

The Effect of Behaviour Change Interventions on Physical Activity and Health-related Outcomes in Ambulatory Secondary Care Patients

Submitted by

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Abstract

Insufficient physical activity (PA) is a widespread public health problem associated with a range of chronic diseases. Hospitals are increasingly being encouraged to broaden their perspective from curative care to incorporate integrated health promotion. This thesis includes six studies that investigate the role of health-promoting behaviour change interventions in ambulatory secondary care.

A systematic review investigated the effectiveness of integrated motivational interviewing and cognitive behaviour therapy (MI-CBT) for changes in lifestyle behaviours. Integrated MI-CBT was subsequently used as the framework for the behaviour change interventions in this thesis. A randomised controlled trial (RCT) demonstrated that the MI-CBT intervention resulted in significant and cost-effective changes in PA in patients who self-selected into the RCT. An additional systematic review evidenced that behaviour change interventions initiated in ambulatory secondary care are effective for increasing PA.

Recruiting individuals via self-selection was unlikely to engage individuals ambivalent about changing behaviours. Using consulting surgeons to instigate behaviour change contemplation offered an avenue to address this. A mixed-methods study identified factors influencing consulting surgeons' choice to undertake health promotion activities. This resulted in the co-design of a referral pathway permitting surgeons to refer insufficiently physically active patients to a behaviour change intervention. A second RCT showed that the MI-CBT intervention resulted in significant and maintained increases in PA in patients referred by the surgeons.

Collectively, these findings confirm that engaging secondary care patients in behaviour change interventions resulted in maintained improvements in PA and other health-related outcomes. To facilitate integrating preventive health interventions in routine care, engagement with practicing clinicians is essential. Understanding the clinicians' perspectives and the co-design of simple referral pathways can facilitate the integration of effective preventive health practice into standard care. This thesis provides recommendations for clinicians and researchers to inform effective behaviour change interventions aimed at promoting health in ambulatory secondary care.

Statement of authorship

This thesis includes work by the author that has been published or accepted for publication as described in the text. Except where reference is made in the text of the thesis, this thesis contains no other material published elsewhere or extracted in whole or in part from a thesis accepted for the award of any other degree or diploma.

No other person's work has been used without due acknowledgement in the main text of the thesis.

This thesis has not been submitted for the award of any degree or diploma in any other tertiary institution.

SIGNATURE:

STEPHEN BARRETT

Date: 06 May 2021

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List of publications and presentations

Publications

Chapter 3

Barrett S, Begg S, O'Halloran P, & Kingsley M. (2018). Integrated motivational interviewing and cognitive behaviour therapy for lifestyle mediators of overweight and obesity in community-dwelling adults: a systematic review and meta-analyses. *BMC Public Health*. 18(1), 1160. <https://doi.org/10.1186/s12889-018-6062-9>.

Chapter 4

Barrett S, Begg S, O'Halloran P, & Kingsley M. (2018). Integrated motivational interviewing and cognitive behaviour therapy can increase physical activity and improve health of adult ambulatory care patients in a regional hospital: the Healthy4U randomised controlled trial. *BMC Public Health*. 18(1), 1166. <https://doi.org/10.1186/s12889-018-6064-7>.

Chapter 5

Barrett S, Begg S, O'Halloran P, & Kingsley M. (2019). Cost-effectiveness of telephone coaching for physically inactive ambulatory care hospital patients: economic evaluation alongside the Healthy4U randomised controlled trial. *BMJ Open*. 9(12). Doi:10.1136/bmjopen-2019-032500

Chapter 6

Barrett S, Begg S, O'Halloran P, Howlett O, Lawrence J, & Kingsley M. (2021). The effect of behaviour change interventions on changes in physical activity and anthropometrics in ambulatory hospital settings: a systematic review and meta-analysis. *International Journal of Behavioral Nutrition and Physical Activity*. 18, 7. <https://doi.org/10.1186/s12966-020-01076-6>.

Chapter 7

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Barrett S, Begg S, Sloane A, & Kingsley M. (2019). Surgeons and preventive health: a mixed methods study of current practice, beliefs and attitudes influencing health promotion activities amongst public hospital surgeons. *BMC Health Services Research*. 19, 358. <https://doi.org/10.1186/s12913-019-4186-y>

Chapter 8

Barrett S, Begg S, O'Halloran P, & Kingsley M. (2020). A physical activity coaching intervention can improve and maintain physical activity and health-related outcomes in adult ambulatory hospital patients: the Healthy4U-2 randomised controlled trial. *International Journal of Behavioral Nutrition and Physical Activity*. 17, 156. <https://doi.org/10.1186/s12966-020-01063-x>

Other work

Barrett S, Begg S, O'Halloran P, Rodda K, & Kingsley M. (2020). Exercise and COVID-19: reasons individuals sought coaching support to assist them to increase physical activity during COVID-19. *Australian & New Zealand Journal of Public Health*. 45(2):133-137. doi: 10.1111/1753-6405.13089.

Conference presentations

Barrett S, Begg S, O'Halloran P, & Kingsley M. Integrated motivational interviewing and cognitive behaviour therapy elicits physical activity change: the Healthy4U RCT. Bendigo Health Research Conference, 2018. Bendigo, Victoria.

Barrett S, Begg S, O'Halloran P, & Kingsley M. Integrated motivational interviewing and cognitive behaviour therapy elicits physical activity change: the Healthy4U RCT. Sports Medicine Australia Conference, 2018. Perth, Western Australia.

Barrett S, Begg S, O'Halloran P, & Kingsley M. Cost-effectiveness of integrating telephone coaching to increase physical activity for non-admitted hospital patients. Public Health Prevention Conference, 2019. Melbourne, Victoria.

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Other presentations

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Contributions to jointly-authored work

The following table details contributions to jointly-authored work that has been published (Chapter 3, 4, 5, 6, 7 and 8).

Author	Contribution to the conception or design	Contributed to acquisition, analysis, or interpretation of data	Drafting of the manuscript	Editorial revision of the manuscript
Chapter 3 - Integrated motivational interviewing and cognitive behaviour therapy for lifestyle mediators of overweight and obesity in community-dwelling adults: a systematic review and meta-analyses				
Stephen Barrett	30%	40%	100%	30%
Steve Begg	20%	20%	0%	20%
Paul O'Halloran	20%	20%	0%	20%
Michael Kingsley	30%	20%	0%	30%
Chapter 4 - Integrated motivational interviewing and cognitive behaviour therapy can increase physical activity and improve health of adult ambulatory care patients in a regional hospital: the Healthy4U randomised controlled trial				
Stephen Barrett	30%	30%	100%	30%
Steve Begg	20%	20%	0%	20%
Paul O'Halloran	20%	20%	0%	20%
Michael Kingsley	30%	30%	0%	30%
Chapter 5 - Cost-effectiveness of telephone coaching for physically inactive ambulatory care hospital patients: economic evaluation alongside the Healthy4U randomised controlled trial				
Stephen Barrett	30%	40%	100%	30%
Steve Begg	30%	30%	0%	30%
Paul O'Halloran	20%	15%	0%	20%
Michael Kingsley	20%	15%	0%	20%

Author	Contribution to the conception or design	Contributed to acquisition, analysis, or interpretation of data	Drafting of the manuscript	Editorial revision of the manuscript
Chapter 6 - The effect of behaviour change interventions on changes in physical activity and anthropometrics in ambulatory hospital settings: a systematic review and meta-analysis				
Stephen Barrett	40%	30%	100%	30%
Steve Begg	20%	15%	0%	15%
Paul O'Halloran	20%	15%	0%	15%
Owen Howlett	0%	15%	0%	15%
Jack Lawrence	0%	10%	0%	10%
Michael Kingsley	20%	15%	0%	15%
Chapter 7 - Surgeons and preventive health: a mixed methods study of current practice, beliefs and attitudes influencing health promotion activities amongst public hospital surgeons				
Stephen Barrett	40%	30%	100%	30%
Steve Begg	30%	30%	0%	30%
Andrea Sloane	0%	10%	0%	10%
Michael Kingsley	30%	30%	0%	30%
Chapter 8 - A physical activity coaching intervention can improve and maintain physical activity and health-related outcomes in adult ambulatory hospital patients: the Healthy4U-2 randomised controlled trial				
Stephen Barrett	30%	30%	100%	30%
Steve Begg	25%	20%	0%	25%
Paul O'Halloran	20%	20%	0%	20%
Michael Kingsley	25%	30%	0%	25%

Ethical approval

This work was approved by the following human research ethics committees:

Chapter 4 and 5: Bendigo Health Human Research Ethics Committee (full review) and La Trobe University Human Ethics Committee (expedited review) – Appendix 4.1

Chapter 7: Bendigo Health Human Research Ethics Committee (full review) and La Trobe University Human Ethics Committee (expedited review) – Appendix 7.1

Chapter 8: Bendigo Health Human Research Ethics Committee (full review) and La Trobe University Human Ethics Committee (expedited review) – Appendix 8.1

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Glossary of abbreviated terminology

ANOVA	Analysis of variance
BMI	Body mass index
CBT	Cognitive behaviour therapy
CEAC	Cost-effectiveness acceptability curve
CI	Confidence interval
CPM	Counts per minute
GEE	Generalized estimating equation
GP	General practitioner
H4U	Healthy 4U
HrQoL	Health-related quality of life
ICER	Incremental cost-effectiveness ratio
MD	Mean difference
MI	Motivational interviewing
MI-CBT	Integrated motivational interviewing and cognitive behaviour therapy
MVPA	Moderate-to-vigorous physical activity
PA	Physical activity
PAR-Q	Physical activity readiness questionnaire
SD	Standard deviation
SDT	Self-determination theory
SMD	Standardized mean difference
RCT	Randomised controlled trial
QALYs	Quality adjusted life years
WC	Waist circumference

Chapter 1

Background

In this doctoral thesis, I explore the effect of behaviour change interventions on physical activity (PA) and health-related outcomes in ambulatory hospital care. Hospitals are important settings in which to offer behaviour change interventions, and hospitals have been increasingly encouraged to undertake more preventive health practice (Groene et al., 2005; Groene & Jorgensen, 2005; Johnson & Baum, 2001). Integrating preventive health into routine care has been a challenge for hospitals (Pelikan et al., 2001). Hospitals have struggled to make sufficient changes in organisational practices which can permit preventive health initiatives lasting beyond 'project phases' (World Health Organization, 2011). Lasting changes requires meaningful engagement with multiple actors for health service planning, decision making and evaluation (Légaré & Witteman, 2013). In this thesis I critically examine the role of behaviour change interventions in ambulatory hospital care and provide implications for research, policy and practice.

The thesis is presented in two parts. In part one, I review the evidence base for the behaviour change intervention used in this thesis. This is followed by a randomised controlled trial (RCT) evaluating the efficacy and cost-effectiveness of the intervention for changes in physical activity (PA) amongst participants who self-selected into the study. Part one concludes with a further systematic review and meta-analysis evaluating the effectiveness of behaviour change interventions for changes in PA in ambulatory hospital patients. In part two, the surgeons consulting in the target clinic played a participatory role in the research. Initially, a mixed method study was used to investigate the preventive health practice of the consulting surgeons. Finally, a second RCT evaluated the effectiveness of the behaviour change intervention for changes in PA and health-related outcomes amongst participants referred to the study by the consulting surgeons. Six studies published in peer reviewed journals sit alongside supporting chapters in which the study methods are described and the results are discussed. These parts converge to form an explanatory whole in the discussion of the thesis (Figure 1.1).

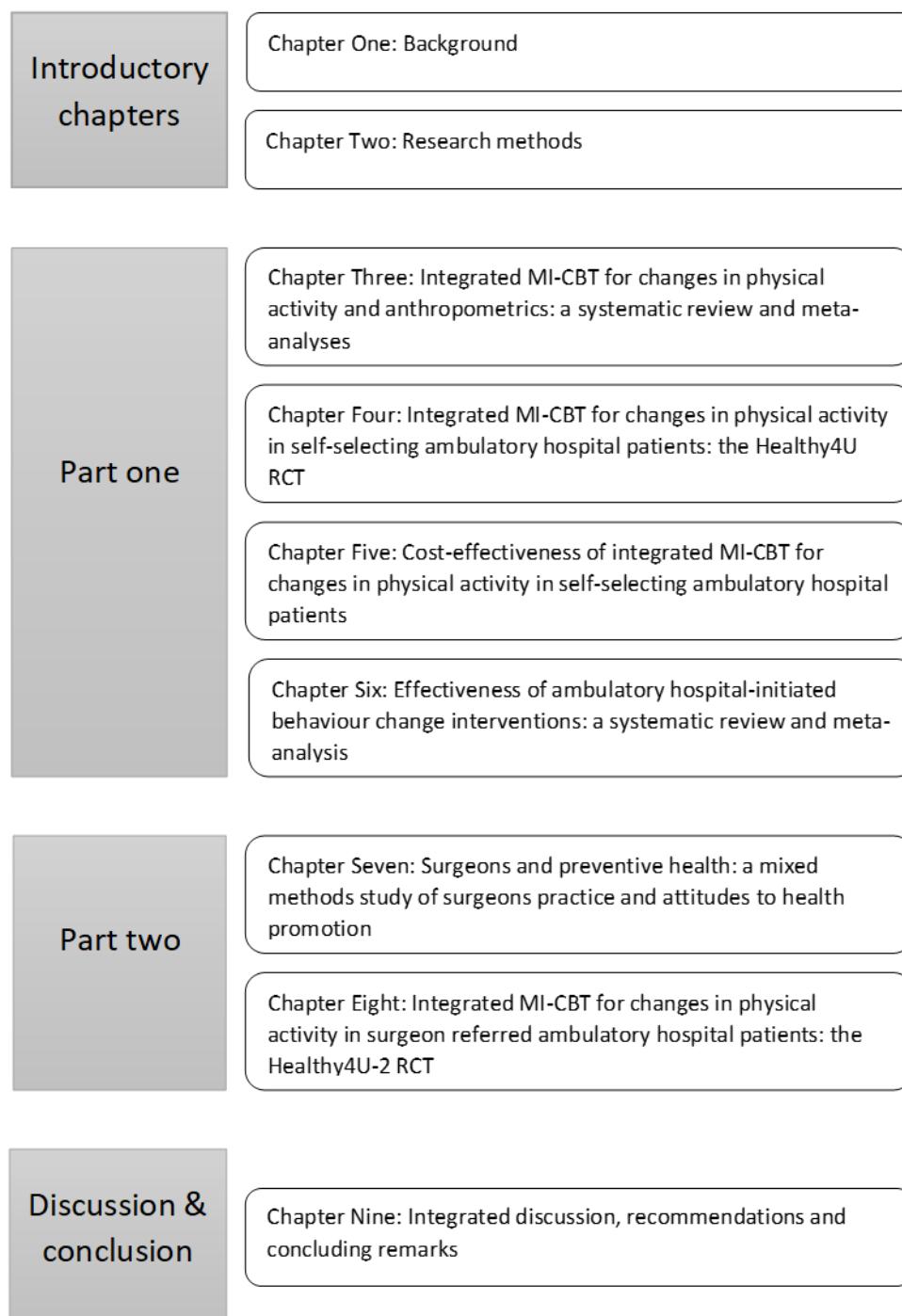


Figure 1.1: Schematic of thesis layout

This research was undertaken in Bendigo Health, a public hospital in regional Victoria, Australia. The ambulatory, or out-patient, clinics chosen to undertake this research in were the Bendigo Health Specialist Clinics. The Specialist Clinics provide ambulatory medical care to individuals in the hospital setting. Specialist Clinics include, but are not limited to, medical specialties such as general and orthopaedic surgery, endocrinology and renal medicine. A referral from a general practitioner (GP) is required to receive an appointment at the Specialist Clinics. For this reason, the term 'secondary care' is often used to describe this specialist care. Approximately 100,000 secondary care appointments are provided annually in the Bendigo Health Specialist Clinics. Due to this volume of patients, it was decided to focus on two medical sub-specialties only, these being General and Orthopaedic surgery.

