrated a significant mean reduction in weight (-7.3 kg, $p<0.001$) and improvements in other key health markers including waist circumference, body-mass index, percent body fat, blood pressure and resting heart rate (all $p<0.001$).

At 12 months (6-month follow up), the weight loss maintenance group had regained 0.6 kg from randomisation (92% maintenance) and the control group had regained 2.1 kg (69% maintenance). Although non-significant, the weight loss maintenance intervention effect at 12 months (-1.5 kg, $p = 0.19$) was comparable to that observed in a recent meta-analytic review of 25 behavioural weight loss maintenance interventions, which were considerably more intensive (weighted mean difference at 12 months against controls: -1.6 kg (95% CI -2.3, -0.9) (49). Encouragingly, positive intervention effects were identified for two key behaviours linked to weight loss maintenance, with the intervention group significantly increasing fruit and vegetable intake (serves/day) and frequency of breakfast consumption compared to the self-help control group.

While no significant difference in weight regain was identified between groups, the effect of the *SHED-IT Weight Loss Maintenance Program* may have been confounded by the relative success of the self-help control group, who outperformed many other control groups, and some intervention groups, in the literature (49). This may have been due to the focus on sustainable changes to weight loss, which was included in both the *SHED-IT Weight Loss Program* and the *SHED-IT Weight Loss Maintenance Program*. Notably, in a recent weight loss maintenance trial, Zinn and colleagues also determined that encouraging a 'small-changes' approach during weight loss phase was associated with successful weight loss maintenance, irrespective of whether an additional maintenance program was provided (315). In addition, the *SHED-IT Weight Loss Program* was also theory-based and gender-tailored, which are program features missing from most previous weight loss interventions for men (217). By increasing men's engagement with the program and the salience of the behavioural messages, these components may also have contributed to the relative effectiveness of the program compared to other weight loss programs in the literature.

9.4.2 Study outcomes for MVPA cognitions and behaviour

Chapter aim: To examine the effect of the SHED-IT Weight Loss Maintenance Program on the MVPA cognitions and MVPA behaviour of men, 12 months after successfully completing the SHED-IT Weight Loss Program (Primary Aim of Thesis).

Considerable research indicates that a sustained increase in physical activity is one of the most powerful predictors of long-term weight loss maintenance (50, 64, 65). In addition, although this thesis determined that SCT has utility for explaining physical activity behaviour, little research has examined the utility of social-cognitive theories in the context of a weight loss maintenance RCT (48, 49). As such, the final paper in this thesis consisted of an investigation into the impact of the *SHED-IT Weight Loss Maintenance Program* on men's MVPA cognitions and MVPA behaviour, which was the primary aim of this thesis. Although the paper also explored the effect of the program on men's dietary cognitions and behaviour (in relation to discretionary food choices), a detailed discussion of the dietary findings in this chapter is beyond the scope of this thesis, which has focused primarily on the utility of SCT to explain physical activity.

During Phase I, randomised men reported a significant mean increase in physical activity social support from family and friends, goal setting, and planning (all $p < 0.01$). No significant changes were observed for physical activity self-efficacy, outcome expectations, or barriers. Intention to participate in regular physical activity significantly decreased during Phase I ($p < 0.001$). In addition, participants reported a significant mean increase in MVPA of 130 minutes per week ($p < 0.001$).

During Phase II, no significant differences were observed between the intervention group and the self-help control group for any of the SCT cognitions or MVPA. However, it is important to note that increases in MVPA cognitions and behaviour were largely maintained in both study arms. Thus, while the primary hypothesis for this thesis was not supported, further research into the utility of theory-based, gender-tailored approaches to generate sustainable increases in MVPA is warranted.

9.4.3 Strengths and limitations

To the authors' knowledge, the *SHED-IT Weight Loss Maintenance Trial* was the first study to investigate the effectiveness of a weight loss maintenance program designed specifically for men. In addition to targeting men, this study addressed many recognised limitations of previous weight loss maintenance trials (49, 245). Strengths of this study include a randomised controlled design with a no-maintenance-intervention control group, intention-to-treat analysis, high participant retention, blinded assessors during the RCT and comprehensive assessment of physical, behavioural and psychological outcomes. Further, this study included a follow-up assessment after the conclusion of the maintenance program, which was a feature missing from 65% of previous weight loss maintenance RCTs (49). This study also answered the recent call for more research into the role of psychological theory in the field of weight loss maintenance (48). Importantly, the weight loss maintenance program targeted two key behaviours linked to success in the literature (i.e., MVPA and energy-dense, nutrient-poor discretionary food intake) and SCT cognitions for these behaviours were captured using scales that demonstrated adequate internal consistency and test-retest reliability in a pilot sample of overweight and obese Australian men. To inform future research, this study also provided clear detail on how SCT was mapped and operationalised onto both the *SHED-IT Weight Loss* and *Weight Loss Maintenance Programs*.

This study also had some limitations to acknowledge. Although the primary aim of this thesis was to examine the effect of the *SHED-IT Weight Loss Maintenance Program* on MVPA cognitions and MVPA behaviour, this was a secondary aim of the RCT. As such, the thesis was not adequately powered to detect differences in these outcomes and the results can only be interpreted as exploratory. Further, the primary behavioural outcome for this thesis (MVPA) was measured via self-report, which may be affected by misreporting bias. In addition, given that the RCT only included men who had lost weight during Phase I, the results of the trial are only generalisable to men who have already achieved some degree of weight loss success. However, this research design aligned with the primary aim of the RCT, which was to test the effectiveness of a weight loss maintenance program. Finally, given that the control group still received the effective, SCT-based *SHED-IT Weight Loss Program* during Phase I of the trial, they demonstrated a slower rate of regain than other control groups, and many intervention groups in the literature (280). Thus, a longer timeframe may have been required to determine the true effectiveness of the *SHED-IT Weight Loss Maintenance Program*.

9.4.4 Implications

9.4.4.1 For research

This thesis has demonstrated the potential for the gender-tailored, theory-based *SHED-IT Weight Loss Maintenance Program* to assist overweight and obese men achieve sustained increases in physical activity and long term weight loss. Although no significant differences were observed between the intervention group and the self-help control group for these variables, it is notable that men in both groups largely maintained the Phase I improvements in physical activity and the intervention group maintained 92% of their initial weight loss. However, to improve the evidence for the utility of the *SHED-IT Weight Loss Maintenance Program*, future research would benefit by considering the following recommendations:

1. Future research with SHED-IT should factor in a longer assessment time-frame. Although previous research suggests that, without additional intervention, approximately 50% of weight is regained in the first year after treatment, this was not observed in the current study. The self-help control group, who only

received the 3-month *SHED-IT Weight Loss Program,* regained only 28% after 12 months, which is comparable to the regain observed in the intensive, personal-contact intervention group from the *U.S. Weight Loss Maintenance Trial* (~25%) (280). This may have been the result of the clear focus on sustainable approaches to weight loss in SHED-IT, which was shared across both programs. As the *SHED-IT Weight Loss Maintenance* group regained only 8% over this time frame, there is some evidence that an additional program may be of greater benefit. However, as the *SHED-IT Weight Loss Program* may be more effective than other weight loss approaches, a longer follow-up period may be required to determine the true long-term effectiveness of the additional maintenance program.

2. As the *SHED-IT Weight Loss Program* also operationalised SCT, control group participants may have continued to use SCT strategies (e.g., goal setting) during the weight loss maintenance phase. If so, this may have partially confounded the effect of the maintenance program on the participants' MVPA behaviours and cognitions. To address this, future research could consider employing sequential research designs, where participants are randomly allocated to different interventions during weight loss and weight loss maintenance, in order to tease out the unique contribution of the SCT program components featured in the *SHED-IT Weight Loss Maintenance Program*.

3. Given the established importance of increases in MVPA for long-term weight loss maintenance, future research with the SHED-IT programs would benefit from measuring this behaviour objectively with accelerometers. Although step count data were reported in the primary outcomes paper (Chapter 7), pedometers measure total physical activity, rather than intensity or bouts of physical activity. In addition, although the primary outcomes for this thesis were MVPA cognitions and behaviour, the analyses were underpowered as the trial was only powered for weight outcomes. Conducting a future trial with a larger sample size and accelerometer-assessed physical activity would provide more

confidence in the utility of the *SHED-IT Weight Loss Maintenance Program* to target these key outcomes.

4. Although SCT was explicitly operationalised within the intervention (287), additional process evaluation would provide important insights into the degree to which participants actually engaged with these intervention components. Notably, a recent study from the SHED-IT community weight loss RCT revealed that, while engagement with SCT tasks was associated with weight loss (85), many men did not fully comply with the tasks, and engagement with reward setting and social support strategies was particularly poor. As men in the intervention group received the *SHED-IT Weight Loss Maintenance Program* after completing the *SHED-IT Weight Loss Program*, it is feasible that fatigue from Phase I may have resulted in even poorer intervention compliance during Phase II. Although it was outside the scope of this thesis, future research should investigate whether this was indeed the case and, if so, whether this potential disengagement had any bearing on the results of the study.

5. This thesis determined that frequency of contact may be a key factor linked to success in male-only trials (217). As such, it may be worth investigating whether men would benefit from some degree of additional contact (e.g., additional text messages, emails, or even phone-based support) during the weight loss maintenance phase. However, any benefits of this additional contact would need to be evaluated against the associated reductions in intervention scalability. This is an important question for future research to consider.

6. Despite examining the effect of weight control programs that were considerably lower in intensity than those in previous research (49, 217), a cost-effectiveness analysis has not yet been conducted. Although the necessary data for this analysis were collected during the trial, this analysis was deemed outside the scope of this thesis. However, a cost-effectiveness analysis of the two *SHED-IT Programs* will provide additional insights into how the interventions can be improved and will allow for important comparisons with previous research.

7. Although this thesis examined the overall effectiveness of the *SHED-IT Weight Loss Maintenance Program*, a mediation analysis of the data in the future may provide important insights for further refinement and improvement of the program. Similarly, further examination of process evaluation data would likely yield key insights into which program components were most useful to the men. As with the cost-effectiveness analysis, although these data were collected during the study, this additional analysis was deemed to be outside the scope of this thesis.

8. In the current trial, the weight loss maintenance RCT started after a three month weight loss phase. Although this decision was partially informed by the timeline of the grant, it was also guided by previous SHED-IT research, which shows that most men experience a weight loss plateau after the first three months (81, 83). However, at the beginning of the RCT, most participants were still overweight and were motivated to continue losing weight. This created some conceptual confusion in the intervention group, who received a new program encouraging them to focus on maintenance at the expense of trying to achieve their pre-conceived weight loss goals. Future qualitative and quantitative research would be useful to determine the optimal duration for the weight loss phase and the potential moderating impact of initial weight loss expectations on longer term success.

9. As noted above, the effect of the *SHED-IT Weight Loss Maintenance Program* on men's discretionary food cognitions and behaviours was not discussed in detail here as the primary aim of this thesis was to investigate the effect of the program on men's MVPA cognitions and MVPA behaviour. To provide a context for this aim, previous chapters explored the utility of SCT to explain physical activity behaviour in men (SCT model; Chapter 6) and in all populations (meta-analytic review; Chapter 3). While this has addressed an important gap in the literature, more research is warranted to synthesise the evidence for the utility of SCT to explain dietary behaviour, including

discretionary food consumption, during weight loss and weight loss maintenance.

10. It is important to acknowledge that this research was informed by previous studies which suggested that overall energy intake is more important than dietary composition for long-term WLM (e.g., (263)). However, this is not a universally accepted argument. Recent research suggests that high-carbohydrate diets combined with various environmental factors may be causing the body to store too many kJs, which leads to decreased energy expenditure and increased hunger (316). This dietary-induced metabolic dysfunction is hypothesised to increase overeating which ultimately affects all weight management efforts. Currently, the role of dietary composition in long term weight loss maintenance is uncertain and well-designed trials are needed to determine whether focusing on total energy intake and expenditure alone is hindering the effectiveness of behavioural weight control programs.

9.4.4.2 For practice

To date, most weight loss maintenance studies have tested programs that include too many personalised contacts for realistic, widespread implementation (49). In addition, the majority of these programs have failed to engage men (49). This thesis provided initial evidence that gender-tailored, theory-based programs may assist men to maintain initial improvements in physical activity and weight during weight loss maintenance. Although the additional benefit of the *SHED-IT Weight Loss Maintenance Program* was not statistically significant compared to the self-help control group (i.e., *SHED-IT Weight Loss Program*-only), both groups demonstrated comparable, if not superior, maintenance to other, far more intensive, intervention groups in the literature.

This thesis has revealed that men who experience weight loss in gender-tailored, scalable programs are susceptible to weight regain, but the magnitude of this regain can be reduced with additional intervention. However, given the difference between groups was not statistically significant, more research is required to determine the optimal mix of intervention components to facilitate the largest intervention effect without compromising the potential of the program for widespread implementation.