1.1 My motivation for this research

The 2013-2018 Bendigo Health Strategic Plan outlined a number of clear visions for the hospital (Bendigo Health Care Group, 2012), one of which was that of 'Healthy Communities'. The vision of healthy communities proposed that: (i) people living in the community value the idea of being healthy, and (ii) individuals access the services they need to stay as healthy as they can be. Healthy communities need fewer hospital stays, recover more quickly from ill-health, and spend more time contributing to the community (Bendigo Health Care Group, Group, 2012). In 2015, I was employed as a Project Officer in the Health Promotion Department at Bendigo Health. One of the directives for this position was to look at potential pathways to increase preventive health practice in the Specialist Clinics, thereby contributing to the vision of 'healthy communities'. I felt that I needed to investigate the role that behaviour change interventions play in the ambulatory secondary care setting in order to potentially facilitate an increase in preventive health practice in the Specialist Clinics.

In order to investigate the role of behaviour change interventions in ambulatory secondary care, a staged approach was required. I needed to further understand the optimal behaviour change intervention to be used, and how it could be integrated into ambulatory secondary care. I also needed to be able to demonstrate the efficacy of the intervention, and the economic implications. It was decided to design a standalone project to undertake this task, which was named the Healthy 4U (H4U) project. The health promotion steering plan at Bendigo Health was titled the Healthy 4U plan, which is where the project name was derived from. Recognising the potential novelty of delivering preventive health in ambulatory secondary care, I sought the

opinions of two academics at La Trobe University: Professor Michael Kingsley and Associate Professor Steve Begg. After these consultations I decided to embark on the process of formalising the H4U project into a research project. In terms of my role, I was responsible for all aspects of the H4U project within Bendigo Health, including project design, data collection, analysis, and reporting. Professor Kingsley and Associate Professor Begg provided academic support and became the supervision team. The decision to formalise components of my work into a PhD was based upon a combination of opportunity and interest.

In terms of opportunity, this project provided a platform from which to explore the factors that shape the delivery of preventive health in secondary care, as well as interventions most likely to increase behaviour change. It was apparent early on that little published evidence existed on the delivery of preventive health in ambulatory secondary care. Even amongst the grey literature, and from telephone contact with other public hospitals both state-wide and nationally, there was very little information available relating to the use of ambulatory hospital visits as an avenue to deliver opportunistic preventive health interventions. Undertaking research offered the potential to rigorously evaluate the effectiveness of this initiative and permitted avenues for information dissemination and research translation.

The H4U project offered a great opportunity to explore surgeons' perspectives on preventive health, behaviour change, and the management of lifestyle risk factors in the ambulatory hospital setting. There is a dearth of evidence regarding surgeons and preventive health. As all patients using the Specialist Clinics engage with the surgeons, I felt it was crucial that the surgeons were included in the research. Having direct and continued access to the surgeons provided an opportunity to explore the complex interplay of factors influencing the management of lifestyle risk factors in ambulatory secondary care. I had the opportunity to work closely with the surgeons over the period of this thesis, which provided avenues for discussion, observation and evaluation. Credit must go to Bendigo Health and the management of the Integrated Care stream (formally 'Healthy Communities' stream), in affording sufficient time and flexibility to the project that enabled a range of research methods to be used. This provided an opportunity to comprehensively explore the effect of behaviour change interventions on physical activity (PA) and health-related outcomes in ambulatory hospital care.

With regards to interest, practicing as a physiotherapist in hospital settings over many years I developed a broader interest in preventive health, particularly as it relates to lifestyle behaviours such as insufficient PA. This interest led to my completion of a Master of Public Health in 2014, with a capstone in health economics research. My current position permits the merging of personal and professional interests. Specific to my areas of interest, I was able to investigate the role of preventive health interventions in ambulatory secondary care to increase and maintain PA. It also permitted the undertaking of an economic analysis of implementing preventive health in the ambulatory secondary care. There was a lack of published research on the economic impact of preventive health interventions for PA changes in ambulatory secondary care. Additionally, economic data on the potential benefits of preventive health in ambulatory secondary care would be beneficial in the argument for the ongoing inclusion of preventive health initiatives in this setting.

This thesis is a representation of the work carried out in the H4U project, a stand-alone project investigating the role that behaviour change interventions play in increasing PA and health-related outcomes in an ambulatory secondary care setting. I felt it was important to put my story to the front of this thesis, as it gives context to the nature of my day-to-day employment which shaped, and was shaped by, this research journey. The remainder of this chapter will provide details on: (i) why it was deemed necessary to undertake preventive health in the ambulatory secondary care setting, (ii) the rationale for undertaking the chosen behaviour change intervention, and (iii) why it was necessary to involve the surgeons in this research to facilitate the potential implementation of preventive health interventions in ambulatory secondary care.

1.2 Preventive health in ambulatory hospital care

Preventive health has been a challenge for hospitals (Armstrong et al., 2007). Hospitals were traditionally built and run as tertiary management facilities, with a focus on acute disease and illness treatment, and not prevention (Haynes, 2008). The hospital model works well for acute conditions, which are generally associated with short episodes of illness (Lawn & Schoo, 2010). In acute illness there are pre-existing assumptions about the nature of the illness and the roles of health professionals and patients. The health professional dictates the problems and the solutions, and the patient is traditionally a passive recipient of their expert advice (Lawn & Schoo, 2010). Treatment adherence is less problematic in acute care as patients are more

inclined to stick to a prescribed regimen for a short period of time for the specific purpose of getting better (Brown & Bussell, 2011; Martin et al., 2005).

Over time, advances in medicine and hospital care have resulted in a decreasing prevalence of acute and infectious illness. This has resulted in decreasing mortality rates and increased life-expectancy. Alongside this transition towards longer life-expectancy there has been an increase in chronic disease prevalence and associated morbidity (Begg, 2014). Chronic diseases such as diabetes, arthritis and cardiovascular disease are one the main causes of poor health and morbidity (Bauer et al., 2014; Murray et al., 2012; World Health Organization, 2014). Chronic diseases also account for large proportions of health-care expenditure (Ding et al., 2016). While it was originally theorised that most chronic illness occurs late in life (Fnnzs, 1980; Mackenbach, 1994), the proportion of individuals developing chronic diseases at younger ages is rising (Australian Institute of Health and Welfare, 2014; Australian Institute of Health and Welfare, 2017). Begg (2014) suggests that time spent with morbidity is likely to increase in numbers of years lived, and, as a proportion of the average life span. These projected trajectories are particularly relevant for public hospitals, where a large proportion of the clinical manifestations of chronic disease morbidity are managed.

The management of chronic diseases and the associated morbidity places a significant burden on the hospital system (Yach et al., 2004). For hospitals, the ongoing management of chronic conditions has resulted in annual growth of resource utilisation and health care expenditure (McPhail, 2016). The demands of managing chronic disease morbidity has policy implications, particularly for the funding of sustainable healthcare services (Bodenheimer et al., 2009; Heidenreich et al., 2011). Prevention and management of chronic diseases across all health sectors, including secondary hospital care has been deemed a public health priority (Geneau et al., 2010; Halpin et al., 2010).

The aetiology of chronic disease is largely driven from a small list of preventable risk factors, including insufficient PA, poor diet, smoking and obesity (Bauer et al., 2014). As chronic diseases and associated morbidity are amenable to lifestyle changes, it is necessary to identify at-risk populations and provide timely interventions (Australian Institute of Health and Welfare, 2014). There is large scope for offering preventive health interventions in the hospital setting (Groene et al., 2005). Hospitals are central to the entire healthcare system, and increased preventive

practice in this setting could have large effects on the outcomes of secondary prevention efforts (Hancock, 1999). The integration of preventive health interventions can encourage hospitals to incorporate holistic care for patients (Lee et al., 2013). The majority of hospital treatments do not cure chronic diseases, rather, they aim to decrease morbidity and improve quality of life (Groene et al., 2005). To do this, effective behaviour change is essential, and hospital patients need to be equipped for effective self-management in the community (Dunbar-Jacob & Mortimer-Stephens, 2001; Garrett et al., 2011). This necessitates a robust understanding of health behaviour change to inform the development and evaluation of effective interventions to increase PA and health-related outcomes in ambulatory secondary care patients.

1.3 Interventions for behaviour change

1.3.1 Health behaviour change

In contrast to acute illnesses, the preventable nature of chronic disease results in a different set of assumptions, roles and realities for patients and health professionals (Tattersall, 2002). Wanger (2000) proposed that in the management of chronic conditions the patient is the expert, with the health professional playing a supporting role. Treatment adherence for acute illness is relatively straightforward, particularly when the intervention and dose are limited to a defined period of time for the specific purpose of getting better; for example, take one pill a day for seven days to clear an infection (Brown & Bussell, 2011). The set of assumptions are markedly different for chronic disease risk when, for example, the intervention and dose changes to thirty minutes of PA a day for the rest of your life, to mitigate potential risk of chronic disease morbidity in the future (Brown & Bussell, 2011; Stewart et al., 2013). Health professionals cannot expect to deliver this prescription and assume it will be taken. The complexity of behaviour change as it applies to chronic disease morbidity necessitates the delivery of appropriate behaviour change interventions to support motivation, self-management and maintenance of change (Newsom et al., 2011).

Addressing individual behaviour change for modifiable risk factors is complex (Frieden, 2010; Tattersall, 2002). At any given point, an individual's health and health behaviours reflect a combination of experiences, social and economic circumstances, all set in distinct social and physical contexts (Short & Mollborn, 2015). These social determinants of health influence the decisions that individuals make too exercise or not, what foods they are going to eat, and the value they place on these choices (Bodenheimer et al., 2002). Individuals with, or at risk of

developing chronic disease are often faced with a myriad of decisions relating to how they will manage their overall health, as well as how they will adhere to professional advice (Corbin & Strauss, 1988). Individuals are forced to make these decisions, not only based on 'knowing what is good for them', but often unaware of the potential long-term consequences of continued risky behaviours (Corbin & Strauss, 1988; Lawn et al., 2010). Preventable chronic diseases take time to develop, and individuals can fail to recognise the association between risky behaviours and disease development (Ezzati & Riboli, 2013). Unhealthy behaviours which have been repeated over long periods of time can become entrenched habits, making them difficult to change (Newsom et al., 2011). Entrenched behaviours can also lead to beliefs that behaviour change is beyond an individual's volitional control (Fishbein & Cappella, 2006). These sub-optimal beliefs require interventions to build motivation, self-belief and self-efficacy for behaviour change (Bandura, 2006).

Behavioural lifestyle changes are advocated as the first line approach for the management of chronic disease risk factors (Anderson et al., 2016; Beaglehole et al., 2011; Hartley, 2014). Lifestyle interventions to change health risk behaviours are the most commonly used measure, regardless of setting (James et al., 2016). Lifestyle interventions are typically defined as any intervention that includes a specific focus on exercise, diet or weight management, and include at least one other component, for example counselling, stress management or motivation change (Sumamo et al., 2011). Lifestyle interventions have demonstrated short-term effectiveness for changes in PA, diet, and weight loss (Anderson et al., 2016; Beaglehole et al., 2011; Dunkley et al., 2012), though none of these studies were undertaken in the ambulatory secondary care setting. The effectiveness of lifestyle interventions for longer-term behaviour change maintenance is less well established. For PA changes, many interventions that include prescriptive exercises have not resulted in long-term changes, with more than 50% of individuals relapsing to insufficiently physically active once the intervention is removed (Nigg et al., 2008). Kaur (2014) suggests that a lack of effective behaviour change maintenance techniques contributed to the recidivism to inactivity.

Behaviour change interventions need to incorporate a myriad of strategies to illicit motivation for change, increase self-efficacy and build resilience to ensure changes are maintained beyond the duration of the intervention (Dunkley et al., 2012; Kaur, 2014). As a result, there is an increasing use of behaviour change interventions utilising counselling techniques to influence health behaviour change and maintenance (Kivelä et al., 2014; Teeter & Kavookjian, 2014;

Wolever et al., 2013). Cognitive behaviour therapy (CBT) and motivational interviewing (MI) are two counselling techniques that have been used to influence changes in PA, diet and anthropometrics (Scott et al, 2018). Cognitive behaviour therapy and MI approaches incorporate a wide range of techniques to increase and maintain behaviour change, and integrating the techniques together (MI-CBT) together has been increasingly recognised as a framework to produce effective and lasting change (Naar-King et al., 2013; Naar & Safren, 2017). An understanding of these behaviour change models, and the justification for integrating them together provides the theoretical perspective for the behaviour change approach used in this research.

1.3.2 Cognitive behaviour therapy

Cognitive behaviour therapy is a behaviour change technique based on the premise that individual choices can be effectively managed using adaptive thinking and cognitive strategies (Beck, 2011; Hawton et al., 1989). Cognitive behaviour therapy focuses on changing maladaptive thoughts that maintain suboptimal behaviours and interfere with functioning (Beck, 2011). Cognitive behaviour therapy approaches are some of the most widely disseminated evidence-based treatments, and they share elements across many treatment areas such as depression, anxiety, pain and obesity (Eccleston et al., 2009; Tolin, 2010). Cognitive behaviour therapy involves a client and therapist working collaboratively to identify current problems, and engage in active problem solving (Persons, 2012). Cognitive behaviour therapy is usually delivered in a structured format, with the therapist teaching and modelling specific skills, including but not limited to goal setting, action planning, self-monitoring, personal feedback and relapse prevention (Eccleston et al., 2009; Tolin, 2010).

Although CBT has demonstrated strong evidence for effective behaviour change (Hofmann et al., 2012; Persons, 2012), many individuals do not respond to CBT treatment. Many individuals do not adhere to CBT treatment tasks or discontinue treatment prematurely (LeBeau et al., 2013; Naar-King et al., 2013). Experts in the field of behaviour change suggest that some CBT approaches do not help strengthen motivation for change at the onset of treatment, and during the course of treatment (Driessen & Hollon, 2011; Naar & Safren, 2017). Indeed, CBT works best with motivated individuals, and is less efficacious with individuals lacking in motivation (Beck, 2016; Beck, 2020; Naar & Safren, 2017). It is suggested that integrating CBT with MI can improve motivation both initially and during treatment, and result in maintenance of change

after the intervention is completed (Naar & Safren, 2017).

1.3.3 Motivational interviewing

Motivational interviewing is a directive therapeutic style aimed at increasing internal motivation for behaviour change. Motivational interviewing aims to achieve this change by exploring and resolving ambivalence about the target behaviour (Miller & Rollnick, 2012). Motivational interviewing is guided by the principles of collaboration (viewing individuals as the experts in managing their own life), evocation (eliciting intrinsic motivation to change) and autonomy (empowering clients to make informed decisions). The core techniques used in MI are: open-ended questions, affirmations, reflective listening and summarising (Miller & Rollnick, 2012).

To explore and resolve ambivalence about change, the therapist specifically highlights the discrepancy between the individual's status quo, and their goals and aspirations (Hettema et al., 2005). This facilitates the individual's active participation in their own arguments for change (Hettema et al., 2005). The specific techniques chosen by the therapist will differ depending on the interpersonal interactions during therapy (Miller & Rollnick, 2012; Rollnick et al., 2008). In MI, 'rolling with resistance' recognises that human motivation constantly fluctuates, and resistance is a normal and expected phenomenon (Miller & Rollnick, 2012). Resistance is a signal for the therapist to respond differently (Miller & Rollnick, 2012; Rollnick et al., 2008). Rather than employing a confrontational approach, the therapist invites the individual to consider a different perspective and more adaptive ways to achieve the desired outcome (Miller & Rollnick, 2012). By using this method, as advocated in chronic disease management, the client is the one to voice the need to change (Wagner, 2000).

Although the concept of MI originated from addiction treatment (Miller & Rollnick, 2012), in more recent years it has been applied to a wide range of health issues, such as PA (O'Halloran et al., 2014; Rubak et al., 2005), treatment adherence (Rüsch & Corrigan, 2002), and diet (Greaves et al., 2011). Motivational interviewing can be applied throughout the process of behaviour change. It can be applied at the front end to address ambivalence about change. It can also be applied throughout treatment as a motivational tool to promote adherence to action plans and maintenance strategies, which is why the integration of MI and CBT has been increasingly proposed (Naar & Safren, 2017; Rüsch & Corrigan, 2002).

1.3.4 Integrating MI and CBT

It is well-documented that improvements in behaviour change diminish over time, and that behaviour change maintenance is difficult to achieve (Naar-King et al., 2013). Across multiple studies, more than half of individuals who underwent initial change did not maintain behaviour changes across target areas such as PA, smoking, and diet (Naar-King et al., 2013; Piasecki, 2006; Wing & Phelan, 2005). As MI was developed to build motivation for initial change (Miller & Rollnick, 2012), the MI strategies for maintaining change are less well established. Miller and Rollnick (2012), the founders of MI, suggest that once initial motivation for change has been established, it might be beneficial to integrate more action-oriented treatments such as CBT alongside MI. Cognitive behaviour therapy has demonstrated efficacy when working with motivated clients; the lack of success in CBT treatments has been attributed to the fact that CBT approaches fail to address lack of motivation (Beck, 2011; Naar-King et al., 2013; Naar & Safren, 2017). Following initial motivation change, the incorporation of action-oriented treatments might strengthen the behaviour change that the MI has helped to initiate (Miller & Rollnick, 2012; Naar & Safren, 2017). Motivation fluctuates in strength and direction during all stages of behaviour change, from the initial change, up to and including the maintenance of change (Naar & Safren, 2017). Fluctuations in motivation can be addressed during treatment through the use of MI, and strengthens the argument for integrating MI with CBT, which together may form a more potent behavioural treatment than either set of strategies alone (Naar-King et al., 2013; Naar & Safren, 2017).

Effective behaviour change interventions need to incorporate strategies to illicit motivation, increase self-efficacy, and build resilience to ensure changes are maintained beyond the duration of the intervention (Burgess et al., 2017; Dunkley et al., 2012; Naar-King et al., 2016; Naar & Safren, 2017). When delivered alone, MI and CBT use some, but not all, of these strategies. The integration of MI and CBT (MI-CBT) broadens the breadth of a behaviour change intervention, and may overcome some of the limitations of the individual counselling approaches (Naar-King et al., 2013; Naar & Safren, 2017; Scott et al., 2018; Westra, 2004; Westra et al., 2009). Integrated MI-CBT can be used to strengthen motivation, evoke from clients their own opportunities for change, and increase clients' capabilities for change. These are key concepts highlighted by Michie and colleagues (2011b) associated with effective behaviour change interventions. Integrating MI with CBT has been shown to be more effective than usual care for changes in anxiety (Westra et al., 2009) depression (Riper et al., 2014), smoking cessation (Heckman et al., 2010), medication adherence (Spoelstra et al., 2015), and body

weight (Naar-King et al., 2016). None of these studies, however, have been undertaken in the ambulatory secondary care setting.

The theory behind the integration of MI-CBT, and the positive findings from the above studies suggested that MI-CBT could play a potential role in preventive health interventions in ambulatory hospital care. To further explore this, there was a need for a robust investigation into the effectiveness of integrated MI-CBT for changes in PA and health-related outcomes in community dwelling adults, a population somewhat analogous to adults attending ambulatory secondary care clinics. This was undertaken using a systematic review with meta-analyses, which is reported in Chapter 3. Further to providing an estimate of the overall efficacy of integrated MI-CBT for changes in PA and health-related outcomes, a systematic review of the literature also provided the opportunity to identify important components of MI-CBT interventions, including the number of treatment sessions and the modes of delivery. The findings of the systematic review with meta-analyses were subsequently used in the design of the RCTs used to assess the effectiveness of integrated MI-CBT for changes in PA and health-related outcomes reported in Chapters 4, 5 and 8. Details on the MI-CBT interventions used in Chapters 4, 5 and 8, including the framework for delivery are provided in Chapter 2 of this thesis.

1.4 Behaviour change in ambulatory secondary care

Hospitals are strongly positioned within the healthcare system to offer health promotion interventions (Groene et al., 2005). The hospital system has the potential to mitigate some of the adverse health consequences of chronic disease by targeting behaviour change interventions to reach individuals with the greatest risk of chronic disease progression (Frieden, 2010). This is important as adults attending ambulatory secondary care hospital clinics in Australia have been shown to be 40% more likely than the general population to have one or more chronic disease (Britt et al., 2008).

Public hospital clinics offer access to members of the community who might not engage readily with health promotion initiatives (Gate et al., 2016). Public hospital clinics also provide opportunities to reach the most disadvantaged in the community, a group that tend to be under-represented in health and health promotion research when compared to their middle and upper class counterparts (Bonevski et al., 2014; McHugh et al., 2010). Their health is likely

to be somewhat compromised, perhaps by modifiable lifestyle factors such as insufficient PA or unhealthy diet (Gate et al., 2016; Lawson et al., 2009). The hospital visit is an opportune time to deliver preventive health interventions (Gate et al., 2016; Lawson et al., 2009; Tønnesen et al., 2009). Hospital patients are suitable audiences for behaviour change interventions (Gate et al., 2016), and individuals can be opportunistically encouraged to change unhealthy behaviours (Tønnesen et al., 2009). The patients coming to the Bendigo Health Specialist Clinic, for example, all present for a consultation with a surgeon. Coming to hospital to see a surgeon has been identified as a major life event (Allender et al., 2008). Experiencing a major life event can be a catalyst for the initiation of healthy behaviours, making secondary care clinics important settings for opportunistic health promotion interventions (Allender et al., 2008; Gate et al., 2016), and strengthens the potential role of preventive interventions in this setting.

Evidence demonstrating the effectiveness of behaviour change interventions for mitigating chronic disease risk factors would support the implementation of behaviour change interventions in ambulatory secondary care clinics. Despite this, no review of the evidence examining the effect of behaviour change interventions for changes in PA and anthropometrics in non-admitted secondary care patients had been undertaken. To address this, a systematic review with meta-analysis was carried out to examine the effect of ambulatory hospital-initiated behaviour change interventions on changes and maintenance on PA, and anthropometrics, which is reported in Chapter 6. The findings of the systematic review were subsequently used in the design of the RCT used to assess the effectiveness of integrated MI-CBT for changes in PA and health-related outcomes reported in Chapter 8.

Healthcare organisations' responsibility to promote health and well-being alongside disease treatment has been recognised worldwide for some time (International Network of Health Promoting Hospitals and Health Services, 2020; Whitehead, 2004). More recently, doctors are increasingly encouraged to engage in preventive health interventions with patients, and to 'make every contact count' towards changing behaviours (Gates, 2016; Mooney, 2012). Hospital surgeons can impact public health by broadening their medicalised role to include more preventive health interventions (Lee et al., 2013; Pelikan et al., 2001). Individuals demonstrate an increased propensity to accept behaviour change advice from doctors (Lee et al., 2013; Pelikan et al., 2001; Tønnesen et al., 2009). For ambulatory secondary care clinics, where patients have a high risk of chronic disease (Britt et al., 2008), broadening the perspective from the primary focus of curative care towards a position of more integrated health promotion

might be effective for the prevention and management of chronic disease (International Network of Health Promoting Hospitals and Health Services, 2020; Johnson & Baum, 2001).

The implementation of a more preventive health oriented service is however, a multifaceted and complex process (Johansson et al., 2010). It requires changes in professional behaviours and working methods (Fixsen et al., 2005). The intended outcome, the delivery of behaviour change interventions for secondary care patients is dependent on the interaction between the innovation itself, the intended adopters, and the setting (Greenhalgh et al., 2004). The intended adopters in the Specialist Clinic setting are the surgeons. It is the surgeon who consults with the patients, and it is the surgeon who makes the operational decision on whether or not to deliver behaviour change advice and interventions such as provide information or referrals (Fixsen et al., 2005; Johansson et al., 2010). As such, surgeons play a key role in the implementation process. If the goal of increasing preventive health in ambulatory secondary care is compatible with the surgeons' own values, norms, and perceived needs, the prospects of successful implementation will increase (Greenhalgh et al., 2004). It was therefore vital to explore the practice and opinions of the hospital surgeons regarding preventive health in order to understand the role of preventive health interventions in ambulatory secondary care.

1.5 Operationalising the study plan

The purpose of this thesis was to investigate the effect of behaviour change interventions on **PA** and health-related outcomes in ambulatory secondary hospital care. As all secondary care patients attend the Specialist Clinics for a consultation with a surgeon, it was always my intention to involve the surgeons in the research. The exact role the surgeons were to play was always going to be dependent on their capacity to participate in the research. I had established a professional relationship with the surgeons from the start of the H4U project, and I provided the surgeons with information outlining the broad aims of the project. I opened a formal dialogue with the surgeons about their potential participation in the research. At that time however, the surgeons indicated that they did not have the capacity to participate in the research.

While this was unfortunate, I carried on with part one of the thesis, undertaking the systematic reviews in Chapters 3 and 6, and the RCT reported in Chapters 4 and 5. For the initial RCT in Chapters 4 and 5, participants were recruited from the Specialist Clinic via self-selection, which

did not require the surgeons' involvement in the pathway. Following the completion of these studies, I reengaged with the surgeons, armed with evidence for the effectiveness of behaviour change interventions for ambulatory hospital patients, including evidence related to the patients who attended the Bendigo Health Specialist Clinic. The high-level evidence from the two systematic reviews and the RCT demonstrated the effectiveness of preventive health in the secondary care setting for health behaviour change and demonstrated that patients from the Bendigo Health Specialist Clinic can change behaviour when engaged in interventions. These factors likely influenced the surgeons' perspectives and after reviewing this evidence, the surgeons expressed an interest in participating in the research (Eccles et al., 2005). I was able to implement the next phase of the research, starting with a mixed-methods study to investigate surgeons' practice and beliefs around preventive health to help understand their role in preventive health and behaviour change interventions in the secondary care setting.

1.6 Surgeons and preventive health in the secondary care setting

The need for hospitals to undertake preventive health practice has been widely endorsed in preventive health literature (Johnson & Baum, 2001; McHugh et al., 2010), as well as international frameworks (Groene & Garcia-Barbero, 2005, International Network of Health Promoting Hospitals and Health Services, 2020). One of the main components recommended for increasing health promotion in hospitals involves advocating for clinicians to increase preventive health practice in routine care (Johnson & Baum, 2001; McHugh et al., 2010). As senior hospital clinicians, surgeons have an important role in advocating for health behaviour change for patients to minimise risk of chronic disease and associated morbidity (Royal Australian College of Surgeons, 2012). Due to their extensive medical training and specialisation, surgeons are regarded as reliable sources of medical advice, extending beyond their expertise in surgical care (Ziglio et al., 2011). The potential of undergoing surgery is a major life event, and individuals demonstrate increased responsiveness to behaviour change in the face of such an event (Allender et al., 2008). Michie and colleagues (2011b) recognise opportunity as the factors that lie outside the individual that make behaviour change possible or prompt it. Therefore, surgeons have potential to influence lifestyle behaviour change in patients (Jones et al., 2004). In Australian hospitals, over 2.2 million elective admissions involving surgery were undertaken in 2015–2016 (Australian Institute of Health and Welfare, 2017). The high volume of ambulatory consultations undertaken annually by surgeons provides large numbers of potential opportunities to address preventive health during clinical interactions (Zeev et al., 2017).

To link surgeons and preventive health will sound to some like an oxymoron. The surgical profession has focused on disease and its treatment rather than its prevention. Surgeons have traditionally focused on the pathogenesis of poor health rather than health promotion (Lawrence, 1990). In preventive health, issues such as personal behaviour, culture, and values are encountered. On the other hand, the triumphs of modern medicine are the results of experimentation and reductionism, of systematic attempts to remove all considerations of personal behaviour, and the like, to understand biologic systems. Due to these seemingly opposing forces separating reductionist medical care and preventive health, it was important to understand surgeons' perspectives on preventive health if they were to contribute to the hospital's aim of increasing preventive health practice in ambulatory secondary care.

The notion of prevention, the altering of risk factors before they have even begun to influence human physiology, is something that doctors have historically relegated to the domain of public health practitioners (Lawrence, 1990). However, the nature of health and illness has changed (Bircher & Hahn, 2016). The declining mortality rates from infectious diseases has intersected the rising rates of morbidity associated with chronic diseases (Bircher & Hahn, 2016). While this epidemiologic transition was forecast (Mackenbach, 1994), the trends of earlier onset of chronic disease and long years of life spent with morbidity were not (Begg, 2014). Given these data and the demands of managing chronic disease morbidity in the hospital setting, surgeons have been recommended to broaden their role to assist patients in adopting healthy behaviours. Surgeons' desire to intervene with modern medicine, particularly with the diagnostic and therapeutic armamentarium now at hand, is insufficient in the prevention and management of chronic disease (Bircher & Hahn, 2016; Lawrence, 1990). Surgeons are now being advised to consider the potential benefits of counselling patients to modify their risk factors, for example helping them find the optimum pathway to quit smoking, or to initiate regular PA (Royal Australasian College of Surgeons, 2012). Addressing behavioural risk factors may pose a challenge to surgeons, and this is likely influenced by two key elements. Firstly, the benefits of preventive health interventions will be measured many years later, far beyond the consultation (Adams, 2010). Secondly, the instantaneous feedback provided by successful treatment of symptomatic disease reinforces surgeons' interest in pathology and therapeutics rather than in preventive health practice (Wade & Halligan, 2004). These factors might influence surgeons' belief about their role in the delivery of preventive health interventions.

Only a small number of studies exist examining implementation rates of lifestyle risk factor management by doctors in ambulatory secondary care. These studies largely consist of cross-sectional studies of self-reported practice (Daley et al., 2008; Hardcastle et al., 2018; Jones et al., 2004; Sheill et al., 2018; Williams et al., 2000; Williams et al., 2015). None of these studies were carried out in Australia. Only two studies included hospital surgeons, and these were in the subspecialty of oncology (Daley et al., 2008; Williams et al., 2015). The authors found that preventive health practice rates by doctors in ambulatory secondary care were low (Daley et al., 2008; Hardcastle et al., 2018; Jones et al., 2004; Sheill et al., 2018; Williams et al., 2000). None of the studies conducted interviews to probe the quantitative findings to understand more about surgeons' beliefs about preventive health practice. This highlighted a clear gap in the published literature.

To implement behaviour change interventions in ambulatory secondary care, the clinicians consulting with the patients, in this case the surgeons, need to value the change to practice (Greenhalgh et al., 2004; Johansson et al., 2010). The prospects of a successful implementation are dependent on the compatibility of the proposed change with the surgeons' own values, working norms, and perceived needs (Greenhalgh et al., 2004). It became clear that in order to understand the role of preventive health interventions in secondary care, further information was required to understand what preventive health interventions surgeons undertake, and what influences their decisions to engage, or not, in preventive health practice. In order to achieve these aims, a mixed-methods study design was used to identify which preventive health activities surgeons carry out in ambulatory secondary care, and to explore the attitudes of surgeons towards preventive health practice. This study design permitted gaining insights on the surgeons' distinct perspectives on current preventive health practice, and the attitudes and beliefs of these clinicians relating to implementing preventive health into ambulatory surgical practice. The findings from Chapter 7 were used to inform the design of the RCT in Chapter 8.