9.5 Concluding Remarks

Overweight and obesity in men is one of the greatest public health challenges facing Australia. Although men are more likely than women to be obese in every age group, they are less likely to self-identify as overweight, or see this as a health concern. Men are less likely than women to attempt weight loss or join weight loss programs and, if they do, they may be less likely to achieve long-term success. Further, although physical activity is a powerful protective factor against the health risks of obesity, and is essential for long-term weight loss maintenance, most overweight men are not sufficiently active to confer these benefits. As a result, identifying effective weight loss and physical activity programs for overweight and obese men is a recognised national and international health priority.

To date, men have been greatly under-represented in weight control and physical activity research. As such, there is a lack of knowledge concerning which theoretical and behavioural factors are most important to target in programs for men. Notably, this thesis has demonstrated that men are willing to engage in weight loss efforts when offered male-only programs tailored to their interests. Further, by synthesising previous research and conducting a novel RCT, a number of key insights have been provided to inform future male-only weight control studies. This thesis also demonstrated that psychological theory plays an important role in the explanation and prediction of physical activity behaviour. Although the primary hypothesis of this thesis was not supported, men who received the SCT-based *SHED-IT Weight Loss Program* reported significant increases in physical activity, which were largely maintained at 12 months in both RCT study arms.

Novel research designs are required to determine the unique benefit of targeting theoretical constructs for physical activity during weight loss maintenance in men. It is anticipated that the information and recommendations in this thesis will inform the development of novel, scalable, and effective programs to help men enjoy the many benefits of sustained increases in physical activity and successful weight loss maintenance.

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APPENDICES

Appendix 1: Ethics approval

Notification of Expedited Approval

To Chief Investigator or Project Supervisor:	**Professor Philip Morgan**
Cc Co-investigators / Research Students:	**Professor Robin Callister** **Professor Clare Collins** **Professor Ronald Plotnikoff** **Mr Myles Young** **Professor Christopher Doran**
Re Protocol:	**Engaging men to maintain weight loss using innovative and cost-effective interventions: The SHED-IT weight loss maintenance pilot study**
Date:	**20-Feb-2012**
Reference No:	**H-2011-0361**
Date of Initial Approval:	**15-Feb-2012**

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

Your submission was considered under **Expedited** review by the Chair/Deputy Chair.

I am pleased to advise that the decision on your submission is **Approved** effective **15-Feb-2012**.

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

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

The full Committee will be asked to ratify this decision at its next scheduled meeting. A formal *Certificate of Approval* will be available upon request. Your approval number is **H-2011-0361**.

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

Conditions of Approval

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

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

- ***Monitoring of Progress***

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

- ***Reporting of Adverse Events***

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

5. Reports of adverse events must include:
    - Participant's study identification number;
    - date of birth;
    - date of entry into the study;
    - treatment arm (if applicable);
    - date of event;
    - details of event;
    - the investigator's opinion as to whether the event is related to the research procedures; and
    - action taken in response to the event.

6. Adverse events which do not fall within the definition of serious or unexpected, including those reported from other sites involved in the research, are to be reported in detail at the time of the annual progress report to the HREC.

- ***Variations to approved protocol***

If you wish to change, or deviate from, the approved protocol, you will need to submit an *Application for Variation to Approved Human Research*. Variations may include, but are not limited to, changes or additions to investigators, study design, study population, number of participants, methods of recruitment, or participant information/consent documentation. **Variations must be**

approved by the (HREC) before they are implemented except when Registering an approval of a variation from an external HREC which has been designated the lead HREC, in which case you may proceed as soon as you receive an acknowledgement of your Registration.

Linkage of ethics approval to a new Grant

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

Best wishes for a successful project.

Dr Jean Harkins

Acting Chair, Human Research Ethics Committee

For communications and enquiries:

Human Research Ethics Administration

Research Services
Research Integrity Unit
HA148, Hunter Building
The University of Newcastle
Callaghan NSW 2308
T +61 2 492 18999
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Linked University of Newcastle administered funding:

Funding body	Funding project title	First named investigator	Grant Ref
Hunter Medical Research Institute/Project Grant(**)	Engaging men to maintain weight loss using innovative and cost-effective interventions: The SHED-IT weight loss maintenance pilot study	Morgan Philip,	G1101216

Appendix 2: Information statement

Prof Philip Morgan
Priority Research Centre in Physical Activity and Nutrition
Faculty of Education and Arts
University of Newcastle
Callaghan NSW 2308
(Ph) 4921 7265
(Fax) 4921 2084
Philip.Morgan@newcastle.edu.au

Information Statement for the Research Project:

Evaluation of a Weight Management Program for Men
Document Version 4; dated 10/07/2012

The Research Team

Dr. Philip Morgan	Faculty of Education and Arts
Dr. Robin Callister	Faculty of Health
Dr. Clare Collins	Faculty of Health
Dr. Ron Plotnikoff	Faculty of Education and Arts
Dr. Chris Doran	Faculty of Health
Mr. Myles Young	Faculty of Education and Arts

You are invited to participate in the research project identified above, which is being conducted at the University of Newcastle. The research is part of Myles Young's studies at the University of Newcastle, supervised by Prof. Philip Morgan, Prof. Ron Plotnikoff, Prof. Robin Callister and Prof. Clare Collins. This research is funded by the Hunter Medical Research Institute and the Priority Research Centre in Physical Activity and Nutrition.

Why is the research being done?

- Overweight men are at increased risk of developing a range of health problems including cardiovascular disease, diabetes, hypertension, respiratory problems, and some cancers, as well as a reduced quality of life.
- Weight loss is recommended to reduce the health risks associated with excess weight.
- The purpose of this research project is to evaluate the effectiveness of a weight management program designed for men which provides information and support for both initial weight loss and long-term weight loss maintenance.

Who can participate in the research?

You have received this information statement as you have expressed interest in this study and have completed the initial online screening questionnaire.

You can participate in this project if you:

- Are a male aged 18-65 years
- Are overweight (determined as a body mass index [BMI] between 25 and 40 kg/m^2)
- Agree to not participate in other weight loss programs during the study
- Are available for assessment sessions (see below for details)
- Have access to a computer with e-mail and Internet facilities
- Agree to comply with the study treatment

You will be ineligible to participate if you:

- Have a history of major medical problems such as heart disease or diabetes that would prevent exercise
- Have orthopaedic or joint problems that would be a barrier to physical activity such as walking
- Have recently lost 5% or more or more of your body weight
- Are taking medications that might be affected by weight loss or cause weight gain
- Are currently participating in an alternative weight loss program

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. 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.

What would you be asked to do?

If you agree to participate, you will be asked to attend up to four assessment sessions at the ***Health and Physical Education Building (Room HPE2.8) at the University of Newcastle***. These sessions will be held in August 2012, November 2012, May 2013 and November 2013. You would be able to select a day and time for these assessments that suits your schedule. All of the following measurements will be taken by the research team led by Dr Robin Callister and trained research assistants.

Physical measures:

- *Weight* – measured in light clothing without shoes and on a set of scales.
- *Height* – measured in light clothing without shoes using a portable stadiometer.
- *Waist circumference* - measured in a private space with a tape measure around two areas of your stomach.
- *Body composition* - measured using the InBody720 bioelectrical impendence analyser; this is a device you stand on and a small amount of electrical current travels through your body and determines your body composition. This procedure is not harmful. However, you must not undergo this test if you have an electrical device implanted in your body such as a cardiac pacemaker.
- *Blood Pressure* - measured using an automated blood pressure monitor.
- *Physical activity* - you will be asked to wear a pedometer for 7 days including 2 weekend days. These is an activity monitor that clips onto your belt or pants waist.

Questionnaire-based measures:

Before attending each assessment at the University, you will be asked to complete an online survey with questions about:

- Your beliefs and practices regarding physical activity
- Your health: how well you feel, and how well you are able to do usual activities
- Your sexual health
- How long you spend sitting each day
- Your mood and the way you have been feeling
- Your age, occupation and postcode

While you are at the university, at each assessment you will be asked to complete two surveys with questions about:

- How much fruit, vegetables, bread, meats you eat and how often you eat them
- Your alcohol consumption
- Your beliefs and practices regarding healthy eating
- Your satisfaction with the study

All your answers to these questions will be kept confidential. Immediately after your assessment sessions your data will be de-identified by replacing your name with a code. No one outside the research team will be able to identify you from your data.

Weight Loss Phase

After completing the first assessment session (Aug., 2012), all participants will be provided with the *SHED-IT Weight Loss Program for Blokes.* This is a self-help weight loss program that has been developed to help men lose weight through gradual and sustainable lifestyle changes. The program does not require you to follow a specified meal plan or engage in any structured exercise sessions. The SHED-IT Weight Loss package includes:

- The *Weight Loss Handbook for Blokes*
- The *Weight Loss Logbook for Blokes*
- The *Weight Loss DVD for Blokes*
- A calorie counter book
- A pedometer and tape measure
- A study website to record food and exercise

Weight Loss Maintenance Phase

After completing the second assessment session (Nov., 2012), all men who have lost at least 4 kg will be randomly allocated to one of the following two study arms for the remainder of the trial:

(i) *SHED-IT Weight Loss Maintenance* group or

(ii) Self-help control group.

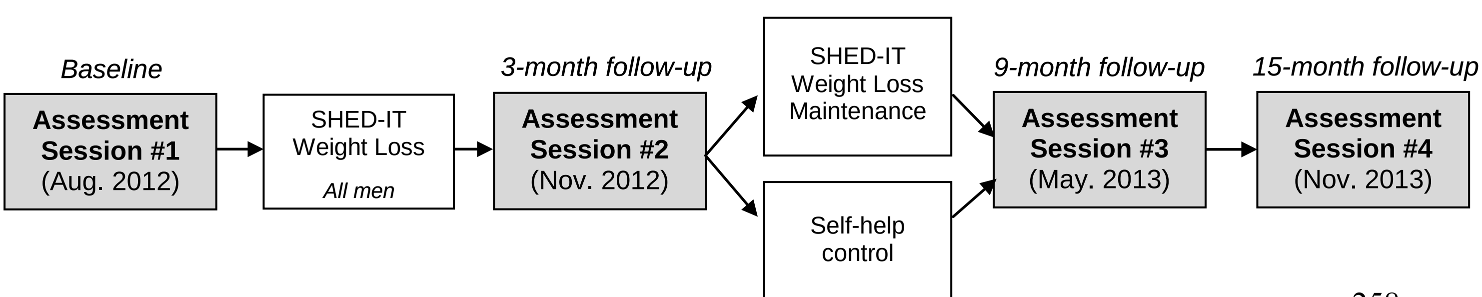
Following the randomisation process will ensure each participant has an equal chance of being allocated to either group; however, it also prevents us from taking individual preferences into account. Men who have not lost 4 kg will be advised to continue with the *SHED-IT Weight Loss Program*, but will not be required to attend any further assessment sessions.

The *SHED-IT Weight Loss Program* has been previously tested for effectiveness with men; however, this is the first trial investigating the effectiveness of the *SHED-IT Weight Loss Maintenance program.* By randomly placing men into the maintenance program or a self-help control, we can compare to see if the additional program makes a difference to long-term weight loss. For this reason, it would be very important that you still attend measurement sessions, regardless of your level of success or the group you have been allocated to.

The *SHED-IT Weight Loss Maintenance Program* includes a DVD, Handbook, Logbook and a Gymstick™ (a portable, elastic tubing, resistance training device). The messages and information in this program relate specifically maintenance of lost weight.

In this research study, we will be recommending a program of graduated exercise of a moderate intensity. During moderately intense exercise, the activity should feel 'moderate to somewhat hard' to perform, but you could still have an uninterrupted conversation. Vigorous intensity exercise would be an activity that feels 'hard' to perform or would be exercise where a conversation couldn't be maintained uninterrupted. While additional health benefits can be obtained from increasing your exercise intensity to a vigorous level, you will need to seek a medical clearance from your doctor if you wish to undertake vigorous intensity exercise'

Timeline of events for this study



How much time will it take?

As the SHED-IT program is a self-help weight loss program the only required time commitments are the 4 assessment sessions. These should take about 60 minutes to complete and you will be able to select a day and time that suits you. However, to get the most out of the program, we make the following recommendations:

Assessments	**Required**	**Total**
Physical assessment at the University + completing questionnaires	1 hr x 4 occasions	4 hrs
Weight Loss Phase	**Recommended**	**Total**
Watch weight loss DVD	½ hr	½ hr
Read weight loss handbook	½ hr	½ hr
Complete weight loss log book	10 min x 13 weeks	~ 2 hrs
Complete online food and exercise diary	~ 5 min x 4 days per week x 13 weeks	~ 4 ½ hrs
Weight Loss Maintenance Phase	**Recommended**	**Total**
Watch weight loss maintenance DVD	½ hr	½ hr
Read weight loss maintenance handbook	½ hr	½ hr
Complete weight loss maintenance logbook	10 min x 26 weeks	~ 4 ½ hrs
Complete online food and exercise diary	~ 5 min x 2 days per week x 26 weeks	~ 4 ½ hrs
	TOTAL for weight loss phase only	~ 11 ½ hrs
	TOTAL for weight loss phase + weight loss maintenance phase	~ 21.5 hrs

What are the risks and benefits of participating?