1.7 The economics of prevention in secondary care

Public health professionals are increasingly skilled at considering the epidemiologic evidence of health issues (Rabarison et al., 2015). Epidemiology is the basic science of public health, and is used to inform policy decisions and evidence-based practice by identifying risk factors for disease, and subsequent targets and interventions for preventive healthcare (Brownson et al., 2017). Contemporary public health professionals, however, need to consider the health needs

of the population alongside environmental constraints such as decreasing healthcare budgets (Rabarison et al., 2015). Australia reportedly spends \$2 billion on prevention each year, which equates to \$89 per person (Sheill et al., 2018). This is approximately 1.3% of all health spending in Australia, and it is considerably less than countries such as Canada and the United Kingdom spend on prevention (Sheill et al., 2018). It is vital that public health professionals use a comprehensive, and economic approach towards decisions on what initiatives to implement.

Adding a preventive health intervention into hospital care typically requires an additional upfront investment. This is exemplified in the case of the work undertaken in my professional role. The hospital invested in prevention by hiring a health professional, in my case an Allied Health clinician, to undertake this preventive health project. In economics, the term 'opportunity cost' represents the benefits an investor or business *misses out on* when choosing one alternative over another (Drummond et al., 2015). For the hospital there was an opportunity cost to my preventive health role, which might be seen as the number of patients who could have been seen by investing in an Exercise Physiologist to consult with individuals 1:1 or in groups, in purchasing additional equipment for the existing hospital gym, or by investing in advertisements within the local community encouraging behaviour change. As the H4U project was carried out in addition to standard care, not as a substitution, undertaking an economic evaluation offered an estimate of the costs and effects of adding this preventative health intervention to clinical care. Determining the costs and benefits of public health interventions provides data for public health professionals and policy makers to use when choosing which interventions are effective, efficient, equitable, scalable, and sustainable (Mays & Smith, 2011; Rabarison et al., 2015).

1.7.1 Conducting economic evaluations in preventive health

To undertake an economic analysis alongside an intervention study, as part of the trial data collection the participants answer questions on their healthcare usage and utility at the specified points post randomisation (Goyder et al., 2014). Together with an estimate of the intervention cost, this data allows for an estimation of the effect of the intervention on health-related quality of life (HrQoL), and an average cost to be produced by comparing costs and utility scores at the end of the intervention with those before the intervention.

Economic analyses of preventive health interventions need to be interpreted under a slightly different set of assumptions to, for example, a typical pharmaceutical RCT. The differences are illustrated in Figure 1.2, which exemplifies a typical pharmaceutical RCT. The patient population is recruited on the basis of suffering from a particular health issue, which has a substantive effect on their HrQoL. The treatment reduces disease progression and a difference in HrQoL is observed between the intervention arm (solid line) and the control arm (dashed line) by the end of the trial.

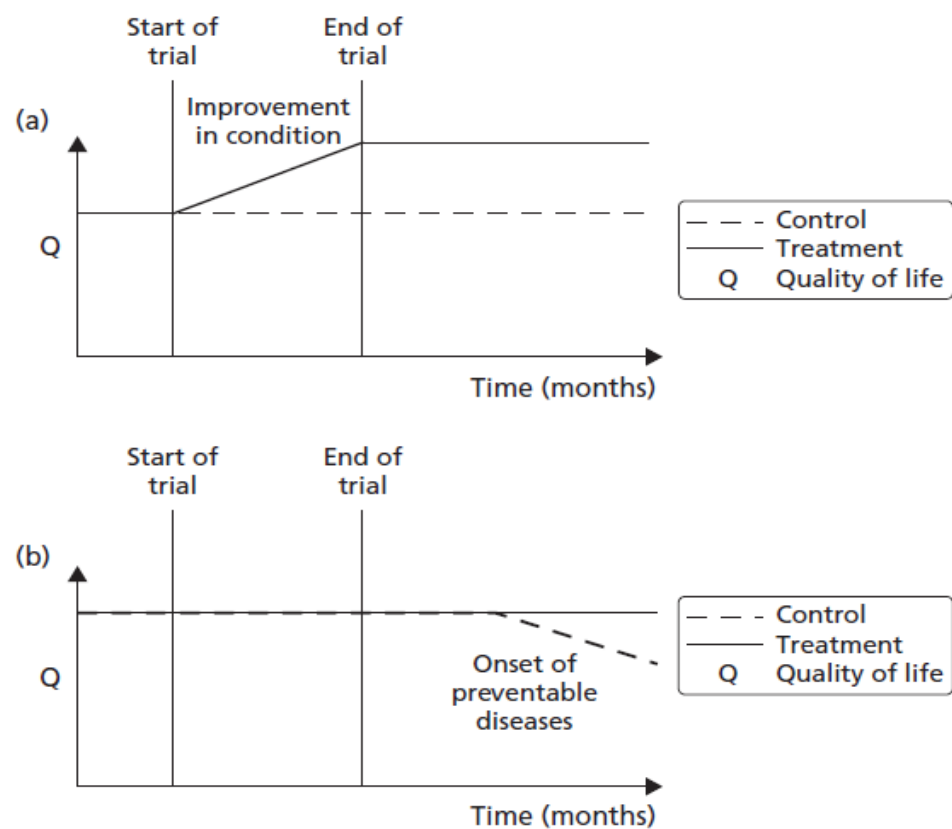


Figure 1.2: Timing of HrQoL benefits. (a) Curative intervention; and (b) preventive health intervention. From Goyder et al, 2014. Reprinted with permission.

Figure 1.2b indicates the potential effect of a preventive health intervention on HrQoL. Both the intervention and control group are in reasonable health initially, however, because of a risk factor such as insufficient PA, both groups are at an increased risk of developing chronic disease and associated morbidity. This predisposes both groups to a decrease in HrQoL over time, as exhibited by the pattern of the control group in Figure 1.2b. Behavioural interventions are not designed to modify a disease but instead modify a lifestyle factor that predisposes people over the long term to increased chronic disease risk. The result of a preventive health intervention in

Figure 1.2b is the avoidance of a decrease in HrQoL as exhibited in the control group. As a result, a straightforward comparison of before-and-after levels of health resource use and HrQoL might be misleading. Often the follow-up measurement may have been too soon for the mediating effect of PA on health to have become apparent (Goyder et al., 2014). While similar economic analyses methods are used in curative and preventive health interventions, understanding the differences in projected changes and associated economic figures is important when reporting the cost-effectiveness of interventions.

The addition of preventive health initiatives to increase PA is likely to require an upfront investment by hospitals. These preventive measures can be worthwhile over the longer term due to the substantial health benefits that they confer in the future, relative to their cost (Martinson et al., 2003). Despite this, the lack of economic evaluations of preventive health interventions remains a significant gap in public health, and influences decision making regarding long-term implementation of interventions (Jacob et al., 2014). Further to the need to investigate the efficacy of behaviour change interventions in secondary care, it is necessary to evaluate the cost-effectiveness of adding preventive health interventions into secondary care. The scarcity of robust economic evaluations in the field represents a considerable challenge for decision making that relates to resource allocation aimed at reducing the burden of chronic disease morbidity in resource-constrained health care systems.

1.8 Summary

Chronic diseases are largely driven from preventable risk factors, including insufficient PA, poor diet and smoking. The management of morbidity associated with chronic diseases has placed significant resource and fiscal demands on the hospital system. This has necessitated that hospitals broaden their role from a primary focus on curative care to a position of more holistic preventive health. Changing hospital practice to become more prevention-oriented is a multifaceted and complex process, requiring changes in professional behaviours and working methods. In ambulatory secondary care, the surgeons are the direct contact point with the patients, yet there was a lack of knowledge regarding preventive health activities carried out by surgeons providing ambulatory secondary care in Australia. A gap in knowledge also existed regarding the optimum design and delivery of behaviour change interventions for ambulatory secondary care patients, and the cost-effectiveness of integrating preventive health into ambulatory secondary care. This thesis sought to investigate the effect of behaviour change

interventions to increase PA and health-related outcomes in ambulatory secondary care patients in an effort to contribute to the prevention and management of chronic disease amongst ambulatory hospital patients in a public hospital in regional Victoria.

1.9 Research Aims

The overall aim of this thesis was to investigate the effect of behaviour change interventions on PA and health-related outcomes in ambulatory hospital care.

Study 1 (Chapter 3) was a systematic review and meta-analyses that compared integrated MI-CBT to standard care for changes in PA and health-related outcomes in community-dwelling adults. The aims of the study were to:

- Examine the effectiveness of integrated MI-CBT for lifestyle mediators of overweight and obesity in community-dwelling adults.
- Investigate if the number of MI-CBT intervention sessions influenced the PA outcomes.
- Provide robust data to inform the design of the RCT studies in Chapters 4, 5 and 8.

Studies 2 and 3 (Chapters 4 and 5) used a RCT design to examine the effectiveness, and cost-effectiveness of MI-CBT for changes in PA, anthropometrics and health-related outcomes in adults presenting to an ambulatory outpatient clinic. The aims of the studies were to:

- Examine the effectiveness of integrated MI-CBT for change and maintenance of physical activity in insufficiently active patients presenting to an ambulatory outpatient clinic in a public hospital.
- Compare 8 x 30-minute sessions of integrated MI-CBT to standard care for improvements in PA, anthropometrics and health-related outcomes in ambulatory secondary care patients who self-selected into the study.
- Evaluate the cost-effectiveness of the Healthy4U programme for increasing measured PA and the number of quality-adjusted life-years (QALYs) experienced over a 6-month period from a hospital perspective.
- Provide robust data to engage with the Specialist Clinic surgeons around the effectiveness of preventive health in this setting, and to inform the design of the studies in Chapter 5 and 6.

Study 4 (Chapter 6) was a systematic review and meta-analyses that investigated the effect of behaviour change interventions on changes in PA and anthropometrics in ambulatory hospital settings. The aims of the study were to:

- Examine the effect of behaviour change interventions on changes and maintenance on PA, and anthropometrics, initiated in the ambulatory hospital setting only.
- Provide robust data to engage with the Specialist Clinic surgeons around the effectiveness of preventive health in the ambulatory hospital setting.
- Examine components of ambulatory hospital-initiated behaviour change interventions to inform the design of the study in Chapter 8.

Study 5 (Chapter 7) was a mixed-methods study to identify preventive health practice undertaken by Specialist Clinic surgeons and to explore the attitudes of the profession towards health promotion practice. The aims of the study were to:

- Identify which preventive health activities surgeons carry out in non-admitted public hospital clinics and to explore the attitudes of the profession towards preventive health practice.
- Explore avenues for increasing preventive health interventions in Specialist Clinics through the interviews with participating surgeons.
- Provide data to inform the design of the study in Chapter 8.

Study 6 (Chapter 8) was a RCT to examine the effectiveness of MI-CBT for changes in PA, anthropometrics and health-related outcomes in adults presenting to an ambulatory outpatient clinic. The aims of the study were to:

- Examine the effectiveness of the PA telephone coaching intervention for change and maintenance of PA in insufficiently active secondary care patients referred by consulting hospital surgeons.
- Investigate the effectiveness of the telephone coaching for changes and maintenance in anthropometry, PA self-efficacy, and health-related quality of life in this population.
- Quantify the number of patients who receive brief PA advice and a referral to the study by the surgeons, and the number of individuals to act on this preventive health intervention.

Chapters 3 to 8 have undergone external peer review and are available in the published literature. In accordance with La Trobe University policy relating to thesis presentation, work that has been published is included in the thesis as published and has not been modified in content.

Chapter 2

Research methods

The methods for each research chapter (Chapters 3 to 8) presented in this thesis are described in the published journal article of each study. This chapter permits the provision of additional detail that could not be provided within these published articles due to word count restrictions.

In accordance with La Trobe University policy relating to thesis presentation, work that has been published is included in the thesis as published and has not been modified in content.

2.1 Participants

Chapter 4 and 5

In the studies presented in Chapters 4 and 5 the participants recruited were insufficiently physically active patients attending the Bendigo Health Specialist Clinics. A single item question “as a rule, do you do at least half an hour of moderate or vigorous exercise (such as walking or a sport) on five or more days of the week?” was used to identify insufficiently physically active individuals (Rose et al., 2008). The single-item screening question has good sensitivity, specificity, and concordance with a validated PA questionnaire (Rose et al., 2008). The question is easy to administer and elicits a simple yes/no response from potential participants.

The participants were aged 18 to 69 years. Interested participants were required to complete a Physical Activity Readiness Questionnaire (PAR-Q). The PAR-Q offers preliminary health screening of candidates aged 18 to 69 for exercise capability and safety (Thomas et al., 1992). If a participant answered ‘yes’ to one or more questions they were required to speak to their doctor regarding the intervention, and the amount of PA that they should perform. Participants were required to provide written clearance to participate in the study from their doctor.

Exclusion criteria included undertaking enough PA to be deemed sufficiently physically active, an existing medical condition that contraindicated PA (indicated by the PAR-Q), diagnosis of diabetes, deaf/hearing impaired, disabling neurological disorder, severe mental illness such as psychosis, learning disability, dementia, registered blind, housebound or resident in a nursing home, non-ambulant, pregnancy, and advanced cancer.

Chapter 7

The participants recruited into the study presented in Chapter 7 were orthopaedic surgeons, orthopaedic surgery registrars, general surgeons and general surgery registrars consulting out of the Specialist Clinic in Bendigo Health. During the recruitment period 20 general and orthopaedic surgeons and 11 general and orthopaedic surgery registrars were consulting in the Specialist Clinics and were eligible to take part.

Chapter 8

In the study presented in Chapter 8 the participants recruited were insufficiently physically active patients attending the Bendigo Health Specialist Clinics referred into the study by consulting surgeons. The same inclusion criteria applied as in Chapters 4 and 5.

In Chapters 4 and 5 a diagnosis of diabetes was an exclusion criteria to participation. A large number of individuals with diabetes enquired about participation in the studies in Chapters 4 and 5, and were excluded. No adverse effects were observed in participants who completed the studies in Chapters 4 and 5. In Chapter 7, a diagnosis of diabetes was not included as an exclusion criterion. It is well established that participation in regular PA improves blood glucose control and can positively affect lipids, blood pressure, cardiovascular events, mortality, and quality of life (Albright et al., 2000; Galassetti & Riddell, 2013). Participation in exercise programs or other means of increasing overall daily PA is important for optimal health in individuals with type 2 diabetes (Albright et al., 2000; Galassetti & Riddell, 2013).

2.1.1 Participant recruitment process

Chapters 4 and 5

Participants were recruited from the Specialist Clinics in Bendigo Health between October 2016 and June 2017. Recruitment was via self-selection. Throughout the recruitment phase of the study, recruitment flyers were posted on the walls, common tables, and in the information display units in the Specialist Clinics. The recruitment flyers provided information about the study and the study rationale. Individuals who were potentially interested in taking part were requested to make direct contact with the research team via the telephone number provided on the initial recruitment flyer (Appendix 4.2). The recruitment flyer was amended to include an email address and an SMS number to provide potentially interested participants additional ways to contact the research team (Appendix 4.3).

Chapter 7

Participation was offered to all general and orthopaedic surgeons and registrars practicing between June 2017 and August 2018. I was anecdotally informed that many of the orthopaedic and general surgeons do not use their Bendigo Health generated email account as their primary mode of email communication. Permission was sought, and granted by the Surgical Services Head of Department to utilise an existing up-to-date email list to contact the target participants. I composed an email on behalf of the Head of Department explaining the rationale for the study and the inherent requirements (Appendix 7.2). The email was sent to all potential participants by the Head of Department.

The email explained that participants could choose to take part in the clinician survey, the interview, or both. The email contained a link to the electronic version of the clinician survey. Participants were informed prior to commencing the survey that informed consent was implied by completing the survey. The email also contained contact details for the research team for those individuals who would like more information. Two subsequent reminder emails containing the clinician survey link were distributed through the same electronic channel, at four-weeks and eight-weeks after the initial email.

Regarding interviews, potential participants were approached individually by me to discuss possible involvement. It was decided that approaching surgeons individually, at the Specialist Clinic was the most efficient way to offer engagement to the surgeons. Outside of Specialist Clinic consulting time, the surgeons predominantly spend their public hospital time in theatre or on the wards, making the Specialist Clinic consulting time the most convenient time to approach them. The consulting times at the Specialist Clinic are coordinated using a scheduling roster. I was provided with a copy of the roster, and used the Specialist Clinic consulting schedule to identify the clinic times for target surgeons. I attended the clinics at the start of the session, and spoke to the surgeons and registrars about the study before they started consulting with patients. In the situation where an individual was interested in participating, a time was arranged to undertake the interview. Every effort was made to allocate sufficient time to discuss informed consent and undertake the interview. Participants were given a Participant Information and Consent Form to complete prior to undertaking the interview. Potential participants were offered a copy of the interview guide prior to the interview to familiarise themselves with the questions. Where individuals expressed interest in participating but could not schedule a time that day, repeated efforts were made with that individual by presenting at

the clinic on subsequent consulting days. Where an individual clearly expressed that they did not want to take part, no further approaches were made to that individual.

Chapter 8

Participants were recruited from the Specialist Clinics in Bendigo Health. Participant recruitment started in January 2019 and was completed in November 2019. During the recruitment period orthopaedic and general surgeons and their registrars were provided with sequentially numbered invitational fliers to be distributed to potential participants. The fliers invited patients to participate in the study (Appendix 8.2). Recruitment involved the consulting orthopaedic and general surgeons providing, during the normal course of the consultation, a verbal recommendation to engage in PA coaching. The surgeons then provided the sequentially numbered research flier to patients who, in their view, would benefit from engaging in increased PA.

This pathway was an important step that emanated from the results of Chapter 7, where the surgeons acknowledged that they are in a good position to highlight the need for behaviour change, and the provision of an information flyer meant that they could discuss PA changes, and point patients towards the study in a time-efficient manner. The information flier briefly detailed to potential participants what the project entailed. Potential participants subsequently contacted the research team of their own volition using information on the flyer. The recruitment flyer included a telephone number, email address and an SMS number to provide potentially interested participants avenues to contact the research team (Appendix 8.2).

The sequentially numbered referral pads permitted the quantification of the number of individuals who were provided with the flier and a verbal recommendation to engage in PA coaching, and the number of individuals who subsequently acted on this referral.

2.2 Education session

Chapter 4, 5 and 8

All enrolled participants were required to attend an education session prior to group allocation. The education session was a facilitated learning session based around self-management and lifestyle modification, and was carried out using a self-determination theory (SDT) framework (Vansteenkiste & Sheldon, 2006). Self-determination theory is a general theory of human motivation that defines motivation as “psychological energy directed at a particular goal” (Ng et al., 2012). Self-determination theory reflects that an individual’s on-going functioning is a product of a continuous interaction between cognitive, behavioural, and contextual factors, and more than a matter of education by itself (Ng et al., 2012). Self-determination theory is used to support, educate and motivate participants around positive lifestyle choices, as well as empower individuals over their health care (Patrick & Williams, 2012; Ryan & Deci, 2008). Self-determination theory was chosen as the framework in which to deliver the education session as it has been shown to complement MI and CBT integration (Markland et al., 2005; Patrick & Williams, 2012). Individuals are more likely to engage in certain behaviours, PA for example, if they value that behaviour, and are motivated for change (Ng et al., 2012; Patrick & Williams, 2012). Self-determination theory was used in this group setting to support, educate and motivate participants around positive lifestyle choices related to PA change (Patrick & Williams, 2012; Vansteenkiste & Sheldon, 2006).

Participants were encouraged to participate actively in the education sessions through group and task orientated learning. Education was delivered through case studies to stimulate vicarious learning (Patrick & Williams, 2012; Ryan & Deci, 2008). Participants were exposed to scenarios of individuals with health risk behaviours. The participants were then encouraged to discuss potential associated behaviour change modifications and given brief tasks to stimulate this thought process. As part of the facilitated learning session participants were asked to undertake tasks relating to PA barriers and enablers individually, and to discuss answers and any questions in a group format.

2.3 Motivational interviewing and cognitive behaviour therapy (MI-CBT) intervention

Motivational interviewing is a collaborative, guiding style intervention used for strengthening an individual's own motivation and commitment for change. Motivational interviewing specifies the use of a communication style that is built upon understanding that relational factors impact behaviour change and provides a clear foundation for client–practitioner communication (Naar & Safren, 2017). Cognitive behaviour therapy focuses on changing maladaptive thoughts that maintain behaviours and interfere with functioning (Beck, 2011). Cognitive behaviour therapy requires the use of in-session techniques, and clients are often provided with between-session tasks. Cognitive behaviour therapy involves clients making changes in areas that have been difficult for them to master in the past, which can lead to frustrations and ambivalence about change (Naar & Safren, 2017). Motivational interviewing can make CBT work better because MI utilises the individual's own motivation for change, and the guiding style of MI permits the individual to suggest their own strategies for undertaking the more difficult CBT work (Driessen & Hollon, 2011).

There are a number of ways in which MI can be combined with CBT (Westra & Arkowitz, 2011). Motivational interviewing can be delivered as a pre-treatment to build motivation for subsequent CBT treatments. Motivational interviewing can be used at specific moments during CBT interventions when individual ambivalence or discord arises. Additionally, MI can serve as an integrative framework in which CBT strategies can be delivered. The behaviour change interventions used in Chapters 4, 5 and 8 followed this final method, delivered using an MI framework, where the underlying spirit of MI was used as a foundational platform from which to conduct CBT strategies. The remainder of this section will detail the principles that underpin the MI framework, and how CBT strategies were integrated into the framework.

2.3.1 The spirit of motivational interviewing

Motivational interviewing is a style of interacting with people, not just a compilation of techniques. At the centre of MI is its 'spirit'. The spirit that epitomises the clinical method of MI, as an approach that is collaborative, evocative, and respectful of client autonomy. The spirit of MI assumes that individuals possess substantial personal expertise and wisdom regarding themselves, and can change if given proper conditions of support (Miller & Rollnick, 2012).

The spirit of MI consists of four interrelated elements: (1) partnership, (2) acceptance, (3) compassion, and (4) evocation (PACE) (Miller & Rollnick, 2012). Partnership is the collaboration between client and practitioner that supports the clients' interests and their self-efficacy. Partnership seeks to establish a guiding relationship with the practitioner and the client side by side instead of one in front of the other. Acceptance involves autonomy support by which the practitioner respects the client's self-determination and their freedom of choice. It is the client who is in charge of his or her change process and whether or not he or she will make any change at all. In addition, acceptance includes expressing accurate empathy and supporting self-efficacy by demonstrating an appreciation for the person's worth and providing an affirming stance. Compassion involves promoting the welfare of others, but it is distinct from personal feelings of sympathy, or from personalisation of the experience (Miller & Rollnick, 2012). Evocation is the principle that the individual has inherent wisdom over their own issues, and has the strength for change that the practitioner draws out. The inherent wisdom of the client is recognised within the spirit of MI; wisdom is not a missing ingredient that must be provided by the practitioner as in a CBT approach (Beck, 2011).

2.3.2 The processes of motivational interviewing

In addition to the spirit, MI is organised in terms of four processes: (1) engaging, (2) focusing, (3) evoking, and (4) planning (Miller & Rollnick, 2012). In the delivery of MI, the four processes overlap. The processes are not delivered in isolation of each other, nor are they delivered in a sequential manner.

Engaging is the process of developing rapport with the client and understanding their issue(s). It is the process of establishing the therapeutic alliance. A strong therapeutic alliance is the foundation of any behaviour change intervention. Using the principles of MI to engage can allow the client to understand that the conversation will be about their issues, and that their opinions on the issues are the most important. Motivational interviewing clearly specifies the practitioner communication behaviours that promote this therapeutic alliance. In contrast, the practitioner communication behaviours necessary to promote therapeutic alliance are rarely specified in the CBT literature (Persons, 2012).

Focusing is the process by which a practitioner and a client become clear on the intended direction and goal(s) of the conversation. The process of focusing goes beyond just agenda

setting or treatment planning, and the formulation of a list of goals or tasks. Focusing is the collaborative process of determining the scope of the conversation, which can include goals and tasks, but can also include thoughts, feelings, and concerns (Lundahl et al., 2010). While MI is a directive therapeutic style focused on achieving behaviour change, the collaborative process empowers the client to focus on the issues that are relevant to them, and how these issues influence their behaviours (Miller & Rollnick, 2012).

Evoking is the process of drawing out the client's own words about the behaviour change. This is a key component of MI as it ensures that it is the client who makes the argument for change for themselves, instead of the practitioner doing it for them. Through the evoking process, the client builds intrinsic motivation to change the target behaviour. The process of MI is built with the understanding that behaviour change is driven by a person's own desire, reasons and ability to change (Rubak et al., 2005). Behaviour change is rarely driven by the opinions of somebody else. This is particularly relevant as it relates to the strategies typically employed in CBT treatments. In CBT, the provider typically tries to underscore the negative consequences of the individual's current thoughts and behaviour (Driessen & Hollon, 2011). The CBT practitioner also presents the rationale for the treatment components and presents the reasons for why particular skills are important. Most individuals, however, are more likely to believe what they say themselves rather than what someone else tells them (Driessen & Hollon, 2011). The process of evocation runs counter to human's natural instinct to 'help' people by correcting what they construe as poor decision making or flawed reasoning through the impartation of unsolicited advice (Lundahl et al., 2010). Miller and Rollnick (2012) describe this as the 'righting reflex', which they recognise as the human tendency to correct things that are considered wrong. The righting reflex often results in premature problem solving and the provision of advice. This in turn prevents individuals from being actively involved in their own reason for change and leads to disengagement. Rather than simply being informed of the need for change, motivation for change is a function of how important the proposed change is to the individual, and their confidence in their ability to make the change. The MI processes and skills specifically address both of these components of motivation, and adherence to MI skills support the individuals own motivation for change, even when the provider is sharing relevant information or providing skills training.

2.3.3 Motivational interviewing microskills

MI uses a set of core microskills, in the spirit of MI, to promote the four processes described above. The MI microskills are open-ended questions, affirmations, reflective listening and summarising (OARS).

In MI, conversations are facilitated through the use of open-ended questions. Similarly, MI deemphasises the use of closed-ended questions that elicit a single-word response. The use of open-ended question permit practitioners to understand the client's point of view, and elicits the client's feelings about a given topic or situation (Miller & Rollnick, 2012). Open-ended questions are important as they facilitate dialog; open-ended questions cannot be answered with a single word or phrase and do not require any particular response. Open-ended questions encourage the client to do most of the talking, and prevents the practitioner from making premature judgments, which together facilitates the conversation moving forward (Lundahl et al., 2010).

Affirmations are statements that recognise the client's strengths. Affirmations assist in building rapport to help the client see themselves in a different, more positive light (Miller & Rollnick, 2012). Affirmations build rapport, demonstrate empathy, and affirm the client's strengths and abilities (Miller & Rollnick, 2012). To carry out this skill, practitioners are required to actively listen for the client's strengths and values, and then reflect these back in an affirming manner. For example, if the client discusses previous efforts to change a particular behaviour from the position of feeling like they have failed, affirming offers an opportunity to reframe what the client has said from negative to positive (Driessen & Hollon, 2011). For example: "*What I am hearing from you is that it is very important for you to change this behaviour. You have made a number of efforts at this over a period of time. It appears that you have yet to find the way that works for you*". This reframing of the information accomplishes an affirmation of the client's efforts and perseverance, and importantly establishes a basis towards finding a solution that will work for the client (Hettema et al., 2005).

In MI, reflective statements are used to communicate accurate empathy. The practitioner offers reflections which state back to the client what the practitioner heard. Reflective statements demonstrate that the practitioner has accurately heard and understood the client's point by restating its meaning. Miller and Rollnick (2012) summarised it with the following description:

"reflective listening is a way of checking rather than assuming that you know what is meant". Reflections can also be used to reinforce or emphasise components of the conversation for strategic purposes (e.g., to explore ambivalence, to strengthen motivation) (Hettema et al., 2005). Reflective statements can be affirming, as they are reflections of what the client said, and accurate reflections can emphasise the client's strengths or efforts.

Summaries are a special type of reflection where the practitioner recaps what has occurred in all or part of the session. Summaries communicate interest, understanding and call attention to important elements of the discussion. Summaries are important skills to move the conversation from the beginning, through the middle, to closing. By summarising, the practitioner can check that they are understanding the client's goals and preferences. Summaries also confirm that the client has an understanding, and is accepting of the key elements of the treatment plan.

2.3.4 Cognitive behaviour therapy strategies

Cognitive behaviour therapy posits that thoughts or cognitions mediate behaviour (Dobson & Dozois, 2010; Hering et al., 2005). Hering and colleagues (2005) put forward 3 fundamental propositions of CBT as: (1) cognitions affect behaviour, (2) cognitions can be altered, and (3) behaviour change can be produced through cognitive changes. Cognitive behaviour therapy aims to build a set of skills that enables the client to be aware of thoughts and emotions. Cognitive behaviour therapy also aims to identify how situations, thoughts, and behaviours influence emotions, and how feelings or emotions can improve by changing dysfunctional thoughts and behaviours (Dobson & Dozois, 2010). The process of skill acquisition using CBT is collaborative. Skill acquisition and the setting of specific tasks, or between session 'homework' for clients is what sets CBT apart from other talk based or counselling therapies (Bond & Dryden, 2005). Cognitive behaviour therapy protocols encourage the use of intervention session time to teach skills to address the presenting problem, and not simply to discuss the issue with the patient or offer advice (Bond & Dryden, 2005).

Cognitive behaviour therapy PA treatment protocols seek to: (1) teach clients specific cognitive and behavioural skills to better manage PA; (2) inform clients regarding the effects that specific cognitions (thoughts, beliefs, attitudes), emotions (fear of failure), and behaviours (activity avoidance) can have on PA and general health; and (3) emphasise the primary role that clients

can play in controlling their own PA levels now and into the future (Beck, 2011; Dalle Grave et al., 2010; Hofmann et al., 2012).

The CBT component of the interventions used in the studies in Chapters 4, 5 and 8 focused on a number of theory-derived determinants of PA (Condello et al., 2017; Cortis et al., 2017). These included PA values, PA outcome expectations, PA self-efficacy, PA outcome experiences, social support and relapse prevention. A toolkit of CBT behaviour change strategies was derived from Michie's behaviour change taxonomy (Michie et al., 2011a), and research investigating the determinants and strategies for PA maintenance (Scott et al., 2015). The CBT behaviour change strategies used in the behaviour change interventions in Chapters 4, 5 and 8 included:

- Elicit PA experiences;
- Elicit PA outcome expectations;
- Probe priority of PA outcome expectations;
- Barrier identification;
- Problem solving;
- Goal setting (behavioural);
- Pros and cons of behaviour change;
- Prompt framing/reframing;
- Goal setting (outcome);
- Action planning;
- Building self-efficacy;
- Self-monitoring (behavioural);
- Coping skills;
- Prompt engage social support;
- Elicit satisfaction with PA outcomes;
- Review of goals;
- Relapse prevention; and
- If-then plans.