Benefits:

- Losing weight will reduce your risks of several serious diseases (e.g. cardiovascular disease and type II diabetes).
- You will be given the opportunity to lose weight and improve your health through developing the skills and knowledge you need to increase your physical activity and improve your food choices.

Risks:

- If exercise is performed incorrectly, there is a small risk of injury to muscles and joints. This risk can be reduced by warming up, cooling down, and taking care when increasing exercise intensity.
  - **While exercising, or at any other stage during this study, if you experience any chest pains, dizziness or shortness of breath, please see your doctor.**
  - **If there is a medical emergency, please dial 000.**
- Some participants may find that they lose less weight than expected and this can be distressing for some men. If you experience feelings that are overwhelming, please seek help from your doctor.
- Some questions in the questionnaire booklet are of a sensitive nature (e.g. your sexual function and mental health). As with all information collected, your answers to these questions will be kept completely confidential and your name will not be stored alongside your responses. You are welcome to discuss any concerns about these questions with the research team. If you experience any feelings that are overwhelming while answering these questions, please seek help from your doctor. You also have the option of contacting contact Lifeline on 13 11 44.

How will your privacy be protected?

Initially, all raw data will be stored in a locked filing cabinet in our research office to ensure its security and the confidentiality of any identified data. Only the research assistants and the chief investigators will have access to the raw data. The research assistant will then enter raw data into a statistics program. As there is a need to be able to identify individual data due to multiple data entry points, the identifiers will be removed and replaced with a code. For the online surveys, raw responses will be extracted and all identifying information will also be replaced with a code. Once the data has been extracted, the surveys will be taken off of the internet.

Once the information is entered on the data file, all raw data will be shredded, the online data will be deleted and no person will be identifiable in the data files or published report. The results of the study will be published in general terms and will not allow the identification of individuals. This data file will be kept for five years beyond the completion of the project but no person will be identifiable in the data files or published reports.

To engage in the online component of the program, you will be asked to create a username and password to protect your identity online.

How will the information collected be used?

The results of the research will be reported and disseminated via national and international conferences and peer reviewed publications. Results will also contribute to Myles Young's PhD thesis. You will not be identified in any reports arising from the study. At the conclusion of the study, you'll receive an email from the chief investigator with a summary of the results.

What do you need to do to participate?

Please read this Information Statement and be sure you understand its contents before you consent to participate. If there is anything you do not understand, or you have questions, contact the researcher.

If you would like to participate, please complete the accompanying consent form and return it to the researchers in the reply paid envelope provided. You will then be contacted to confirm a time convenient for you to complete the first assessment.

Further information

If you would like further information please contact:

Mr Myles Young
Project PhD Candidate
Phone: (02) 49 216 096
Email: Myles.Young@newcastle.edu.au

OR

Prof Philip Morgan
Project Chief Investigator
Phone: (02) 217 265
Email: Philip.Morgan@newcastle.edu.au

Thank you for considering this invitation.

Prof. Philip Morgan
Project Chief Investigator
School of Education
Priority Research Centre
in Physical Activity and Nutrition

Mr Myles Young
PhD Candidate
School of Education
Priority Research Centre
in Physical Activity and Nutrition

Complaints about this research

This project has been approved by the University's Human Research Ethics Committee, Approval No. H-2011-0361.

Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, to the Human Research Ethics Officer, Research Office, The Chancellery, The University of Newcastle, University Drive, Callaghan NSW 2308, Australia, telephone (02) 49216333, email Human-Ethics@newcastle.edu.au.

Appendix 3: Consent form

Prof Philip Morgan
Priority Research Centre in Physical Activity and Nutrition
Faculty of Education and Arts
University of Newcastle
Callaghan NSW 2308
(Ph) 4921 7265
(Fax) 4921 2084
Philip.Morgan@newcastle.edu.au

Consent Form for the Research Project:

Evaluation of a Weight Management Program for Men
Document Version 2; dated 07/06/2012

The Research Team

Dr. Philip Morgan	Faculty of Education and Arts
Dr. Robin Callister	Faculty of Health
Dr. Clare Collins	Faculty of Health
Dr. Ron Plotnikoff	Faculty of Education and Arts
Dr. Chris Doran	Faculty of Health
Mr. Myles Young	Faculty of Education and Arts

I agree to participate in the above research project 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 project at any time and do not have to give any reason for withdrawing. I am aware that I am required to lose at least 4 kg to be eligible inclusion in the weight loss maintenance phase. I am aware that if I am eligible for the weight loss maintenance phase, I have **an equal chance of being allocated into the weight loss maintenance program or a self-help control group**.

I consent to:

- Participate in a weight loss program
- Have my height, weight, waist circumference, blood pressure and body composition measured.
- Complete questionnaires about my eating habits and beliefs, exercise habits and beliefs, quality of life, sexual health, demographic information, use of health services and thoughts on the program.
- Wear a pedometer for 7 days after each assessment, and record my step counts

Please indicate your preferred times to attend a morning, afternoon, or evening assessment. These will be conducted in August 2012, November 2012, May 2013 and November 2013.

MONDAY	**TUESDAY**	**WEDNESDAY**	**THURSDAY**	**FRIDAY**
☐ *7am - 9am*	☐ *7am - 9am*	☐ *7am - 9am*	☐ *7am - 9am*	☐ *7am - 9am*
☐ *9am - 11am*	☐ *9am - 11am*	☐ *9am - 11am*	☐ *9am - 11am*	☐ *9am - 11am*
☐ *3pm - 5pm*	☐ *3pm - 5pm*	☐ *3pm - 5pm*	☐ *3pm - 5pm*	☐ *3pm - 5pm*
☐ *5pm - 7pm*	☐ *5pm - 7pm*	☐ *5pm - 7pm*	☐ *5pm - 7pm*	☐ *5pm - 7pm*

I understand that my personal information will remain confidential to the researchers. I have had the opportunity to have questions answered to my satisfaction.

I am happy to be contacted after the conclusion of the study to be invited to participate in long-term follow-up:

Yes ☐ No ☐

Name (print):

Signature:	**Date:**

Please return the completed consent in the prepaid envelope enclosed. Your cooperation is greatly appreciated

Appendix 4: Pre-program screening questionnaire

SHED-IT (2012) Pre-Program Screener

1. Introduction

Thank you for your interest in the SHED-IT Weight Loss Maintenance Study. SHED-IT is a program run through the University of Newcastle (Australia) that aims to teach men the skills they need to lose weight.

During the program you will be given information about how you can lose weight by making simple changes to what you eat and becoming more active, without needing to completely give up beer or your other favourite foods. Past participants have successfully lost weight, improved their eating habits and have reported being more active.

After an initial assessment day at the University of Newcastle in August 2012, all men who take part in this study will receive the SHED-IT Weight Loss Program. This is a weight loss program specifically designed for men, which does not include any face-to-face commitments. It includes a Weight Loss DVD, Handbook, Logbook and some resources (a pedometer, tape measure and kJ counter book).

After using the SHED-IT Weight Loss Program for 3 months, there will be a follow up assessment at the University in November, 2012. At this follow-up assessment, all men who have lost at least 4 kg will be eligible for the second phase of this study. These men will be allocated into a self-help control group or the SHED-IT Weight Loss Maintenance group. This allocation will be done randomly, like drawing names out of a hat.

Men who have not yet lost 4 kg will be advised to continue with the SHED-IT Weight Loss Program for the remainder of the study.

The reason we have two groups in the second phase is because the SHED-IT Weight Loss Maintenance Program is new and we are running this trial to see if it works. We will test this by holding two further assessments with men from both groups in May 2013 and November 2013. For this reason, it’s extremely important for everyone to attend all four assessments, regardless of which group you are in.

Assessment sessions will involve some physical measures and some surveys:

• Assessments will be held at the university on week days at times that suit you – before or after work.
• Height, weight, waist circumference, body composition and blood pressure will be measured.
• No blood tests or other invasive or potentially uncomfortable or painful measures will be taken.
• We will also ask you to wear a pedometer and another small activity monitor for 7 days and write down how many steps you take each day.

If you are interested in taking part in this research trial, please continue on to the next page and complete the pre-program screener. This will help us determine whether you meet our eligibility criteria for inclusion in the study. After you have completed the screener we will get in touch as soon as possible to let you know if you are eligible.

Thank you again for your interest in the SHED-IT Weight Loss Maintenance study.

SHED-IT (2012) Pre-Program Screener

2. SHED-IT Eligibility Screener

Please complete all questions.

***1. What is your FIRST name?**

***2. What is your FAMILY name?**

***3. What is TODAY's date**

DD/MM/YYYY DD / MM / YYYY

***4. How did you hear about the SHED-IT Weight Loss Maintenance Trial? (tick all that apply)**

- [ ] Recruitment Flyer
- [ ] Newcastle Herald
- [ ] Email
- [ ] Text Message
- [ ] Newcastle University Website
- [ ] A Friend
- [ ] A Family Member
- [ ] Other (please describe)

***5. Are you a male?**

- ( ) Yes
- ( ) No

***6. What is your age?**

***7. What is your date of birth?**

DD/MM/YYYY DD / MM / YYYY

***8. What is your current height, to the nearest cm? (number only)**

***9. What is your current weight, to the nearest kg? (number only)**

SHED-IT (2012) Pre-Program Screener

***10. Do you have readily available access to the internet?**

○ Yes

○ No

***11. Do you have an e-mail account that you can use whilst in the study?**

○ No (note: you will need an email to be involved in the study)

○ Yes (please provide)

***12. Do you have a mobile phone that you can use whilst in the study?**

○ No (note: you will need a mobile phone to be involved in the study)

○ Yes (please provide)

***13. Are you currently involved in any weight loss programs?**

○ No

○ Yes (please provide detail)

***14. Are you currently or have you ever taken medication to lose or gain weight?**

○ No

○ Yes (please provide detail)

***15. If you are accepted into the study, do you agree not to participate in any other specific weight loss programs until after your last assessment session at the University (in November, 2013)?**

○ Yes

○ No

***16. Assessment sessions will be held in August 2012, November 2012, May 2013 and November 2013. Will you be available to attend all of the assessments, which will be held at the University of Newcastle, Australia? (you will be reminded about the dates).**

○ Yes

○ No

***17. Do you have diabetes requiring insulin treatment?**

- Yes
- No

***18. Have you lost any weight in the last six months?**

- No
- Yes (please estimate how much weight to the nearest kg)

***19. We need to work out if you are taking any medications that could affect your ability to lose weight (or if losing weight might not be recommended for people taking your medication). Are you currently taking any medications?**

- No
- Yes (please specify)

SHED-IT (2012) Pre-Program Screener

3. Adult Pre-Exercise Screener

*20. Please choose one response for each question.

	Yes	No
1. Has your doctor ever told you that you have a heart condition or have you ever suffered a stroke?	◯	◯
2. Do you ever experience unexplained pains in your chest at rest or during physical activity/exercise?	◯	◯
3. Do you ever feel faint or have spells of dizziness during physical activity/exercise that causes you to lose balance?	◯	◯
4. Have you had an asthma attack requiring immediate medical attention at any time over the last 12 months?	◯	◯
5. Do you have any diagnosed muscle, bone or joint problems that you have been told could be made worse by participating in physical activity/exercise?	◯	◯
6. Do you have any other medical condition(s) that may make it dangerous for you to participate in physical activity/exercise?	◯	◯

*21. 7. If you have diabetes (type I or type II) have you had trouble controlling your blood glucose in the last 3 months?

◯ Yes

◯ No

◯ I do not have diabetes

22. If there is anything from the above questions that you wish to clarify with additional detail, please do so below.

*23. We are interested in the advertising method or materials that lead you to contact us about the SHED-IT Study. We are also interested in the different types of men who apply for this research project.

If you allow us to retain the information you have given us today, this information would be entered into a database and your name permanently removed so that your identity is not available for use. The results of the research will be reported at national and international conferences and scientific publications.

You will not be identified in any reports arising from the study as individual information will never be used in the analysis and reporting of this information.

Regardless of your entry status into the study, do you give permission for us to retain the information you have given us?

◯ Yes

◯ No

4. Contact Information

*24. What is your address?

Address 1:

Address 2:

City/Town:

State:

Post Code:

Country:

25. What is your home phone number?

*26. What is the best time to call you?