2.3.5 Cognitive behaviour therapy strategies and their integration with motivational interviewing

The behaviour change interventions used in Chapters 4, 5 and 8 were delivered using an MI framework, where the underlying spirit of MI was used as a foundational platform from which to conduct CBT strategies (Westra & Arkowitz, 2011; Westra et al., 2009). Using some of the most commonly used CBT strategies, this section illustrates how, using the models of integration proposed by Westra & Arkowitz (2011) and Naar-King and colleagues (2013), the intervention integrated the relational and technical components of MI with the use of specific CBT strategies.

Goal setting

Once clients have focused on an area of change, goal setting is an important action-oriented step towards undertaking intended behaviour change. Goal setting assists individuals to identify specific behaviours to change, and the steps required to go about making the change (Bailey, 2019). Forced goal setting however can affect treatment (DiClemente, 1991). Clients who are required to set rigid, 'all or nothing' goals are more likely to view slips as failure, and experience what is known as the goal violation effect (Marlatt & Gordon, 1985). The violation of a goal (the failure to attain a particular goal) can be demotivating to continuing efforts, and results in a deterioration of performance (Soman & Cheema, 2004). In contrast, when behaviour change goals are flexible, individuals are more likely to return to positive behaviour change, even in the presence of a slip (Marlatt & Gordon, 1985; Soman & Cheema, 2004). For example, clients who are insufficiently physically active are taught to think about 'one day at a time' instead of a rigid goal of achieving 150 minutes of exercise every week. While the ultimate long-term goal for the client can be engaging in 150 minutes of exercise every week, setting flexible short-term goals permits the normalisation of slips or setbacks (Marlatt & Gordon, 1985). Indeed, individuals who had more flexible definitions of long-term PA goals were more likely to achieve PA maintenance (Marcus et al., 2000).

Motivational interviewing integration

Motivational interviewing offers several ways to support CBT skill acquisition around goal setting. To encourage and facilitate the client's autonomy over goal setting in a supportive manner, MI encourages the practitioner to seek permission before offering a number of short-term goals from which the client may choose. The client is less likely to reject suggestions when

they feel that they have the power to choose (Naar-King et al., 2013). In addition, offering several options for change supports the idea that multiple paths to success are possible, and if one path is unsuccessful, another path may be considered in the future (DiClemente, 1991). Another technical component of MI relevant to CBT goal setting includes eliciting the client's reasons for maintaining behaviour change, which can highlight potential barriers and facilitators to achieving the goal (Driessen & Hollon, 2011). The client's plans for maintaining behaviour change are reviewed during each session, a process that can normalise slips and supports flexible goal setting.

Building self-efficacy

Self-efficacy is a key predictor of behaviour change success, including changes and maintenance in PA (McAuley et al., 2011). Building client self-efficacy is considered an important element of successful CBT (Zlomuzica et al., 2015). Though the importance of self-efficacy is discussed in theoretical approaches to behaviour change, CBT interventions rarely specify exactly how a practitioner might support client self-efficacy (Beshai et al., 2011; Minami et al., 2008; Nigg et al., 2008). Cognitive behaviour therapy approaches commonly encourage the use of skills building to increase feelings of competence, and prevent relapse (Marlatt & Gordon, 1985). However, in the absence of specific strategies to build self-efficacy, the use of skills building alone may not be sufficient to support self-efficacy around behaviour change (Naar-King et al., 2013).

Motivational interviewing integration

In contrast to CBT, MI uses specific strategies to support client self-efficacy (DiClemente et al., 2017). The MI microskills aim to specifically facilitate change talk about the client's ability to both undertake and maintain behaviour change (Miller & Moyers, 2006; Miller & Rollnick, 2012). The use of open-ended questions may support self-efficacy, particularly when discussing past success in behaviour change, either directly related to the target behaviour or in general. Examples of such questions include, "*How did you make these changes in the past*" or "*How do you feel after you set yourself a goal to make a change, and then succeeded in making the change?*" Motivational interviewing techniques draw perspectives from the client relating to past successes, which can reinforce self-belief and self-efficacy (Miller & Moyers, 2006). Utilising the MI microskills, it is the client that brings forward ways in which actions can be taken to improve self-efficacy and behaviour change. Integrating MI microskills into specific CBT

strategies aimed at building self-confidence can avoid an expert-led approach, and facilitate client engagement (Miller & Moyers, 2006; Naar-King et al., 2013; Westra & Arkowitz, 2011; Westra et al., 2009). In addition, Polivy and Herman (2002) suggest that overconfidence and setting unrealistic goals often undermines successful change. Self-efficacy at the end of an intervention is more predictive of success than high levels of self-efficacy at the onset of treatment (Rubak et al., 2005, Polivy & Herman, 2002). Self-belief that is earned is more likely to be associated with future success than self-belief that has not been earned (Beck, 2011). During the CBT process of planning behaviour change, if the client is unable to detail how they will accomplish the goal and overcome associated barriers it may be an indication that the client's self-efficacy to attain the goals is insufficient. This may also indicate that the CBT goals are not appropriate, and the integration of MI can be used to guide the discussion towards more realistic goal setting and planning.

Develop coping skills

The literature regarding management of slips and the development of coping skills has typically centred on identifying potential triggers and then utilising CBT skills to manage this (Beck, 2011). These skills can include managing negative thoughts, stress management, and managing triggers (Westra & Arkowitz, 2011). In smoking cessation, the most commonly used CBT interventions were skills training to identify and resolve situations where there was a temptation to smoke (Lancaster et al., 2006). Cognitive behaviour therapy interventions to promote weight loss also used similar approaches including identification of triggers and problem solving (Svetkey et al., 2008). The development of coping skills for PA change has some contextual differences, where unlike smoking for example, PA is not a risk behaviour that individuals are tempted towards. Instead, individuals tend to avoid PA, and skills training centres on management of PA thoughts and perceptions. The rates of PA relapse following the completion of prescriptive exercise interventions remain high, and the PA literature has looked to develop a taxonomy of triggers to assist in guiding skills training specific for PA change and maintenance (Amati et al., 2007).

Motivational interviewing integration

Client motivation during CBT skills training is key for engagement in the learning process (Beck, 2011). In CBT skills training, clients are required to undertake specific tasks both in-session and at home to build skills. If the client is not sufficiently motivated for change, the tasks that are

required to build coping skills are unlikely to be given the necessary commitment (Beck, 2011; Burke, 2011). The CBT practitioner needs to be cognisant that should they take the expert role during this CBT skills teaching phase, in the absence of motivation it can have a negative impact on therapeutic alliance (Naar-King et al., 2013). The provision of education and direction without first obtaining the client's perspective may result in the client passively accepting the practitioner's information, but not fully engaging and committing to learning the skill (Naar & Safren, 2017). The integration of MI alongside CBT skills training can ensure that the therapeutic relationship is maintained throughout the CBT component of treatment. One of the primary MI strategies that conveys to clients that the process is collaborative and that their autonomy is respected is requesting for permission before engaging in a task (Miller & Rollnick, 2012). This process increases engagement because it requires the client to verbally agree to engage in the task. The use of the MI framework ensures that clients are engaged and ready for the CBT education and skills components, or if not, opens a channel for discourse around this (Cully & Teten, 2008).

Relapse prevention

The goal violation effect refers to the phenomenon of giving up the pursuit of behaviour change in the face of a setback (Marlatt & Gordon, 1985). If setbacks or lapses in behaviour are viewed as irreparable failures by the client, true relapse is more likely to occur (Marlatt & Gordon, 1985; Naar-King et al., 2013). The establishment of flexible goals is one strategy to counter this. In contrast to irreparable failures, lapses that are viewed as learning experiences by clients are more likely to promote long-term maintenance (Martin et al., 2005). Facilitating behaviour change often requires a focus on changing cognitions around how the client views lapses. Understanding the difference between slips/lapses and true relapse is an important step in preventing the goal violation effect (Marlatt & Gordon, 1985; Naar-King et al., 2013). The strategy of distinguishing between slips/lapses and true relapse has been used in behaviour change interventions for type 2 diabetes (Wing, 2010) weight loss (Svetkey et al., 2008) and PA and dietary changes (Michie et al., 2009).

Motivational interviewing integration

Miller (2019) proposed that the use of the term relapse actually promotes the violation effect; the term assumes that there are only two states, namely behaviour change success and failure. The true course of behaviour change is a process of ebbs and flows, where clients can return to

ambivalent states, and motivation for change can vary in frequency and intensity (DiClemente, 1991). While preventing relapses is an important part of CBT, a MI approach suggests avoiding the terms lapse and relapse when discussing with clients (Miller et al., 2019; Miller & Rollnick, 2012). Instead, expressing empathy about the difficulties of maintaining changes in the context of temporary setbacks is the commonly used MI approach (Miller & Moyers, 2006; Miller & Rollnick, 2012). This is an important relational component of MI, where the client's perspective on temporary slips is evoked. Instead of providing education and teaching specific skills as per traditional CBT approaches, the integration of MI supports the client's autonomy and the client's opinion with regard to returning to behaviour change actions and goals. Instead of focusing on motivation to avoid negative behaviours, emphasising change talk about maintaining new behaviours may be more important, particularly when discussing any slip in behaviour (Naar & Safren, 2017). Motivational interviewing skills can be integrated into the CBT strategy of eliciting satisfaction with PA outcomes to elicit change talk about the enjoyment of exercise, where the positive reinforcement of success might be more powerful to maintain beneficial behaviour change cognitions and actions.

2.3.6 Intervention fidelity

The increased focus on changing individual behaviours to mitigate the risk of chronic disease related morbidity has resulted in the generation of increasingly complex interventions. These interventions have multiple interacting components, which can pose challenges with implementation and evaluation (Medical Research Council, 2008). Intervention fidelity is defined as "the use of methodological strategies to monitor and enhance the reliability and validity of behavioural programmes" (Bellg et al., 2004). It is recognised as the extent to which a behaviour change intervention was designed, implemented and received as intended (Perepletchikova, 2011).

The concept of intervention fidelity originated from psychotherapeutic interventions that had concerns over the integrity of treatments (Moncher & Prinz, 1991). Michalic (2004) highlighted the importance of measuring and assessing intervention fidelity as intervention fidelity can mediate study outcomes, and assist in explanations of research findings. A failure to assess intervention fidelity increases the risk of type 1 and type 2 errors and can result in spurious conclusions about intervention effectiveness (Bellg et al., 2004). Should an intervention not produce significant changes, this can reflect issues with implementation failure rather than true

ineffectiveness (Medical Research Council, 2008). Assessment of intervention fidelity can also strengthen the validity of research by permitting the replication and evaluation of the intervention across differing studies and settings (Mars et al., 2013).

While the importance of intervention fidelity is unchallenged, the concept has become increasingly differentiated and multi-faceted (Steckler & Linnan, 2002). The proliferation of research regarding intervention fidelity for complex interventions presents conceptual, methodological and operational challenges for researchers. Debates remain in relation to the definition and measurement of core elements of fidelity. Alongside this, the need for reliable instruments for fidelity measurement continues.

Chapter 4

In Chapter 4, the Motivational Interviewing Treatment Integrity scale 3.1.1 scale was used to measure the fidelity of the behaviour change intervention (Moyers et al., 2010). The Motivational Interviewing Treatment Integrity scale 3.1.1 scale was designed to measure the extent to which the clinician conveys an understanding that motivation for change, and the ability to move toward that change predominantly resides within the client. The therapist focuses their efforts on eliciting and expanding client motivation and abilities within the therapeutic interaction.

Chapter 8

The systematic review and meta-analysis of hospital-initiated behaviour change interventions in Chapter 6 included studies with heterogeneous intervention components, with a variation in the depth of detail provided in relation to the behaviour change intervention content. As a result, for the H4U-2 study in Chapter 8, the intervention content, theory, determinants and behaviour change techniques were clearly specified and demonstrated in Table 8.1. This detail permits the demarcation of strategies used within and across the intervention sessions.

In Chapter 8, intervention fidelity was assessed using a MI-CBT fidelity scale designed and examined by Haddock et al (2012). In keeping with the desire to provide detail on the intervention content, theory, determinants and behaviour change techniques, it was appropriate to examine the fidelity of the integration of MI and CBT skills. Separate scales for MI and CBT permit the evaluation of therapist skills in the delivery of either or both therapies;

separate scales do not indicate whether the therapist has been able to integrate the two approaches in an effective manner (Gearing et al, 2010). The MI-CBT scale demonstrated good inter-rater reliability when used to rate adherence versus non-adherence (Haddock et al., 2012). In terms of validity, the MI-CBT scale also related well to CBT and MI scales (Haddock et al., 2012).

2.4 Measurement of physical activity

2.4.1 Accelerometer Details and Placement

Participants wore a triaxial accelerometer (wGT3X-BT; Actigraph, USA; Dimensions: 4.6 x 3.3 x 1.5 cm; mass: 19 g) during all waking hours over 7 consecutive days. The accelerometer was worn over the right hip on an elasticised waist band except for times when participants were sleeping or in contact with water (such as when bathing or swimming). In adults, the hip-mounted Actigraph has demonstrated high inter-device reliability ($r = 0.98$) and validity against indirect calorimetry ($r = 0.56$, $p < 0.001$) (Hills et al., 2014). The accelerometer recorded at a sample frequency of 100 Hz.

2.4.2 Accelerometer Data Extraction

Raw 100 Hz triaxial accelerometer data were downloaded using the manufacturer's software (Actilife v6.13.14 Actigraph, USA). This generated an output file in a comma separated variable file format. Accelerometer wear time was based on activity counts per minute (CPM). Measures of PA were calculated using the manufacturer's software (Actilife; Actigraph, USA), with cut points by Freedson Adult (1998) used to provide daily measures of MVPA (> 1951 cpm). Non-wear time was defined as 60 min or more of consecutive activity counts of zero, with a spike tolerance of 2 min and 100 cpm. Accelerometer data were considered valid if the accelerometer was worn > 10 h per day for at least 5 of the 7 days, including at least 1 weekend day (Esliger et al., 2005).

2.5 Anthropometry

Body mass, stature and waist circumference were measured according to procedures from the guidelines of the International Society for the Advancement of Kinanthropometry (Marfell-Jones et al., 2012).

2.5.1 Body mass

To measure body mass, calibration of the scales was performed prior to and after the testing periods using verified calibration weights (Marfell-Jones et al., 2012). Participants were measured barefoot or wearing thin socks or stockings. In general, the mass in minimal clothing is of sufficient accuracy, and the removal of bulky garments was required. The examiner ensured that the scale was reading zero, and that the subject stood on the centre of the scales with the weight distributed evenly on both feet. The reading from the scales was recorded by the examiner. Measurements of body mass were recorded three times to provide the mean figure.

2.5.2 Stature

To measure stature, participants were measured using a stadiometer that was mounted on a straight wall at a true 90° angle to the floor. Calibration of the stadiometer was performed prior to and after the testing periods using verified calibration rods. The stadiometer had a range of measurement from 60 cm to 220 cm, and offered an accuracy of measurement to 0.1 cm (Norton et al., 1996). A sliding board 6 cm wide was lowered to the vertex of the head. The floor in the recording room was level and free of carpeting. There was more than 30 cm of unoccupied wall space on either side of the stadiometer. The participants were measured barefoot or wearing thin socks or stockings. Participants were asked to remove any hairpiece or rearrange any hair styling that might have interfered with firm contact between the headboard and the scalp. Participants stood with their back against the wall-mounted stadiometer, heels together. The back (scapulae), buttocks and both heels were touching the wall-plate. The participants were instructed to stand with the head erect and in the Frankfort horizontal plane and informed that the back of the head did not need to be in contact with the wall-plate (Marfell-Jones et al., 2012; Norton et al., 1996). The examiner checked that the participants were in the correct position, starting with the heels and checking each point of contact with the wall-plate. To ensure that the Frankfort Plane was achieved the examiner was occasionally

required to grip the head with their open hands and pivot it gently backwards and forwards while observing the counter. The counter registered the greatest height when the head is tilted not too far forward or backwards. The participants' stature was measured and recorded three times to provide a mean figure.

Deviations and exceptions to standard positioning were established for situations where it was required (Marfell-Jones et al., 2012). Obese participants and those with a kyphotic posture were not always able to place the heels, buttocks, and scapulae in a single vertical plane while maintaining a reasonable natural stance. These participants were positioned so that only the buttocks, and where possibly the scapula, were in contact with the wall-plate. The essential point was that the participant stood erect with the buttocks in contact with the wall plate and the legs as close together as possible. In situations where participants were obese and not able to stand comfortably with the heels touching, they were permitted to stand with the legs together and the heels separated. For participants with severe spinal curvature, if the spine was the part that protruded the farthest, then the spine was the part that was touching the wall plate, together with heels and buttocks. The head was always measured in the Frankfurt Horizontal Plane.

2.5.3 Waist Circumference

A flexible steel tape of 1.5 m in length was used for measuring waist circumference (Marfell-Jones et al., 2012). The tape was calibrated in centimetres with millimetre gradients. In line with recommendations the tape was non-extendible, flexible, not wider than 7 mm and had a stub (blank area) of at least 4 cm before the zero line (Marfell-Jones et al., 2012). The tape was enclosed in a case with automatic retraction.

Participants assumed a relaxed standing position with the arms folded across the thorax. The measurement was taken at the level of the narrowest point between the lower costal (10th rib) border and the iliac crest. The examiner stood in front of the participant who was asked to abduct the arms slightly to permit the tape to be passed around the abdomen. The stub of the tape and the housing were both held in the right hand while the examiner used the left hand to adjust the level of the tape at the back to the adjudged level of the narrowest point. The examiner resumed control of the stub with the left hand and using the cross-hand technique positioned the tape in front at the target level. The participant was instructed to lower their

arms to the relaxed position. The tape was then readjusted as necessary to ensure it had not slipped and did not excessively indent the skin. The participant was informed to breathe normally and the measurement was taken at the end of a normal expiration (end tidal). The measurement was called by the recording examiner, who entered the number on the record screen. The participant's waist circumference was recorded three times to provide a mean figure.

2.6 Qualitative data analysis

Qualitative description was selected as the theoretical framework for the qualitative component of the study presented in Chapter 7 (Sandelowski, 2000). Qualitative description provides straightforward, rich descriptions of experiences or events in a language similar to the participant's own, and can draw descriptions from the participants' stories to reveal how they view and understand their lives (Sandelowski, 2000). Semi-structured interviews were used to draw forth participant stories with the aim of addressing the 'why' and 'how' of the phenomenon under study, namely perceptions and attitudes toward preventive health in non-admitted secondary care.

Qualitative description analysis involves the reading and re-reading of transcripts, permitting the development of a coding scheme that accurately reflected concepts in the text (Patton, 1990; Rice & Ezzy, 1999). Coding is a critical part of the data analysis stage and was used to merge concepts that emanated from reviews of the interview text (Charmaz & Belgrave, 2012). The qualitative description process used open and axial coding of transcripts, which, in keeping with the sequential explanatory methodological approach, occurred simultaneously (Rice & Ezzy, 1999; Sandelowski, 2000). The open coding required the reading of interview transcripts linearly which aimed to identify concepts or codes. Codes are considered as the smallest unit of text that conveys the same meaning for the purpose of the research (Rice & Ezzy, 1999; Saldaña, 2015; Sandelowski, 2000; Strauss & Corbin, 1990). The codes were derived from data rather than being determined a-priori. Axial coding is the process of developing connections between code categories and sub-categories via a combination of inductive and deductive thinking (Patton, 1990). The identified codes were grouped into more general categories that these codes were instances of, such as institutional practices, work activities, personal beliefs and so forth (Charmaz & Belgrave, 2012). Consistent sub-categories were integrated, reducing the overall number of categories (Patton, 1990; Sandelowski, 2000). The emerging categories

were reviewed by the research team which permitted the use of the categories to explain the factors that influenced surgeons' decisions to undertake health promotion activities.

Following open and axial coding, a process of selective coding was undertaken (Saldaña, 2015). Selective coding is the process that defines the central or core themes (Saldaña, 2015; Strauss & Corbin, 1990). The central themes have the analytic power to combine all categories to form an explanatory whole (Rice & Ezzy, 1999; Sandelowski, 2000; Strauss & Corbin, 1990).

Fourteen semi-structured interviews were undertaken. The recorded interviews were transcribed verbatim by me. The transcripts were analysed and coded line-by-line using the qualitative data analysis software NVivo 10.0 (QSR International, Cambridge, MA, USA). All the interview transcripts were independently coded and analysed by Andrea Sloane and me. To improve reliability and to reach consensus, two additional authors reviewed the codebook and samples of transcripts. No new codes or categories emerged from the data between the twelfth and thirteenth interview, indicating that data saturation was reached by the twelfth interview (Guest, Bunce, & Johnson, 2006). To ensure data saturation, one additional participant was interviewed. As this additional interview did not bring forward new information, data saturation was deemed to have occurred (Guest et al., 2006), and interviewing was ceased.

Chapter 3

Integrated motivational interviewing and cognitive behaviour therapy for lifestyle mediators of overweight and obesity in community-dwelling adults: A systematic review and meta-analyses

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3.1 Abstract

Background: The aim of this study was to investigate whether integrated motivational interviewing and cognitive behaviour therapy leads to changes in lifestyle mediators of overweight and obesity in community-dwelling adults.

Methods: Six electronic databases were systematically searched up to 04 October, 2017. Analyses were restricted to randomised controlled trials that examined the effect of integrated motivational interviewing and cognitive behaviour therapy on lifestyle mediators of overweight and obesity (physical activity, diet, body composition) in community-dwelling adults. Meta-analyses were conducted using change scores from baseline in outcome measures specific to the lifestyle mediators of overweight and obesity to determine standardized mean differences (SMD) and 95% confidence intervals (95% CI). The Grades of Recommendation, Assessment, Development and Evaluation approach was used to evaluate the quality of the evidence.

Results: Ten randomised controlled trials involving 1949 participants were included. Results revealed moderate quality evidence that integrated motivational interviewing and cognitive behaviour therapy had a significant effect in increasing physical activity levels in community-dwelling adults (SMD: 0.18, 95% CI: 0.06 to 0.31, $p < 0.05$). The combined intervention resulted in a small, non-significant effect in body composition changes (SMD: -0.12, 95% CI: -0.24 to 0.01, $p = 0.07$). Insufficient evidence existed for outcome measures relating to dietary change.

Discussion: The addition of integrated motivational interviewing and cognitive behaviour therapy to usual care can lead to modest improvements in physical activity and body composition for community-dwelling adults. The available evidence demonstrates that it is feasible to integrate MI with CBT and that this combined intervention has the potential to improve health-related outcomes.

Conclusion: This review details recommendations for future research including the adoption of uniform objective outcome measures and well-defined interventions with sufficient follow-up durations and assessments of treatment fidelity.

Keywords: Body composition; Health behaviour; Health promotion; Obesity; Physical activity.

3.2 Background

The epidemic of overweight and obesity continues to rise worldwide, and constitutes a serious public health concern (Flegal et al., 2010). In 2016, more than 650 million adults were classified as obese (according to the World Health Organizations (WHO) body mass index (BMI) classification of obese $\geq 30 \text{ kg/m}^2$) (World Health Organization, 2016). Overweight and obesity presents a major challenge to population health due to its intricate association with a number of chronic diseases (Malnick & Knobler, 2006). Overweight and obese individuals experience increased morbidity, functional limitations and psychosocial problems as a result of excess adiposity (Must et al., 1999). Due to the increasing prevalence of overweight and obesity, developing effective treatment approaches has been identified as a research and population health priority (Stevens et al., 2012).

The aetiology of obesity is complex and multifaceted (Hruby & Hu, 2015). However, as individual and personal choices play a critical role in the manifestation of overweight and obesity, behaviour modification and lifestyle interventions are recommended as the primary steps in overweight and obesity management (Looney & Raynor, 2013; Pigeyre et al., 2016). Interventions typically target changes in lifestyle mediators of overweight and obesity namely physical activity (PA), diet, and body composition (waist circumference; mass; body mass index) (Pigeyre et al., 2016; Teixeira et al., 2015). Psychological strategies such as increasing motivation for change, improving self-efficacy, and self-regulatory capabilities are required for addressing the lifestyle mediators of overweight and obesity and are the best predictors of beneficial PA and weight outcomes (Armstrong et al., 2011; Donnelly et al., 2009; Looney & Raynor, 2013; Lundahl & Burke, 2009).

Motivational interviewing (MI) is a directive, behaviour change technique that is effective in overcoming ambivalence and increasing desire for behaviour change (Miller & Rollnick, 2012). The principles and methods of MI address issues associated with ambivalence about behaviour change, including decreased confidence and low self-efficacy (Rubak et al., 2005). MI has well established efficacy for initiating health behaviour change (Heckman et al., 2010; Looney & Raynor, 2013; Rubak et al., 2005), but is less effective in goal-oriented action planning, which can lead to behaviour change relapse (Lundahl & Burke, 2009; Naar-King et al., 2013). Not surprisingly, therefore, it has shown to be more effective and longer lasting when combined with other active treatments, rather than delivered alone (Hettema et al., 2005). Cognitive

behaviour therapy (CBT) on the other hand, posits that therapeutic strategies designed to change maladaptive cognitions can lead to improvements in behaviours (Beck, 2016; Ellis, 1962). CBT is most commonly used to maintain behaviour change, utilising prominent strategies around relapse prevention and self-regulation (Ryan et al., 2011). In contrast to MI, CBT has shown less effectiveness in resolving ambivalence to behaviour change (Westra, 2004), demonstrating its greatest efficacy when working with voluntary, motivated clients (Ryan et al., 2011).

Multiple studies have identified that the main factors associated with suboptimal health behaviour adoption are the lack of motivation to change and failures in strategies to maintain behaviour change (Ashenden et al., 1997; Piasecki, 2006; Wing & Phelan, 2005). A recent systematic review of self-regulatory mediators indicates that a lack of autonomous motivation, self-efficacy and self-regulation skills are associated with relapses in lifestyle change intervention (Teixeira et al., 2015). Findings such as this, and the respective strengths and limitations of MI and CBT alone, have led to the proposal of integrating MI and CBT (MI-CBT) into a single intervention (Burke, 2011; Naar-King et al., 2013; Westra, 2004). Both MI and CBT share integral components necessary for the expert use of the approach (Flynn, 2011). Both approaches emphasise working in a collaborative, directive way with clients, with a clear focus on changing behaviour (Beck, 2016; Miller & Rollnick, 2012; Naar-King et al., 2013; Westra, 2004). Both approaches are also understood to be most effective when focused on specific behaviours (Flynn, 2011). Supporting client self-efficacy and behavioural self-monitoring, key principles of MI have also been utilised in most conceptualisations of CBT (O'Leary & Wilson, 1987). Utilising a combination of behavioural interventions has been put forward as the most effective strategy for behaviour change (Burgess et al., 2017).

Several systematic reviews have demonstrated only modest effectiveness for MI alone (Armstrong et al., 2011; Donnelly et al., 2009), and CBT alone (Burke, 2011) in addressing lifestyle mediators of overweight and obesity, while others have shown more promising results for behaviour change in other areas using integrated MI-CBT (Baker et al., 2012; Riper et al., 2014), though the outcomes were not related to lifestyle mediators of overweight and obesity. Together these reviews provide some preliminary evidence that integrated MI-CBT might be effective for overweight and obesity, however, no systematic review has yet been undertaken that focuses specifically on the effectiveness of integrated MI-CBT interventions for addressing the lifestyle mediators of overweight and obesity in community-dwelling populations. The

primary aim of this review was to examine the effectiveness of integrated MI-CBT for lifestyle mediators of overweight and obesity in community-dwelling adults. Given the prevalence of overweight and obesity, and the recommendations for lifestyle behaviour interventions, clinicians and researchers would benefit from a systematic review that focuses on identifying the benefits associated with the use of the intervention to effect lifestyle mediators of overweight and obesity.

3.3 Methods

3.3.1 Search strategy

This review with meta-analysis adheres to the guidelines outlined in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Statement (Moher et al., 2009). An electronic database search was conducted in Ovid Cochrane CENTRAL, Ovid MEDLINE, Ovid EMBASE, Ovid PsycINFO, CINAHL and Elsevier Scopus from inception until 04 October 2017. Search terms were grouped into three constructs: motivational interviewing, cognitive behaviour therapy, and health behaviour change. The search terms were entered as keywords or MeSH terms where possible, and initially searched with the OR operator; search constructs were combined using the AND operator. The complete search strategy for Embase PsycINFO is presented in detail (Appendix 3.1). A manual search of reference lists from relevant articles was also conducted. Reference lists of selected trials were also examined to identify other relevant publications.

To be included in the current systematic review and meta-analysis, studies had to meet the following eligibility criteria: (1) an original, randomised controlled trial; (2) written in English-language; (3) adult population; (4) community-dwelling participants; (5) no active, serious mental health conditions, typically involving a diagnosis of psychosis; (6) intervention includes integrated MI-CBT; (7) intervention has at least one component that is delivered one-to-one; (8) outcome measures include a measured change in lifestyle mediators of overweight and obesity. Data were extracted using a standardised checklist. A unanimous decision was required between two reviewers to exclude a study during both abstract and full-text review. Where there was a lack of agreement between two reviewers, the disagreement was resolved by consensus via a third reviewer.

3.3.2 Data extraction

Data describing population characteristics, settings, intervention characteristics including duration and mode of delivery, measurement and verification of treatment fidelity, control group details, follow-up times, and outcomes were extracted from the included studies. Means and standard deviations of change scores for both intervention and control groups were included in one of the extracted studies (Lakerveld et al., 2013). Utilising these change data, the correlation coefficients for intervention and control groups were calculated, giving an average r of 0.50 (Higgins & Green, 2011). For all included studies, the standard deviation of change scores from baseline in outcome measures were calculated using a correlation coefficient of 0.5 (Higgins & Green, 2011), and entered directly into Review Manager 5.3 (The Nordic Cochrane Centre, The Cochrane Collaboration, Copenhagen, Denmark) for analysis (Cochrane Collaboration, 2014). Analyses based on changes from baseline were used because they are more efficient and powerful than comparison of final values, through the removal of between-person variability from the analysis (Higgins & Green, 2011). Sub-group analysis was conducted to determine the potentially moderating effect of number of intervention sessions on the outcomes. All analyses were repeated for pre–post test correlations set at lower (0.20) and higher (0.80) values than the calculated value of 0.50. Potential publication bias was evaluated via a funnel plot.

3.3.3 Data analysis

Standardised mean differences (SMD) with 95% confidence intervals (CIs) were calculated using Review Manager 5.3 as the mean difference divided by the pooled standard deviation (Higgins & Green, 2011). For dichotomous variables, odds ratio (OR) with 95% CIs were calculated using Review Manager 5.3. Meta-analyses were conducted on clinically homogenous data using a random effects model, to provide an estimate of the overall effect of integrated MI-CBT on health behaviour change (Higgins & Green, 2011). Cohen suggests that a standardised mean difference of 0.2 is small, 0.5 is moderate, and 0.8 or more is large (Cohen, 1988). In keeping with recommendations, I^2 was used to assess statistical heterogeneity across trials (Cohen, 1988; Higgins & Green, 2011). Heterogeneity was considered statistically significant if the p -value for the Chi-square test was less than 0.10 and the I^2 statistic was 50% or more (Higgins & Green, 2011; Thorlund et al., 2012). In line with recommendations, if intention to treat analysis using imputed values was reported in a trial, these data were used (Higgins & Green, 2011). In regards to outcome for PA, if more than one measure of PA was reported in a trial, the measure

that best reflected total activity was selected and included in the analysis. Where only medians were reported, these values were treated as means and the standard deviations were derived according to the formula: standard deviation = interquartile range/1.35 (Higgins & Green, 2011).