- Before 9am
- 9am - 5pm
- After 5pm
- Any time
- Other (please specify)

5. Thank you

Thank you for completing the SHED-IT pre-program screening survey. A member of our research team will review your records as soon as possible and we will be in touch shortly to let you know if you are eligible for this research project.

cheers
The SHED-IT team

Appendix 5: Anthropometric measurement sheet

Name: ______________________________

SHED-IT Weight Loss Maintenance Trial

STUDY ENTRY ASSESSMENT

ID: ___________

Date of Birth:	**Time**:
Height:	**Clothing**:

WEIGHT [kg] *Record to 0. 01 kg Tolerance of .1 kg*					*Initial*
1.	2.	*If needed*			
InBody BIA					*Initial*
InBody Weight (kg):	Fat Mass (kg):				
Waist Circumference [Umbilicus] *Record to .1cm Tolerance of .5 cm*					*Initial*
1.	2.	If needed	If needed	If needed	
Waist Circumference [Narrowest] *Record to .1cm Tolerance of .5 cm*					*Initial*
1.	2.	If needed	If needed	If needed	
Resting Blood Pressure + Resting Heart Rate *Tolerance of Systolic 10mmHg, Diastolic 5mm Hg, HR 5 bpm*					*Initial*
1. /	2. /	3. /	If needed /	If needed /	
RHR 1.	RHR 2.	RHR 3.	If needed	If needed	
Questionnaires					*Initial*
Health Beliefs (all pages checked and complete)					
Food Frequency (all pages checked and complete)					
Lifestyle (all pages checked and complete)					

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

SHED-IT™ Self-Help, Exercise, Diet & Information Technology

HMRI Hunter Medical Research Institute

Appendix 6: Health beliefs questionnaire

The SHED-IT Weight Loss Maintenance Study

Health Beliefs Questionnaire (Baseline)

Prof. Philip Morgan
Prof. Ron Plotnikoff
Prof. Clare Collins
Prof. Robin Callister
Prof. Chris Doran
Mr Myles Young

Name: ____

To protect your privacy, this cover page will be removed once a participant number has been assigned and all answers to the questionnaire will be kept confidential.

Instructions

1. In each section, please read the instructions and questions carefully and answer each question according to what is true for you.
2. If you are unsure about how to answer a question, choose the response for the closest answer to how you feel. There are no right or wrong answers.
3. Please note that some of the questions may appear similar, but these small differences are important to our study. Therefore, it is important that you answer all questions, even if it seems that they are asking the same thing.

If you have any questions while filling out the questionnaire, please ask one of the SHED-IT research assistants at your station.

Thank you again for participating in this study.

This cover page will be removed and destroyed.

SECTION ONE: ‘Regular Physical Activity’ Beliefs and Practices

Through SECTION ONE of this questionnaire, we ask about your beliefs and practices regarding ‘*Regular Physical Activity*’.

‘*Regular Physical Activity*’ is defined as accumulating AT LEAST 60 minutes of physical activity on 5 or more days per week during your free time.

This physical activity must be at a MODERATE INTENSITY or greater.

Moderate intensity physical activity will cause a slight, but noticeable, increase in breathing and heart rate. Some good examples are:

- Brisk walking (this is a pace where you could comfortably talk, but not sing)
- Mowing the lawn
- Medium paced swimming
- Medium paced cycling

Examples of moderate intensity physical activity

To be considered REGULAR, this type of physical activity must:

1. Add up to a total of 60 minutes or more per day
2. Be done at least 5 days per week
3. Add up to a total of 300 minutes or more per week

There are a number of ways that you could reach your 60 minute total. You could, for example:

Take one 60-minute brisk walk or bicycle ride.

Or

Take three 20-minute periods of activities (e.g. a brisk walk for 20 minutes, swimming for 20 minutes and climbing stairs for 20 minutes, all in the same day)

Please think carefully about this definition of ‘*Regular Physical Activity*’ when you answer the following questions.

Study ID (office use only): ________________

Current Physical Activity

- For this question, we would like you to recall your average weekly participation in physical activity over THE PAST MONTH.
- How many times per week on average did you do the following kinds of physical activity during your free time over THE PAST MONTH?
- When answering these questions please:
    - Consider your average over THE PAST MONTH.
    - Only count physical activity sessions that lasted **10 minutes or longer** in duration.
    - Do not count physical activity that was done as part of your employment or household chores.
    - Note that the main difference between the three categories below is the **intensity** of the physical activity.
    - Please write the average number of times per week in the first column and the average time per session in the second column for strenuous, moderate, and mild physical activity.
    - Please write an answer in ALL 6 boxes, even if it's 0 (zero)

	Times per week	Average time per session (minutes)
A. Strenuous physical activity *(heart beats rapidly, sweating)* (e.g. jogging, hockey, soccer, squash, judo, vigorous swimming, vigorous long distance bicycling, vigorous aerobic dance classes, heavy weight training)		
B. Moderate physical activity *(not exhausting, light perspiration)* (e.g. fast walking, baseball, tennis, easy bicycling, volleyball, badminton, easy swimming)		
C. Mild physical activity *(minimal effort, no perspiration)* (e.g. easy walking, yoga, fishing, bowling, lawn bowling, golf)		

Is the amount of activity you did in THE PAST MONTH less, more, or about the same as your usual physical activity habits?

1	2	3	4	5
I am now much less active	*I am now less active*	*I am now about the same*	*I am now more active*	*I am now much more active*

Study ID (office use only): _______________

Regular Physical Activity: *Confidence*

- The next questions ask how confident you are about *accumulating at least 60 minutes of physical activity (at a moderate intensity or greater) on 5 or more days per week* in a number of different circumstances.
- When deciding how certain you are, think about your confidence in getting this amount of physical activity every week for the NEXT 6 MONTHS.
- Please circle one response for each question.

In the NEXT 6 MONTHS, I am confident that I can get *at least 60 minutes of physical activity (at a moderate intensity or greater) on 5 or more days each week*:

	Not at all confident	*Not very confident*	*Moderately confident*	*Very confident*	*Extremely confident*
When I am a little tired	1	2	3	4	5
When I am in a bad mood or feeling depressed.	1	2	3	4	5
When I have to do it by myself.	1	2	3	4	5
When it becomes boring.	1	2	3	4	5
When I can't notice any improvements in my fitness.	1	2	3	4	5
When I have many other demands on my time.	1	2	3	4	5
When I feel a little stiff or sore.	1	2	3	4	5
When the weather is bad.	1	2	3	4	5

In the NEXT 6 MONTHS, I am confident that I could RESTART getting *at least 60 minutes of physical activity (at a moderate intensity or greater) on 5 or more days each week*, even if:

	Not at all confident	*Not very confident*	*Moderately confident*	*Very confident*	*Extremely confident*
I did not get *'Regular Physical Activity'* for some time because I felt weak.	1	2	3	4	5
I did not get *'Regular Physical Activity'* for some time because I had no time for doing it on a regular basis.	1	2	3	4	5
I would have to reschedule my physical activity.	1	2	3	4	5
I had a break from *'Regular Physical Activity'* due to vacation.	1	2	3	4	5

Study ID (office use only): ________________

Regular Physical Activity: *Intention*

- The following questions ask you about your intention to engage in '*Regular Physical Activity'* over the NEXT 6 MONTHS.
- Remember, '*Regular Physical Activity*' = at least 60 minutes of physical activity (at a moderate intensity or greater) on 5 or more days each week.
- For each statement, please circle the answer that best represents you.

1. I am motivated to get *at least 60 minutes of physical activity (at a moderate intensity or greater) on 5 or more days each week* over the NEXT 6 MONTHS.

1	2	3	4	5	6	7
Extremely Unmotivated	Quite Unmotivated	Slightly Unmotivated	Neutral	Slightly Motivated	Quite Motivated	Extremely Motivated

2. I am determined to get *at least 60 minutes of physical activity (at a moderate intensity or greater) on 5 or more days each week* over the NEXT 6 MONTHS

1	2	3	4	5	6	7
Extremely Undetermined	Quite Undetermined	Slightly Undetermined	Neutral	Slightly Determined	Quite Determined	Extremely Determined

Regular Physical Activity: *Support*

- The next two questions relate to the support you would expect to receive if you were trying to get '*Regular Physical Activity*' over the NEXT 6 MONTHS.
- Remember, '*Regular Physical Activity*' = at least 60 minutes of physical activity (at a moderate intensity or greater) on 5 or more days each week.
- Please tell us how much you agree or disagree with each statement.

Over the NEXT 6 MONTHS:	*Strongly Disagree*	*Disagree*	*Neither Agree nor Disagree*	*Agree*	*Strongly Agree*
1. People in my social network are likely to help me get '*Regular Physical Activity*'.	1	2	3	4	5
2. I feel that someone in my social network will provide the support I need to get '*Regular Physical Activity*'.	1	2	3	4	5

Study ID (office use only): ________________

Regular Physical Activity: *Expectations*

- Please indicate how strongly you agree or disagree with the following statements about the outcomes of getting '*Regular Physical Activity*' over the NEXT 6 MONTHS.
- Remember: '*Regular Physical Activity*' is defined as getting *at least 60 minutes of physical activity (at a moderate intensity or greater) on 5 or more days each week.*

Over the NEXT 6 MONTHS:	*Strongly Disagree*	*Disagree*	*Neither Agree nor Disagree*	*Agree*	*Strongly Agree*
1. '*Regular Physical Activity*' would help me reduce tension or manage stress.	1	2	3	4	5
2. I would feel more confident about my health by getting '*Regular Physical Activity*'.	1	2	3	4	5
3. I would sleep better if I got '*Regular Physical Activity*'.	1	2	3	4	5
4. '*Regular Physical Activity*' would take up too much of my time.	1	2	3	4	5
5. I would have less time for family and friends if I participated in '*Regular Physical Activity*'.	1	2	3	4	5
6. I'd be too tired to get '*Regular Physical Activity*' because of my other daily responsibilities.	1	2	3	4	5
7. '*Regular Physical Activity*' would help me have a more positive outlook.	1	2	3	4	5
8. '*Regular Physical Activity*' would help me control my weight.	1	2	3	4	5
9. I'd worry about looking awkward if others saw me being physically active.	1	2	3	4	5
10. Participating in '*Regular Physical Activity*' would cost too much money.	1	2	3	4	5

Study ID (office use only): _______________

Regular Physical Activity: *Motivation*

- The following questions relate to the reasons why you would either start to get '*Regular Physical Activity*' or continue to do so.
- Different people have different reasons for doing that and we want to know how true each of the following reasons is for you.
- Remember: '*Regular Physical Activity*' is defined as getting *at least 60 minutes of physical activity (at a moderate intensity or greater) on 5 or more days each week.*
- *Please circle one response for each question.*

The reason I would get *'Regular Physical Activity'* is:

		Not at all true			*Somewhat true*			*Very true*
1.	Because I want to take responsibility for my own health	1	2	3	4	5	6	7
2.	Because I personally believe it is the best thing for my health	1	2	3	4	5	6	7
3.	Because I have carefully thought about it and believe it is very important for many aspects of my life	1	2	3	4	5	6	7
4.	Because it is an important choice I really want to make.	1	2	3	4	5	6	7
5.	Because it is consistent with my life goals.	1	2	3	4	5	6	7
6.	Because it is very important for being as healthy as possible.	1	2	3	4	5	6	7

Regular Physical Activity: *Your Plans*

- These statements relate to creating specific plans for getting '*Regular Physical Activity*'
- Please choose the answer that best represents you CURRENTLY.

1. I make plans concerning *'when'* I am going to engage in '*Regular Physical Activity'*

1	2	3	4	5	6	7
Strongly Disagree	*Moderately Disagree*	*Slightly Disagree*	*Neutral*	*Slightly Agree*	*Moderately Agree*	*Strongly Agree*

2. I make plans concerning *'where'* I am going to engage in '*Regular Physical Activity'*

1	2	3	4	5	6	7
Strongly Disagree	*Moderately Disagree*	*Slightly Disagree*	*Neutral*	*Slightly Agree*	*Moderately Agree*	*Strongly Agree*

3. I make plans concerning *'what'* kind of physical activities I am going to engage in

1	2	3	4	5	6	7
Strongly Disagree	*Moderately Disagree*	*Slightly Disagree*	*Neutral*	*Slightly Agree*	*Moderately Agree*	*Strongly Agree*

4. I make plans concerning *'how'* I am going to get to a place to engage in '*Regular Physical Activity'*

1	2	3	4	5	6	7
Strongly Disagree	*Moderately Disagree*	*Slightly Disagree*	*Neutral*	*Slightly Agree*	*Moderately Agree*	*Strongly Agree*

Study ID (office use only): _______________

Regular Physical Activity: *Goals*

- The following questions refer to how much you set physical activity goals and plan for physical activity.
- Please indicate the extent to which each of these statements below describes you CURRENTLY.

	Strongly Disagree	*Disagree*	*Neither Agree nor Disagree*	*Agree*	*Strongly Agree*
I often set physical activity goals	1	2	3	4	5
I usually have more than one major physical activity goal	1	2	3	4	5
I usually set dates for achieving my physical activity goals	1	2	3	4	5
My physical activity goals help to increase my motivation for doing physical activity	1	2	3	4	5
I tend to break more difficult physical activity goals into a series of smaller goals	1	2	3	4	5
I usually keep track of my progress in meeting my physical activity goals	1	2	3	4	5
I have developed a series of steps for reaching my physical activity goals	1	2	3	4	5
I usually achieve the physical activity goals I set for myself	1	2	3	4	5
If I do not reach a physical activity goal, I analyse what went wrong	1	2	3	4	5
I make my physical activity goals public by telling other people about them.	1	2	3	4	5

Study ID (office use only): ________________

Regular Physical Activity: *Family and Friends*

- Below is a list of things people might do or say to someone who is trying to get *'Regular Physical Activity'.*
- If you are not trying to do this currently, then some of the questions may not apply to you, but please read and give an answer to every question.
- Remember: '*Regular Physical Activity*' is defined as getting *at least 60 minutes of physical activity (at a moderate intensity or greater) on 5 or more days each week.*
- Please rate each question *twice*.
  - o Under *family*, rate how often anyone living in your household has said or done what is described during the PAST MONTH.
  - o Under *friends*, rate how often your friends, acquaintances, or co-workers have said or done what is described during the PAST MONTH
- Please write one number from the following rating scale in each space.

Never	Rarely	A few times	Often	Very often	Does not apply
1	2	3	4	5	8

During the PAST MONTH, my family (or members of my household) or friends:	Family	Friends
1. Were active with me		
2. Offered to be active with me		
3. Gave me helpful reminders to be active (e.g. "*Are you going to exercise tonight?*")		
4. Gave me encouragement to stick with my physical activity program		
5. Changed their schedule so we could be active together		
6. Discussed physical activity with me		
7. Planned for physical activity on recreational outings		
8. Helped plan activities around my physical activity		
9. Asked me for ideas on how *they* can get more physical activity		
10. Talked about how much they like to be active		

Study ID (office use only): ________________

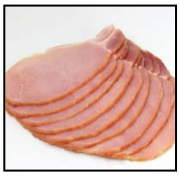
SECTION TWO: Junk Food Beliefs and Practices

Thankyou for completing SECTION ONE of this questionnaire.

Throughout SECTION TWO, we ask about your beliefs and practices regarding *Junk Food*. Please refer to the following definitions of 'Junk Food' and 'Healthy Food' as you complete the following sections.

JUNK FOODS

- 'Junk' foods (or non-core foods) are foods that aren't essential to provide the nutrients the body needs.
- These foods contain a lot of added salt, fat or sugar and most also contain lots of kilojoules or calories.
- Examples of junk foods that men commonly eat are:

Bacon

Chocolate

Cakes

Muffins

Ice cream

Potato Chips


Biscuits

Hot Chips / Fries

Meat Pies

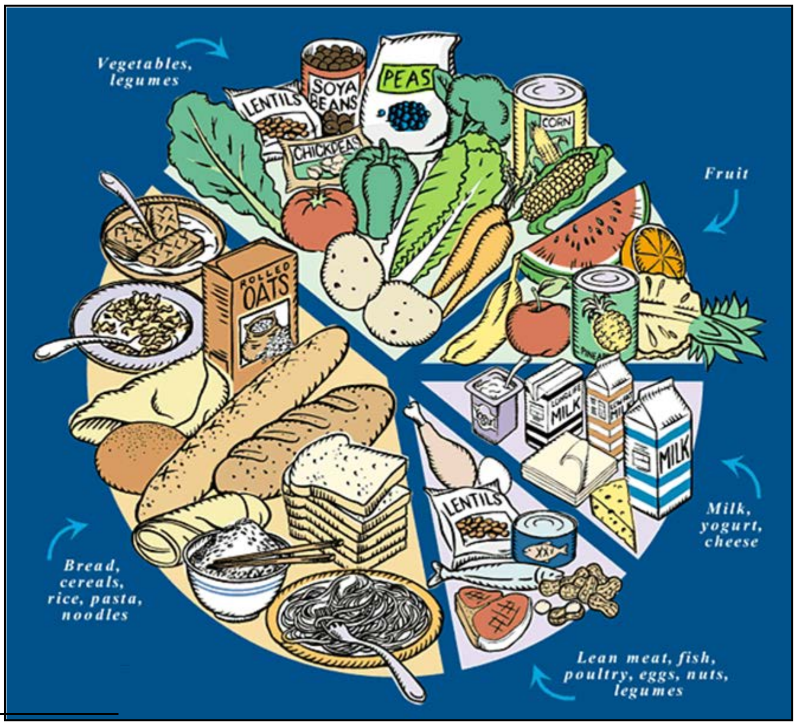
Sausage Rolls

Sausages

Pizza


HEALTHY FOODS

- Healthy foods should be eaten regularly and examples are included on this 'healthy eating' plate.
- These foods provide the important nutrients that the body needs for optimal health.



Study ID (office use only): ________________

Eating Less Junk Food: *Confidence*

- These questions ask about how tempted you would be to eat your favourite junk food in a variety of situations over the NEXT 6 MONTHS.
- For examples of junk food that men commonly eat, please refer to your laminated card.
- As you read each situation below, think of a junk food you really like to eat
- Then, circle the number that indicates **how tempted** you would be to eat that junk food in each situation.

In the NEXT 6 MONTHS, how tempted would you be to eat your favourite junk food:

		Not at all tempted	*Not very tempted*	*Moderately tempted*	*Very tempted*	*Extremely tempted*
1.	While having a good time with friends at a party.	1	2	3	4	5
2.	When you have experienced a tough day and are not feeling good about yourself.	1	2	3	4	5
3.	When it would be very difficult to substitute a healthy food because only junk foods are available.	1	2	3	4	5
4.	In situations in which you are celebrating with friends and are happy.	1	2	3	4	5
5.	During those times when you feel depressed about something.	1	2	3	4	5
6.	In situations when eating healthy food is just too much trouble.	1	2	3	4	5
7.	While eating out at a restaurant with friends.	1	2	3	4	5
8.	On days when things are not going your way and you feel frustrated.	1	2	3	4	5
9.	When it's difficult to swap a healthy food for the junk food you would really prefer to eat.	1	2	3	4	5
10.	While enjoying the company of others at a barbeque.	1	2	3	4	5
11.	When you have an argument with someone close to you and you feel upset.	1	2	3	4	5
12.	When you have to prepare meals for yourself that are healthy.	1	2	3	4	5

Study ID (office use only): _______________

Eating Less Junk Food: *Expectations*

- Please indicate how strongly you agree or disagree with the following statements about the outcomes of eating less junk food over the NEXT 6 MONTHS.

If I eat less junk food over the NEXT 6 MONTHS, I expect:

		Strongly Disagree	*Disagree*	*Neither Agree nor Disagree*	*Agree*	*Strongly Agree*
1.	I will have more energy	1	2	3	4	5
2.	I will lose weight	1	2	3	4	5
3.	I will live healthier and happier	1	2	3	4	5
4.	I will feel better in my clothes	1	2	3	4	5
5.	I will be hungrier	1	2	3	4	5
6.	I will be unhappy and irritable	1	2	3	4	5
7.	My health will improve	1	2	3	4	5
8.	I will miss eating the foods I love	1	2	3	4	5
9.	I will have healthier skin, hair, or teeth	1	2	3	4	5
10.	Shopping for healthy foods will be a lot of trouble	1	2	3	4	5
11.	I will be bored with what I have to eat	1	2	3	4	5
12.	I will have to change a lot of my favourite foods	1	2	3	4	5
13.	I won't be able to eat the same foods as the rest of my family	1	2	3	4	5
14.	I will have to spend too much time keeping track of what I eat	1	2	3	4	5
15.	The food I eat will not taste as good	1	2	3	4	5
16.	It will take too long to prepare meals and snacks	1	2	3	4	5
17.	I will have to plan my meals too far in advance	1	2	3	4	5
18.	I will be more attractive	1	2	3	4	5
19.	I will be doing what I know I should	1	2	3	4	5
20.	I won't be able to stick with it – I will just go back to my old habits	1	2	3	4	5

Study ID (office use only): _______________

Eating Less Junk Food: *Support*

- The next two questions relate to the support you would expect to receive if you were trying to eat less junk food over the NEXT 6 MONTHS.

- Please tell us how much you agree or disagree with each statement.

Over the NEXT 6 MONTHS:	*Strongly Disagree*	*Disagree*	*Neither Agree nor Disagree*	*Agree*	*Strongly Agree*
1. People in my social network are likely to help me eat less junk food.	1	2	3	4	5
2. I feel that someone in my social network will provide the support I need to eat less junk food	1	2	3	4	5

Eating Less Junk Food: *Environment*

- How frequently are the following foods available in your day-today life (i.e. your home, work and places you frequently visit)

	Never / Rarely	*Sometimes*	*Usually*	*Always*
1. Bacon	1	2	3	4
2. Chocolate	1	2	3	4
3. Cakes	1	2	3	4
4. Muffins	1	2	3	4
5. Ice cream	1	2	3	4
6. Potato chips	1	2	3	4
7. Biscuits	1	2	3	4
8. Hot chips / Fries	1	2	3	4
9. Meat pies	1	2	3	4
10. Sausage rolls	1	2	3	4
11. Sausages	1	2	3	4
12. Pizza	1	2	3	4
13. Hamburgers	1	2	3	4

Study ID (office use only): ________________

Eating Less Junk Food: *Strategies*

- The following are activities, thoughts and feelings people use to help them eat less junk food
- Think of any similar experiences you may be having or have had in the PAST MONTH.
- Then, rate HOW OFTEN you did each of the following:

In the PAST MONTH:	*Never*	*Almost never*	*Sometimes*	*Often*	*Many times*
1. I looked for information on ways to help me eat less junk food.	1	2	3	4	5
2. I kept track of how much junk food I ate.	1	2	3	4	5
3. I found ways to get around the barriers of eating less junk food.	1	2	3	4	5
4. I thought about how my surroundings affect the junk food I eat (surroundings are things like fast food restaurants, your home and workplace and pre-packaged foods in shops).	1	2	3	4	5
5. I put reminders around my home to eat less junk food.	1	2	3	4	5
6. I rewarded myself for eating less junk food.	1	2	3	4	5
7. I did things to make eating less junk food less difficult	1	2	3	4	5
8. I thought about the benefits I will get if I ate less junk food.	1	2	3	4	5
9. I tried to think more about the benefits of eating less junk food and less about the hassles of healthy eating.	1	2	3	4	5
10. I said positive things to myself about the benefits of eating less junk food.	1	2	3	4	5
11. When I got off track and ate lots of junk food, I told myself that I could start again and get right back on track.	1	2	3	4	5
12. I had a friend or family member who encouraged me to eat less junk food.	1	2	3	4	5
13. I tried different kinds of healthy foods so that I had more options to choose from.	1	2	3	4	5
14. I set goals to eat less junk food.	1	2	3	4	5
15. I made back up plans to be sure I ate less junk food.	1	2	3	4	5

Study ID (office use only): _______________

Eating Less Junk Food: *Family and Friends*

- Below is a list of things people might do or say to someone who is trying to eat less junk food.
- If you are not trying to do this, then some of the questions may not apply to you, but please read and give an answer to every question.
- Please rate each question twice - once in relation to your family and once in relation to your friends.
    - Under *family*, rate how often anyone in the household said or did what is described during the PAST MONTH.
    - Under *friends*, rate how often your friends, acquaintances, or co-workers said or did what is described during the PAST MONTH.

Please write *one* number from the following scale in each space for family and friends.

1	2	3	4	5	8
Never	Rarely	A few times	Often	Very often	Does not apply

During the PAST MONTH, my family (or members of my household) or friends:

	Family	*Friends*
1. Encouraged me not to eat junk food when I'm tempted to do so.		
2. Discussed my eating habit changes with me (asked me how I'm doing with my eating changes).		
3. Reminded me not to eat junk food.		
4. Complimented me on changing my eating habits ("Keep it up", "I am proud of you").		
5. Commented if I went back to my old eating habits.		
6. Ate junk food in front of me.		
7. Refused to eat the same foods I eat.		
8. Brought home (or brought over) junk foods I'm trying not to eat.		
9. Got angry when I encouraged them to eat less junk food.		
10. Offered me junk food I'm trying not to eat.		

Study ID (office use only): _______________

Eating Less Junk Food: *Plans*

- The following statements refer to plans a person might make if they were trying to eat less junk food.
- IMPORTANT: If you are not trying to do this currently, then some of the statements may not apply to you, but please read and give an answer to every question.
- Please choose the answer that best represents you CURRENTLY.

i.e. When it comes to eating less junk food, I make detailed plans regarding:

	Strongly Disagree	*Disagree*	*Agree*	*Strongly Agree*
1. What to do if something interferes with my plans	1	2	3	4
2. How to cope with possible setbacks	1	2	3	4
3. What to do in difficult situations in order to act according to my intentions	1	2	3	4
4. Which good opportunities for action to take	1	2	3	4
5. When I have to pay attention to prevent lapses	1	2	3	4

Thank you for completing this survey

Study ID (office use only): _______________

Appendix 7: Lifestyle questionnaire

The SHED-IT Weight Loss Maintenance Study

Lifestyle Questionnaire (Baseline Assessment)

Prof. Philip Morgan
Prof. Ron Plotnikoff
Prof. Clare Collins
Prof. Robin Callister
Prof. Chris Doran
Mr Myles Young

Name: ______________________________________

To protect your privacy, this cover page will be removed once a participant number has been assigned and all answers to the questionnaire will be kept confidential.

Instructions

1. In each section, please read the instructions and questions carefully and answer each question according to what is true for you.
2. If you are unsure about how to answer a question, choose the response for the closest answer to how you feel. There are no right or wrong answers to any of these questions.
3. Please note that some of the questions may appear similar, but these small differences are important to our study. Therefore, it is important that you answer all questions, even if it seems that they are asking the same thing.

If you have any questions while filling out the questionnaire, please ask one of the SHED-IT research assistants at your station.

Thank you again for participating in this study.

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Sitting Time

- Please estimate how much time you spend SITTING EACH DAY in the following situations.
- Please write an answer in every box, <u>even if it is 0</u>

	On a WEEK day		On a WEEKEND day	
	Hours	Minutes	Hours	Minutes
While travelling to and from places				
While at work *(If you are not working, write NW)*				
While watching television				
While using a computer at home				
In your leisure time, NOT including television or computer use (e.g. visiting friends, movies, dining out, etc.)				

Participant ID: ___________

General Health

- The following questions ask for your views about your health, how you feel and how well you are able to do your usual activities.
- If you are unsure about how to answer any questions please give the best answer you can.
- Do not spend too much time in answering as your immediate response is likely to be the most accurate.

1. In general, would you say your health is …

Tick one box

☐ Excellent
☐ Very Good
☐ Good
☐ Fair
☐ Poor

HEALTH AND DAILY ACTIVITIES

2. The following questions are about activities you might do during a typical day. Does your health limit you in these activities? If so, how much? (please tick one box on each line)

a) Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf.

Tick one box

☐ Yes, limited a lot
☐ Yes, limited a little
☐ No, not limited at all

b) Climbing several flights of stairs

☐ Yes, limited a lot
☐ Yes, limited a little
☐ No, not limited at all

3. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? *(Please answer Yes or No to each question)*

a) Accomplished less than you would like

☐ Yes
☐ No

b) Were limited in the kind of work or other activities

☐ Yes
☐ No

Participant ID: ___________

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)? *(Please answer Yes or No to each question)*

   a) Accomplished less than you would like

   - ☐ Yes
   - ☐ No

   b) Didn't do work or other activities as carefully as usual

   - ☐ Yes
   - ☐ No

5. During the past 4 weeks how much did pain interfere with your normal work? (Including work both outside the home and housework)

   Tick one box

   - ☐ Extremely
   - ☐ Quite a bit
   - ☐ Moderately
   - ☐ A little bit
   - ☐ Not at all

YOUR FEELINGS

6. These questions are about how you feel and how things have been with you during the past month. For each question, please indicate the one answer that comes closest to the way you have been feeling.

a) How much time during the last month have you felt calm and peaceful?

Tick one box

- ☐ All of the time
- ☐ Most of the time
- ☐ A good bit of the time
- ☐ Some of the time
- ☐ A little of the time
- ☐ None of the time

b) How much time during the last month did you have a lot of energy?

Tick one box

- ☐ All of the time
- ☐ Most of the time
- ☐ A good bit of the time
- ☐ Some of the time
- ☐ A little of the time
- ☐ None of the time

Tick one box

Participant ID: ___________

c) How much time during the last month have you felt downhearted and low?

- ☐ All of the time
- ☐ Most of the time
- ☐ A good bit of the time
- ☐ Some of the time
- ☐ A little of the time
- ☐ None of the time

7. How much time during the last month has your health limited your social activities (like visiting friends/close relatives)?

Tick one box

- ☐ All of the time
- ☐ Most of the time
- ☐ Some of the time
- ☐ A little of the time
- ☐ None of the time

---

8. What is your PRESENT relationship status?

- ☐ Single
- ☐ In a relationship
- ☐ Living with a partner
- ☐ Married
- ☐ Separated
- ☐ Divorced
- ☐ Widowed

Participant ID: ___________

Your Mood

- Over the last 2 weeks, how often have you been bothered by any of the following problems?

	Not at all	Several days	More than half the days	Nearly every day
Little interest or pleasure in doing things	1	2	3	4
Feeling down, depressed, or hopeless	1	2	3	4
Trouble falling or staying asleep, or sleeping too much	1	2	3	4
Feeling tired or having little energy	1	2	3	4
Poor appetite or overeating	1	2	3	4
Feeling bad about yourself - or that you are a failure or have let yourself or your family down	1	2	3	4
Trouble concentrating on things, such as reading the newspaper or watching television	1	2	3	4
Moving or speaking so slowly that other people could have noticed? Or the opposite - being so fidgety or restless that you have been moving around a lot more than usual	1	2	3	4

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

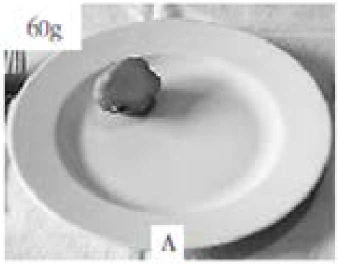
- ☐ I did not check off any problems
- ☐ Not difficult at all
- ☐ Somewhat difficult
- ☐ Very difficult
- ☐ Extremely difficult

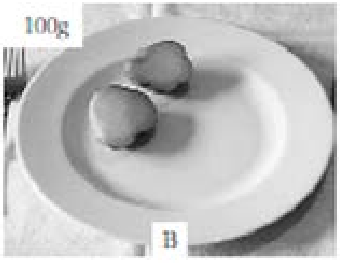
Participant ID: ___________

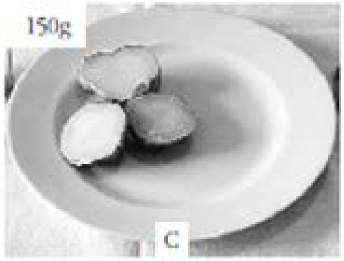
Portion size (Page 1)

- For each food shown on this page, please indicate how much on average you would usually have eaten at main meals **during the past 3 months**.
- When answering each question, think of the **amount** of food that you usually ate, even though you may rarely have eaten the food on its own.
- If you usually ate more than one helping, please circle the serving size closest to the **total amount** you ate.

1. POTATO



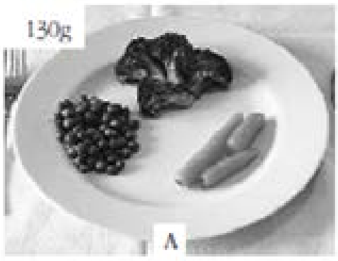


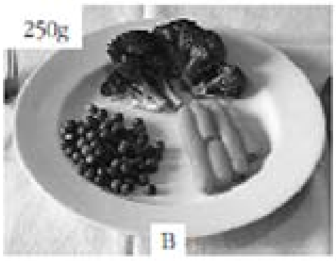


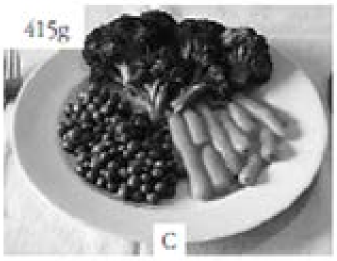
☐ Less than A	☐ A	☐ Between A and B	☐ B	☐ Between B and C	☐ C	☐ More than C

☐ I never ate potato

2. VEGETABLES







☐ Less than A	☐ A	☐ Between A and B	☐ B	☐ Between B and C	☐ C	☐ More than C

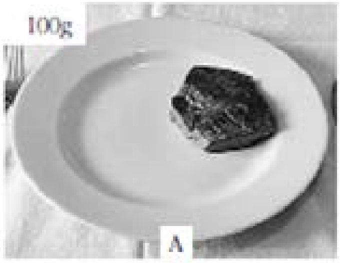
☐ I never ate vegetables

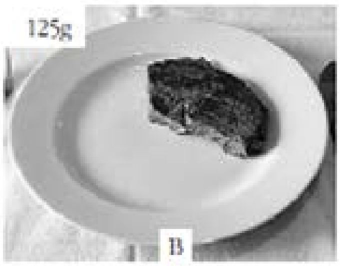
Participant ID: ___________

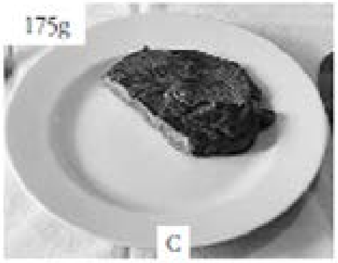
Portion size (Page 2)

- For each food shown on this page, please indicate how much on average you would usually have eaten at main meals **during the past 3 months**.
- When answering each question, think of the **amount** of food that you usually ate, even though you may rarely have eaten the food on its own.
- If you usually ate more than one helping, please circle the serving size closest to the **total amount** you ate.

3. STEAK



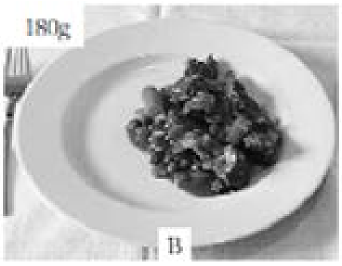


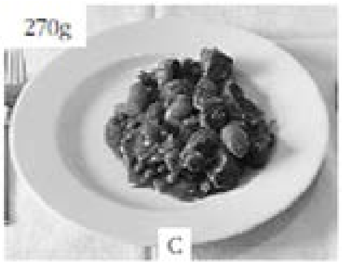


☐	☐	☐	☐	☐	☐	☐
Less than A	A	Between A and B	B	Between B and C	C	More than C

☐ I never ate steak

4. MEAT OR VEGETABLE CASSEROLE





☐	☐	☐	☐	☐	☐	☐
Less than A	A	Between A and B	B	Between B and C	C	More than C

☐ I never ate casserole

Participant ID: ___________

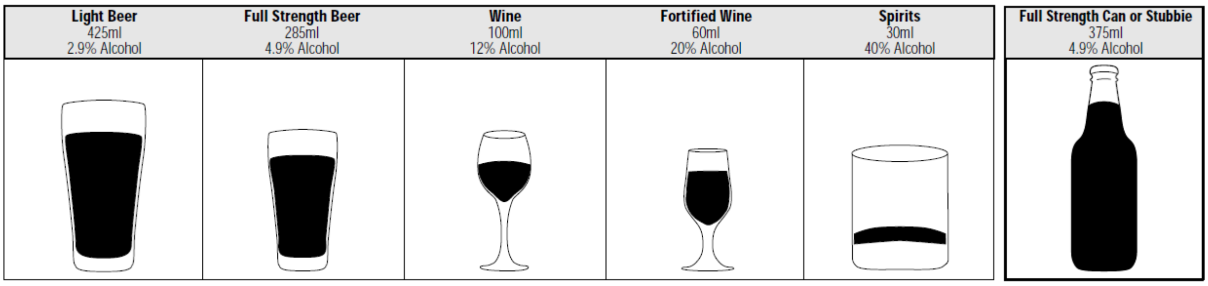
Sexual function

1.	*Over the past 3 months*, how do you rate your confidence that you could get and keep an erection?	☐ Very low ☐ Low ☐ Moderate ☐ High ☐ Very high
2.	*Over the past 3 months*, when you had erections with sexual stimulation, how often were your erections hard enough for penetration?	☐ No sexual activity ☐ Almost never or never ☐ A few times (much less than half the time) ☐ Sometimes (about half the time) ☐ Most times (much more than half the time) ☐ Almost always or always
3.	*Over the past 3 months*, during sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner?	☐ Did not attempt intercourse ☐ Almost never or never ☐ A few times (much less than half the time) ☐ Sometimes (about half the time) ☐ Most times (much more than half the time) ☐ Almost always or always
4.	*Over the past 3 months*, during sexual intercourse, how difficult was it to maintain your erection to the completion of intercourse?	☐ Did not attempt intercourse ☐ Extremely difficult ☐ Very difficult ☐ Difficult ☐ Slightly difficult ☐ Not difficult
5.	*Over the past 3 months*, when you attempted sexual intercourse, how often was it satisfactory for you?	☐ Did not attempt intercourse ☐ Almost never or never ☐ A few times (much less than half the time) ☐ Sometimes (about half the time) ☐ Most times (much more than half the time) ☐ Almost always or always

Participant ID: __________

Alcohol consumption

- Try to answer these questions in terms of 'standard drinks' (see picture below).
- For each question, please circle the response that best fits your drinking habits over the past 3 months.



The guide above contains examples of ***one standard drink***. A full strength can or stubbie contains ***one and a half standard drinks***.

1. How often do you have a drink containing alcohol?

Never *(Skip Q2 & Q3)*	Monthly or less	2-4 times a month	2-3 times a week	4 or more times a week

2. How many standard drinks do you have on a typical day when you are drinking?

1 or 2	3 or 4	5 or 6	7 to 9	10 or more

3. How often do you have six or more standard drinks on one occasion?

Never	Less than monthly	Monthly	Weekly	Daily or almost daily

Breakfast

Currently, how many days per week did you usually eat breakfast? *Please circle one option*

0	1	2	3	4	5	6	7

Transport

Which mode of transport did you use to travel to this assessment?

☐ Car ☐ Train ☐ Other: ________________

☐ Bus ☐ Motorbike

☐ Walk ☐ Bicycle

Participant ID: ___________

Eating Habits

The following questions are about your eating habits. Please circle one response for each statement.

1. I deliberately take small helpings as a means of controlling my weight.

1	2	3	4
Definitely false	Mostly false	Mostly true	Definitely true

2. I consciously hold back at meals in order not to gain weight.

1	2	3	4
Definitely false	Mostly false	Mostly true	Definitely true

3. I do not eat some foods because they make me fat.

1	2	3	4
Definitely false	Mostly false	Mostly true	Definitely true

4. How frequently do you avoid 'stocking up' on tempting foods?

1	2	3	4
Almost never	Seldom	Usually	Almost always

5. How likely are you to consciously eat less than you want to?

1	2	3	4
Unlikely	Slightly likely	Moderately likely	Very likely

6. What number would you give yourself on a scale of 1 to 8, where:

   1 = no restraint (eating whatever you want, whenever you want it) and

   8 = means total restraint (constantly limiting food and never 'giving in')

1	2	3	4	5	6	7	8

Self-weighing

Currently, how often do you weigh yourself?

- ☐ Several times per day
- ☐ 1 time per day
- ☐ Several times per week
- ☐ 1 time per week
- ☐ Less than 1 time per week
- ☐ Less than 1 time per month

Participant ID: ___________

Food Labels

Please use the following scale to indicate how strongly you agree or disagree with the following statements regarding *food labels*, which can be found on most packaged foods and drinks).

NUTRITION INFORMATION

Servings per package: 8

Serving size: 20g (1 bar)

	Quantity per serving	Quantity per 100g
Energy	350 kJ	1770 kJ
Protein	1.5 g	7.7 g
Fat - total	2.1 g	10.4 g
- saturated	0.3 g	1.4 g
Carbohydrates	14.2 g	70.8 g
- sugars	4.5 g	22.7 g
Sodium	60 mg	305 mg

Figure 1. Example of a food label

It is important to read *food labels* on foods and drinks when shopping.	☐ Strongly Disagree ☐ Disagree ☐ Neither Agree nor Disagree ☐ Agree ☐ Strongly Agree
It is important to check the *food label* before consuming a food or drink.	☐ Strongly Disagree ☐ Disagree ☐ Neither Agree nor Disagree ☐ Agree ☐ Strongly Agree
Reading *food labels* is important for weight loss.	☐ Strongly Disagree ☐ Disagree ☐ Neither Agree nor Disagree ☐ Agree ☐ Strongly Agree
Over the last 3 months, I have read the *food labels* on foods and drinks	☐ Never ☐ Rarely ☐ Sometimes ☐ Frequently ☐ Extremely often

Weight Loss Expectations

These questions relate to your weight loss expectations. Please write one answer per line.

Expectation	Description	Weight
Dream weight?	*A weight you would choose if you could weigh whatever you wanted*	_______ kg
Happy weight?	*This weight is not as ideal as the first one. It is a weight, however, that you would be happy to achieve.*	_______ kg
Acceptable weight?	*A weight that you would not be particularly happy with, but one that you could accept, since it is less than your current weight.*	_______ kg
Disappointed weight?	*A weight that is less than your current weight, but one that you could not view as successful in any way. You would be disappointed if this were your final weight after the program.*	_______ kg

Health professionals

- Over the past 3 months, how many times did you visit the following health professionals?
- Please write an answer in every box EVEN IF IT IS ZERO (0)

1. General Practitioner ________*times*
2. Dietitian ________*times*
3. Nutritionist ________*times*
4. Exercise Physiologist ________*times*
5. Pharmacist (Chemist) ________*times*
6. Physiotherapist ________*times*
7. Personal trainer ________*times*
8. Naturopath ________*times*

Thank you for completing this survey

Participant ID: ___________

Appendix 8: Sample resources: SHED-IT Weight Loss Maintenance Handbook

Introduction

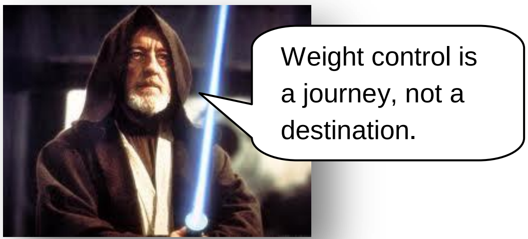
WELCOME to the *SHED-IT Weight Loss Maintenance Program for Blokes.* This is the world's first male only program to help men who lose weight keep it off for good.

SHED-IT™
Self-Help, Exercise, Diet & Information Technology

Congratulations on your weight loss so far. Losing weight is a big challenge, so be proud of your success!

You have probably started noticing some of the great physical and psychological health benefits of weight loss. You may also be wondering '*why do I need a weight loss maintenance program*?'

However, do you remember this saying?



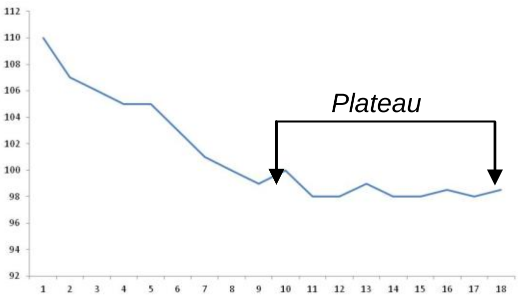
This wisdom is now more relevant than ever. There is a unique set of knowledge and skills needed to keep weight off in the long term.

The SHED-IT Weight Loss Maintenance program will give you all the information you need to be a lifelong success story.

Embrace the plateau

Research shows that many men lose weight steadily for the first three months of a weight loss regime. This is followed by a slowing down phase, known as a *weight loss plateau*.

Example of a weight loss plateau



Although the science behind weight loss plateaus is quite complex, here are a few of the possible reasons why your weight loss may slow down over time:

1. *Smaller bodies burn fewer kilojoules*: As you lose weight, your smaller body won't need as many kilojoules to fuel itself. This is like switching from a 4-wheel drive to a sedan.

Before SHED-IT

After SHED-IT

2. *You become a more efficient exerciser*: As you become more skilled at exercising, your body will burn fewer kilojoules for the same results, like a finely tuned engine.

Tip 1: *Jump on small gains*

Weigh in Wednesday

During weight loss maintenance, it is still vital to weigh yourself once a week. We recommend that you stick with *Weigh in Wednesday*, because it's in the middle of the week and removed from the weekend (where your eating and exercise habits can be slightly different).

Remember to weigh yourself at the same time of the day and wearing the same clothing each time.

Plotting your weekly weight on a graph will help you see the big picture. Weight can creep up on you little by little, but a graph will help you see the trends.

Did you know?

75% of successful losers from the *National Weight Control Registry* weigh themselves at least once per week.

Restart weight loss if you hit your 'red alert' weight

During weight loss maintenance it can be easy to let your new, healthy lifestyle behaviours slip for a couple of weeks. During this time, your weight can creep up on you slowly and steadily.

RED ALERT

A 2.5kg weight gain from now on means 'action stations' and you need to go back to weight loss mode.

To ensure that you don't let your weight creep too far, you need to keep an eye out for your 'red alert' weight. This is a 2.5 kg weight gain from your weight at the beginning of the maintenance program.

Your red alert weight will serve as an 'early warning system' and give you an indication that it's time to transition back into weight loss mode for a while until you get yourself back on track.

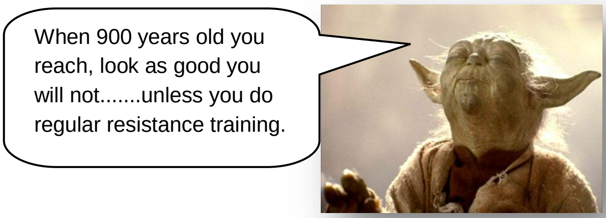
If you find that your weight has crept up to the red alert level, we encourage you to re-engage with the SHED-IT weight loss program resources until you are out of the 'red alert' or danger zone.

Tip 3: *Build muscle with resistance training*

Use the force

Resistance training (also known as weight training or strength training) is a strength-based activity which challenges your muscles to overcome a particular weight or force.

This force can be created using different equipment (e.g. free weights, weight machines and elastic tubing) or just your own body weight. You can also create the force with a simple Jedi mind trick although this will take you a few more years of training.



When performed correctly and consistently, resistance training helps you to become bigger, stronger and healthier. This is because the muscle cells will adapt and increase in size when challenged at the right level.

Darth Vader makes a common mistake by applying the force to someone else's muscles

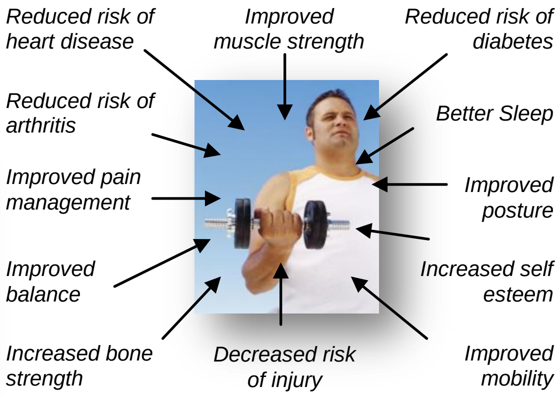
Resistance training and weight management

When it comes to burning kJs, the more muscle mass you have, the better. Compared to fat cells (which use almost no kJs), muscle cells have a huge 'appetite' for kJs and are constantly burning them up through the day.

You can see now why it is so important to maintain your muscle mass. With regular resistance training, you can turn your body into a fat burning machine, even when you aren't exercising.

Other health benefits of resistance training

In addition to increasing your muscle mass and the number of kJs you burn through the day, resistance training is also associated with a wide variety of other health benefits.



Expectations

Before you get too excited, it's important to note that the aim here is not to grow rippling muscles or look like Arnie.

However, by engaging in regular resistance training you will be able to gain all of the health benefits listed above. You will feel fitter and stronger, walk taller and you can be confident in the knowledge that you are protecting and strengthening your body and mind.

The Hulk may be ripped, but that guy has some serious issues…

Tip 7: *Refuel with fruit and vegetables*

We can appreciate that some men don't think of fruits and vegetables as exciting or particularly appealing food choices. We also know that some blokes believe that real men don't eat vegetables.

However, once they understand the health benefits and assistance for long term health and weight loss, they may start questioning what it actually means to be a real man.

Ultimate Fighting Championship cage fighters are some of the fittest men in the world and follow strict diets consisting of a heap of fruit and vegetables.

It's probably not a good idea to tell him he's not a real man….

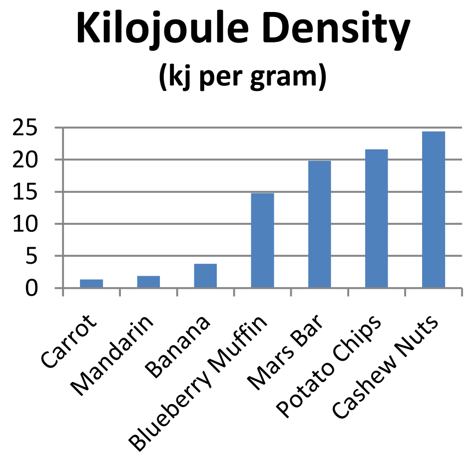
Fruits and vegetables really are super foods. They are completely natural and contain a stack of vitamins and minerals that our bodies need to perform at a peak level. They protect us from chronic diseases and you can eat a lot of them without taking in many kilojoules.

Here are a few of the main reasons why fruits and vegetables are essential for good health and weight management:

1. You get more, for less

Most fruits and vegetables are very low in 'kJ density', which is a way of comparing foods (or drinks) by the number of kJs they contain per gram (or mL). In other words, fruits and vegetables look big (and are very filling), but when it comes to kJs they are small.

If you aren't convinced, take a look at the graph below. You can see that 'gram for gram' fruits and vegetables are far more economical food choices compared to the other (perhaps more appealing) options.



2. They protect your health

Good evidence now shows that people who eat high amounts of fruits and vegetables have a lower risk of many diseases including:

- Type 2 diabetes
- Heart disease
- High blood pressure
- Macular degeneration

Tip 8: *Don't skip meals*

Skipping meals might sound like a time saver or seem like a logical way of reducing your kJ intake. However, you will pay later with negative effects on your metabolism, blood sugar and appetite. Skipping meals is like trying to drive a car without putting any fuel in the tank.

When you skip a meal your blood sugar levels drop, which will make you feel tired, unable to concentrate and can lead to increased snacking throughout the day. Skipping meals leads to greater kJ intake over the day because it wreaks havoc on your appetite cues.

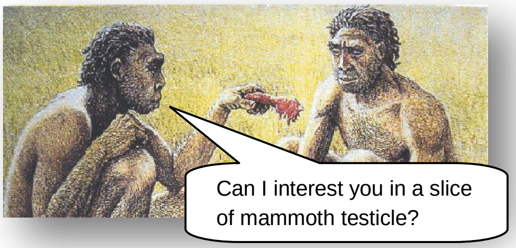
Breakfast – break the fast!

Eating breakfast is essential to get you started for the day. Eating breakfast is associated with a whole host of health benefits, including improved mental functioning (e.g. alertness, concentration and memory) and improved mood. A healthy breakfast provides you with essential nutrients like B vitamins. These are like spark plugs which really give you a great start to the day.

While you are asleep your body uses just enough energy to keep everything ticking over through the night. Eating breakfast (i.e. *break*ing the overnight *fast*) actually kick starts your metabolism in the morning. It's like the fuel injection that gets the lawn mower going.

This is most likely a survival mechanism our ancestors developed a long time ago when food was scarce. This adaptation has stuck around and our bodies are still hardwired to use as little energy as possible until knowing that more food is around.

Luckily for us we can just grab a bowl of cereal instead of leftover mammoth meat!



Breakfast and weight control

Despite the many health benefits, it appears that many men still skip breakfast. This may be due to the myth that skipping breakfast will help them manage their weight as they are eating less.

However, this actually isn't true. Here are a few examples of how eating breakfast could help you manage your weight:

- Eating breakfast reduces the hunger seen later in the day, which could lead to overeating.

- Studies show that people who skip meals actually end up eating *more* kilojoules throughout the day, compared to people who have 3 meals and eat healthy snacks.

- Breakfast eaters are more likely to make healthy food choices through the day (we all know it's 10 times harder to resist hot chips if you're starving).

- Eating breakfast will give you more energy to get through your daily exercise routine.

Appendix 9: Sample resources: SHED-IT Weight Loss Maintenance Logbook

INTRODUCTION

The *SHED–IT Weight Loss Maintenance Log Book for Blokes* is where you need to keep a record of key strategies that will help you maintain your weight loss for the next 6 months.

There are 6 key sections to this log book:

1. Updating your *CalorieKing* Profile
2. Weight Chart
3. Physical Activity Monitoring
    a. Step Count Chart
    b. Physical Activity Minutes Chart
4. Goal Setting
5. Strategies to Engage Family and Friends
6. SHED-IT Resistance Training Program

By completing these sections as required, you will give yourself the best chance at long term success.

Everything you need is here. We wish you all the best and look forward to seeing you at your next assessment in May, 2013.

The SHED–IT Research Team

SECTION 2

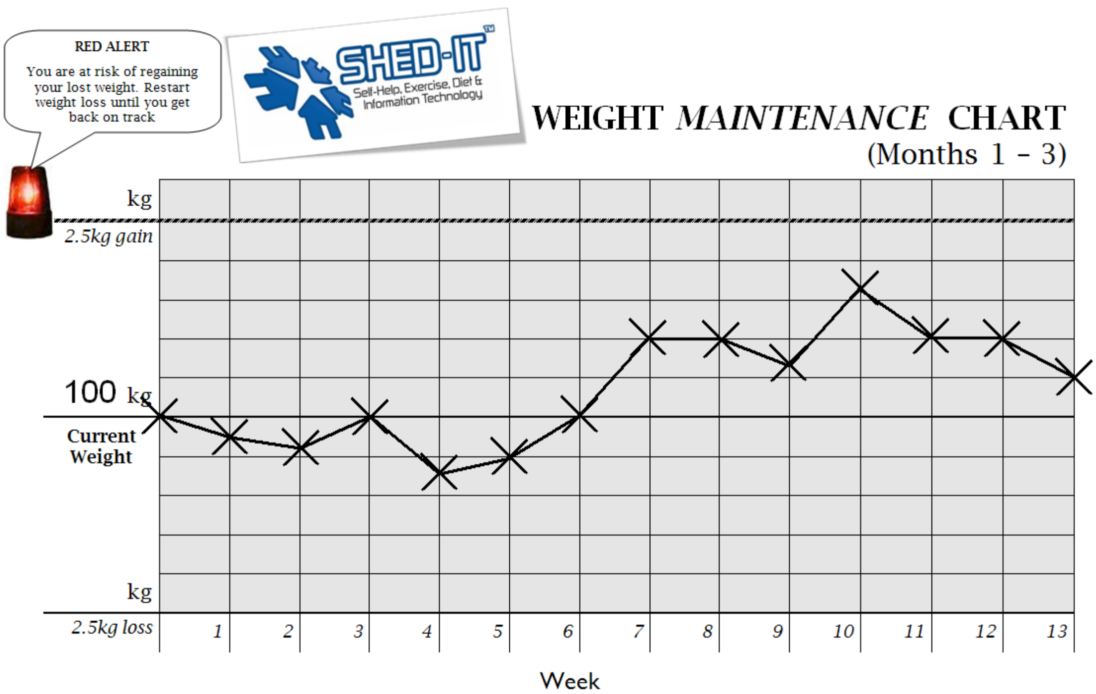
WEIGHT CHART

- Keeping track of your weight is still a fundamental behaviour associated with long term weight loss success.
- This needs to be the first order of the day, every Wednesday morning **without fail.**
- Over the next 6 months it is critical that you jump on any small gains right away. This will prevent your weight from creeping back up on you.

Weight Chart Instructions

1. Weigh yourself on a set of scales and plot your weight on the chart, corresponding to each week of the program.
2. Please also enter your weight on the CalorieKing Website.

EXAMPLE OF A COMPLETED WEIGHT MAINTENANCE CHART



RED ALERT

You are at risk of regaining your lost weight. Restart weight loss until you get back on track

WEIGHT *MAINTENANCE* CHART
(Months 1 – 3)

kg													
2.5kg gain													
kg													
Current Weight													
kg													
2.5kg loss	*1*	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*11*	*12*	*13*

Week

SECTION 3

GOAL SETTING

- Goal setting is a fundamental component of the SHED-IT program. Research shows that men who set goals are more likely to maintain their health improvements
- Remember to make your goals S.M.A.R.T.

SPECIFIC	Make sure your goal is clear and well defined
MEASUREABLE	In terms of quantity and time, so you know how to achieve your goal and when it has been achieved
ATTRACTIVE	It has to be something you are keen to do
REALISTIC	Make sure the goal is something you can achieve, otherwise you'll be setting yourself up for disappointment.
TIME-TARGETED	Give yourself an end point so you know if and when you have achieved your goal

Be as specific as you can. Keep yourself accountable.

GOAL INSTRUCTIONS

1. Write 2 goals every 2 months (examples on the next page).
    - One goal for your WEIGHT
    - One goal for EXERCISE or EATING/DRINKING

2. Note down an appropriate reward that you will give yourself at the end of the month, if you have achieved both of your goals.

3. Tick the box if you have achieved your goal.

4. Remember to reassess your goals at the end of every second month.

S.M.A.R.T. Goal Examples

Exercise

- This month, I will get 60 minutes of activity on 3 or more days each week.
- This month I will complete all resistance training sessions outlined in the log book.
- Time permitting, I will take the stairs instead of the elevator every day at work this month.
- I will play a ½ hour game of backyard cricket or soccer with my kids at least 2 times per week for the next month.
- For the next month, I will stand on the train rather than sit.
- This month, I will walk at least 10,000 steps on the 4 days per week that I wear my pedometer.
- I will increase my average step count by 10% each week this month.

Eating

- I will drink coke zero rather than coke on the next 10 occasions I feel like a soft drink.
- This month I will eat at least at least 3 serves of veges every day.
- When buying petrol this month, I will *surf the urge* and resist the temptation to buy junk food.
- This month, I will eat breakfast at least 4 days per week.
- I will eat no more than 4 takeaway meals for dinner over the next 4 weeks.
- I will drink 8 glasses of water, at least 3 days per week, for the next month.

Example Rewards

- A golfing afternoon with a few mates
- A steak dinner at the local club (complete with a cheeky beer or two)
- A new pair of joggers
- Take the family away on a weekend holiday

Appendix 10: Contribution statement (Chapter 2)

Statement of contribution

I attest that Research Higher Degree candidate Myles David Young contributed substantially in terms of study concept and design, data collection and analysis, and preparation of the following manuscript:

Young, M.D., Morgan, P.J., Plotnikoff, R.C., Callister, R., & Collins, C.E. (2012). Effectiveness of male-only weight loss and weight loss maintenance interventions: A systematic review with meta-analysis. *Obesity Reviews,* 13, 393-408.

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Prof. Ronald Plotnikoff	Date

Prof. Clare Collins	Date

Prof. Robin Callister	Date

Associate Prof. Rosalind Smith *Assistant Dean (Research Training)*	Date

Appendix 11: Contribution statement (Chapter 3)

Statement of contribution

I attest that Research Higher Degree candidate Myles David Young contributed substantially in terms of study concept and design, data collection and analysis, and preparation of the following manuscript:

Young, M.D., Plotnikoff, R.C., Collins, C.E., Callister, R., & Morgan, P.J. (2014). Social Cognitive Theory and physical activity: A systematic review and meta-analysis. *Obesity Reviews*, 15, 983-995.

Prof. Philip Morgan Date

Prof. Ronald Plotnikoff Date

Prof. Clare Collins Date

Prof. Robin Callister Date

Associate Prof. Rosalind Smith Date
Assistant Dean (Research Training)

Appendix 12: Contribution statement (Chapter 4)

Statement of contribution

I attest that Research Higher Degree candidate Myles David Young contributed substantially in terms of study concept and design, data collection and analysis, and preparation of the following manuscript:

Young, M.D., Lubans, D.R., Collins, C.E., Callister, R., Plotnikoff, R.C., & Morgan, P.J. (2015). Behavioral mediators of weight loss in the SHED-IT community randomized controlled trial for overweight and obese men. *Annals of Behavioral Medicine*, 49, 286-292.

Prof. Philip Morgan	Date
Prof. Ronald Plotnikoff	Date
Prof. Clare Collins	Date
Prof. Robin Callister	Date
Prof. David Lubans	Date
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Appendix 13: Contribution statement (Chapter 5)

Statement of contribution

I attest that Research Higher Degree candidate Myles David Young contributed substantially in terms of study concept and design, data collection and analysis, and preparation of the following manuscript:

Young, M.D., Collins, C.E., Callister, R., Plotnikoff, R.C., Doran, C.M., & Morgan, P.J. (2014). The SHED-IT weight loss maintenance trial protocol: A randomised controlled trial of a weight loss maintenance program for overweight and obese men. *Contemporary Clinical Trials,* 37, 84-97.

Prof. Philip Morgan	Date

Prof. Ronald Plotnikoff	Date

Prof. Clare Collins	Date

Prof. Robin Callister	Date

Prof. Christopher Doran	Date

Associate Prof. Rosalind Smith *Assistant Dean (Research Training)*	Date

Appendix 14: Contribution statement (Chapter 6)

Statement of contribution

I attest that Research Higher Degree candidate Myles David Young contributed substantially in terms of study concept and design, data collection and analysis, and preparation of the following manuscript:

Young, M.D., Morgan, P.J., Collins, C.E., Callister, R., & Plotnikoff, R.C. (under review). A test of Social Cognitive Theory to explain physical activity changes in a weight loss program for men. *American Journal of Men's Health*.

Prof. Philip Morgan Date

Prof. Ronald Plotnikoff Date

Prof. Clare Collins Date

Prof. Robin Callister Date

Associate Prof. Rosalind Smith Date
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Appendix 15: Contribution statement (Chapter 7)

Statement of contribution

I attest that Research Higher Degree candidate Myles David Young contributed substantially in terms of study concept and design, data collection and analysis, and preparation of the following manuscript:

Morgan, P.J., **Young, M.D.,** Collins, C.E., Plotnikoff, R.C., & Callister, R. (under review). Efficacy of a scalable, gender-tailored intervention to prevent weight regain in men: The SHED-IT weight loss maintenance randomised controlled trial. *International Journal of Obesity*.

Prof. Philip Morgan	Date

Prof. Ronald Plotnikoff	Date

Prof. Clare Collins	Date

Prof. Robin Callister	Date

Associate Prof. Rosalind Smith *Assistant Dean (Research Training)*	Date

Appendix 16: Contribution statement (Chapter 8)

Statement of contribution

I attest that Research Higher Degree candidate Myles David Young contributed substantially in terms of study concept and design, data collection and analysis, and preparation of the following manuscript:

Young, M.D., Plotnikoff, R.C., Callister, R., Collins, C.E., & Morgan, P.J. (in press). Impact of a male-only weight loss maintenance program on social-cognitive determinants of physical activity and healthy eating: A randomised controlled trial. *British Journal of Health Psychology*.

Prof. Philip Morgan Date

Prof. Ronald Plotnikoff Date

Prof. Clare Collins Date

Prof. Robin Callister Date

Associate Prof. Rosalind Smith Date
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