3.3.4 Assessment of study quality

Study and outcome quality was assessed according to the GRADE approach for systematic reviews (Balshem et al., 2011; Higgins & Green, 2011). Quality of evidence for meta-analyses began at the high level and was downgraded to lower levels of evidence when risk of bias, inconsistency, indirectness, imprecision or publication bias were present (Balshem et al., 2011; Higgins & Green, 2011).

3.4 Results

The literature search yielded a total of 1,436 potentially relevant studies (Figure 3.1). A total of 1,241 studies were excluded after review of titles and abstracts, resulting in 195 studies undergoing full-text review. A total of 185 studies were excluded during full-text review leaving 10 studies remaining for data extraction. The characteristics of the included studies are listed in Table 3.1. All included studies were parallel randomised controlled trials that evaluated behaviour change relating to the lifestyle mediators of overweight and obesity. Of the included studies, 10 studies included an integrated MI-CBT intervention that measured PA as a behavioural outcome (Bennett et al., 2007; Conn et al., 2003; Greaves et al., 2008; Groeneveld et al., 2011; Janssen et al., 2014; Knittle et al., 2015; Lakerveld et al., 2013; Marques et al., 2017; Martens et al., 2012; Murphy et al., 2013), and 4 studies investigated integrated MI-CBT intervention for changes in body composition (Greaves et al., 2008; Groeneveld et al., 2011; Janssen et al., 2014; Murphy et al., 2013). The outcome measures extracted from the studies related to dietary changes were highly heterogeneous and of insufficient quality to be combined for meta-analysis.

Follow-up duration varied amongst the included articles; 3 studies had a 12-month follow-up (Groeneveld et al., 2011; Lakerveld et al., 2013; Marques et al., 2017), 4 studies lasted 6 months (Bennett et al., 2007; Greaves et al., 2008; Janssen et al., 2014; Knittle et al., 2015), and the remaining 3 studies had a follow-up of 4 months (Murphy et al., 2013), 3 months (Conn et al., 2003), and one 1 month respectively (Martens et al., 2012). For PA outcomes, objective

measures were employed in 1 study using a pedometer (Groeneveld et al., 2011), while self-reported instruments were used in the other 9 studies (Bennett et al., 2007; Conn et al., 2003; Greaves et al., 2008; Janssen et al., 2014; Knittle et al., 2015; Lakerveld et al., 2013; Marques et al., 2017; Martens et al., 2012; Murphy et al., 2013).

The measures of body composition in the reviews included mass (Groeneveld et al., 2011) and waist circumference (Greaves et al., 2008; Janssen et al., 2014; Murphy et al., 2013).

Professional background of the persons delivering the intervention included PA counsellors (Bennett et al., 2007), nurses (Groeneveld et al., 2011; Lakerveld et al., 2013), occupational physicians (Groeneveld et al., 2011), psychologists (Janssen et al., 2014; Marques et al., 2017), graduate students in psychology (Martens et al., 2012), health counsellors (Greaves et al., 2008) and post-graduate students in sports and health science (Greaves et al., 2008). The most common methods of MI described in the studies included MI microskills (open-ended questions; affirmations; reflections; summaries) as well as feedback, affirmation and expressions of empathy. The CBT components described in the studies included problem solving, goal setting, action planning, relapse prevention, progress-related feedback and barrier identification.

3.4.1 Integrated MI-CBT versus standard care for physical activity change

The meta-analysis for MI-CBT versus standard care for change in PA demonstrated a 'moderate' quality of evidence (Appendix 3.2) with a significant effect in favour of the intervention (7 studies, 1,139 participants; SMD: 0.18, 95% CI: 0.06 to 0.31; Figure 3.2) (Bennett et al., 2007; Conn et al., 2003; Groeneveld et al., 2011; Janssen et al., 2014; Knittle et al., 2015; Marques et al., 2017; Murphy et al., 2013). There was a 'low' quality of evidence, with a significant effect in favour of integrated MI-CBT when the intervention lasted for 5 sessions or more (4 studies, 498 participants; SMD: 0.18, 95% CI: 0.06 to 0.35; Figure 3.2) (Groeneveld et al., 2011; Janssen et al., 2014; Knittle et al., 2015; Murphy et al., 2013). Interventions lasting 4 sessions or less demonstrated a 'low' quality of evidence with a non-significant effect in favour of integrated MI-CBT (3 studies, 241 participants; SMD: 0.23, 95% CI: -0.02 to 0.49; Figure 3.2) (Bennett et al., 2007; Conn et al., 2003; Marques et al., 2017).

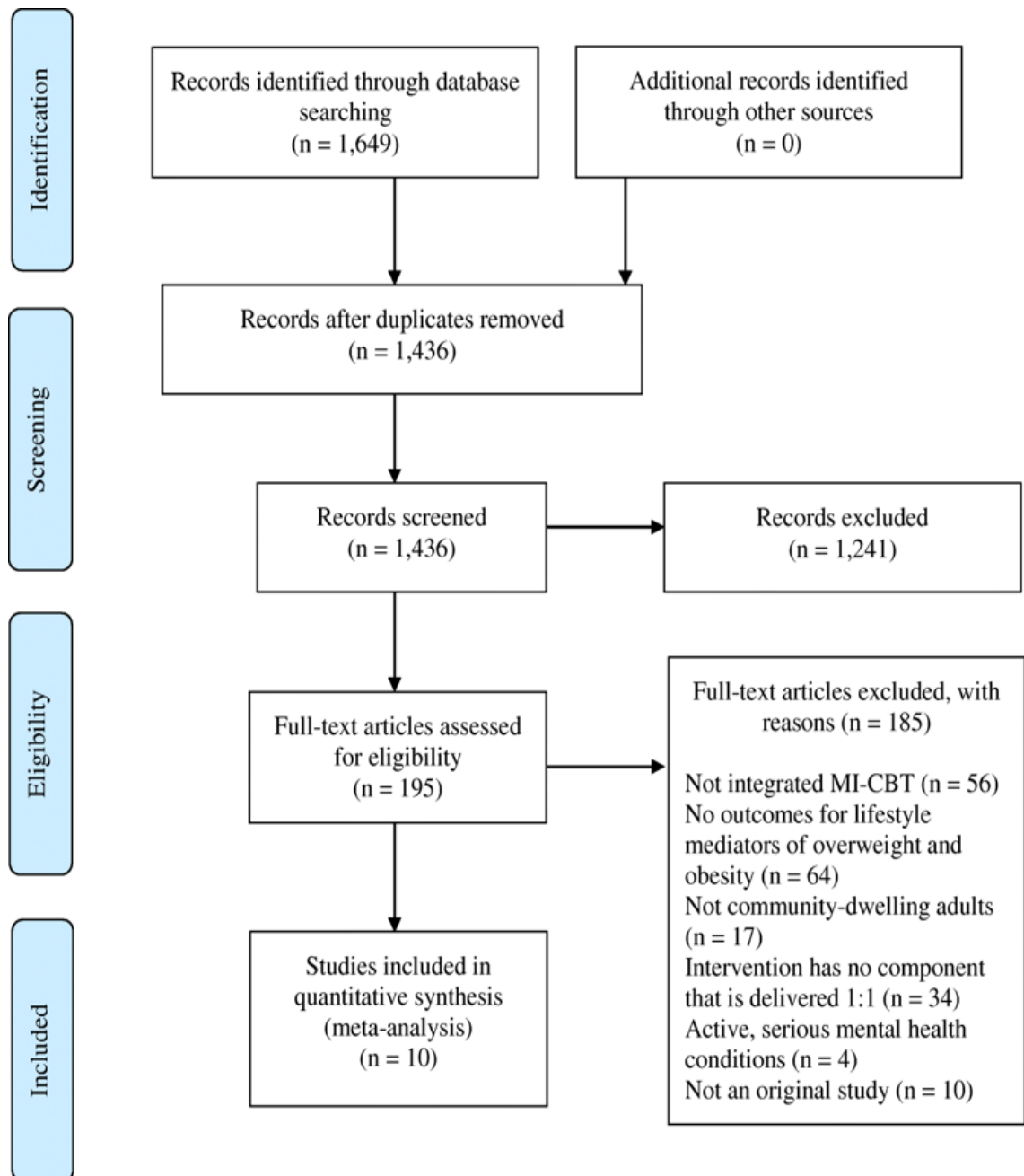


Figure 3.1: Process for identification of included trials

Table 3.1 Characteristics of the included studies

Study	Country	Participants	Number of participants, n (% male)	Mean age at baseline (SD)	Comparator	Intervention	Outcome measures
Bennett et al., 2007	USA	Physically underactive cancer survivors	56 (10%)	57.8 ± 9.9	Advice to maintain regular physical activity	4 x 20 min telephone calls	Physical Activity: CHAMPS Physical Activity Questionnaire
Conn et al., 2003	USA	Females	190 (0%)	75.0 ± 6.7	Standard care emphasizing benefits of exercise.	1 group session plus 2 1:1 sessions*	Physical Activity: Baecke Physical Activity Scale
Greaves et al., 2008	UK	Community-dwelling adults	141(42%)	51.9 (NS)	Standardised information pack promoting diet and physical activity.	11 x 30 min 1:1 sessions	Anthropometric: Measured waist circumference Physical Activity: Modifiable Activity Questionnaire
Groeneveld et al., 2011	Holland	Male construction workers	816 (100%)	46.5 ± 9.0	Standard care, consisting of brief oral or written information from the occupational physician about their CVD risk	3 x 45 min 1:1 sessions plus 4 x 15 min telephone calls	Anthropometric: Measured body mass Physical Activity: Short Questionnaire to Assess Health-Enhancing Physical Activity
Janssen et al., 2014	Holland	Former cardiac rehabilitation patients	210 (80%)	57.7 ± 9.2	1-hour individual interview with a health psychologist. No motivational interviewing techniques were used	7 x 2 hour group sessions plus 1 x 1:1 session*	Anthropometric: Measured waist circumference Physical Activity: Pedometers

Knittle et al., 2015	Holland	Patients with rheumatoid arthritis	78 (33%)	62.0 ± 11.7	A small group educational session around the importance of physical activity for people with rheumatoid arthritis	1 group session* plus 3 x 60 min 1:1 sessions and 3 x 20 min telephone calls	Physical Activity: Short Questionnaire to Assess Health-Enhancing Physical Activity
Lakerveld et al., 2013	Holland	People at risk of developing cardiovascular disease and diabetes	22 (41%)	43.5 ± 5.3	Received brochures containing health guidelines regarding physical activity	6 x 30 min 1:1 plus 3 x 30 min telephone calls	Physical Activity: Short Questionnaire to Assess Health-Enhancing Physical Activity
Marques et al., 2017	Portugal	Chronic fatigue	91(4%)	48.1 ± 10.9	Routine consultations with assistant physician and received a flyer with information about general physical activity	2 x 1:1 sessions plus 2 x telephone calls*	Anthropometric: Measured waist circumference Physical Activity: Short Questionnaire to Assess Health-Enhancing Physical Activity
Martens et al., 2012	USA	College students	70 (18%)	19.6 ± 2.3	Participants received informational packets about exercise	1 x 30 min 1:1 session:	Physical Activity: 7-day recall self-reported physical activity
Murphy et al., 2013	Australia	Patients with cardiovascular disease	275 (86%)	59.0 ± 9.1	Usual medical care	8 x 90 min 1:1 sessions	Physical Activity: 8-item Active Australia Survey

* Intervention duration not stated. CHAMPS: Community Healthy Activities Model Program for Seniors; NS: Not stated

3.4.2 Integrated MI-CBT versus standard care for achieving physical activity guidelines

The meta-analysis for integrated MI-CBT versus standard care for achieving PA guidelines demonstrated a 'low' quality of evidence (Appendix 3.4) with a significant effect in favour of the intervention (4 studies, 805 participants; OR: 1.36, 95% CI: 1.02 to 1.81; Figure 3.3) (Greaves et al., 2008; Knittle et al., 2015; Lakerveld et al., 2013; Martens et al., 2012).

3.4.3 Integrated MI-CBT versus standard care for change in anthropometrics

The meta-analysis for integrated MI-CBT versus standard care for change in anthropometric measures demonstrated a 'moderate' quality of evidence (Appendix 3.4) with a non-significant effect in favour of integrated MI-CBT (4 studies, 979 participants; SMD: -0.12, 95% CI: -0.24 to 0.01; Figure 3.4) (Greaves et al., 2008; Groeneveld et al., 2011; Janssen et al., 2014; Murphy et al., 2013).

3.4.4 Sensitivity analyses

For all of the meta-analyses, a sensitivity analysis was then conducted for lower ($r = 0.20$) and higher ($r = 0.80$) pre-post test correlation values. This revealed that effect sizes remained within the 95% confidence interval. Finally, funnel plots were consulted and indicated that potential publication bias could be ruled out.

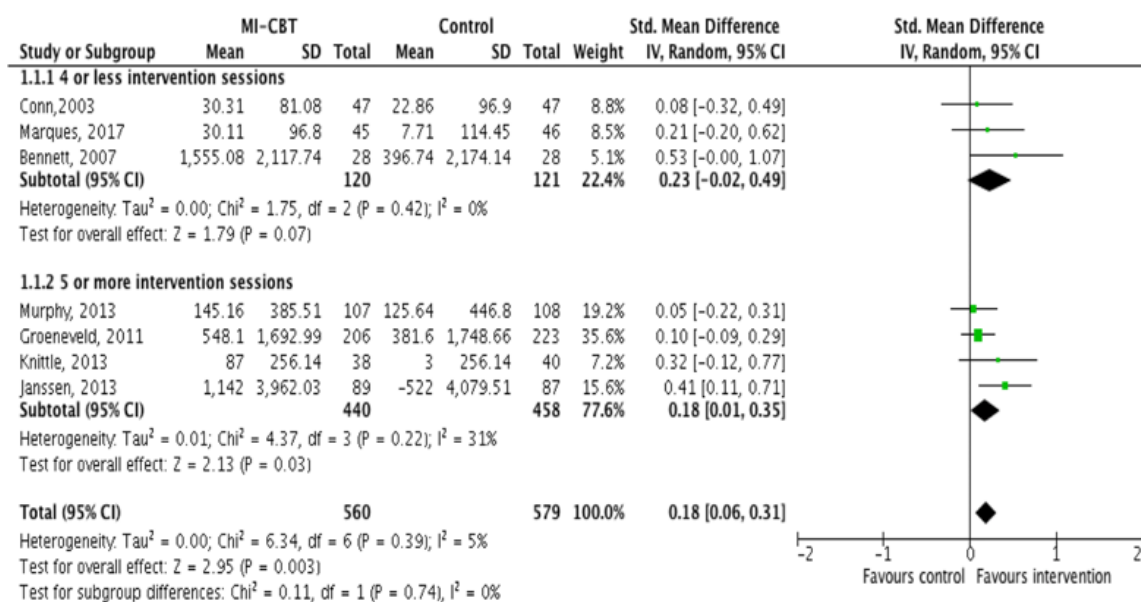


Figure 3.2: Meta-analysis investigating MI-CBT for physical activity change

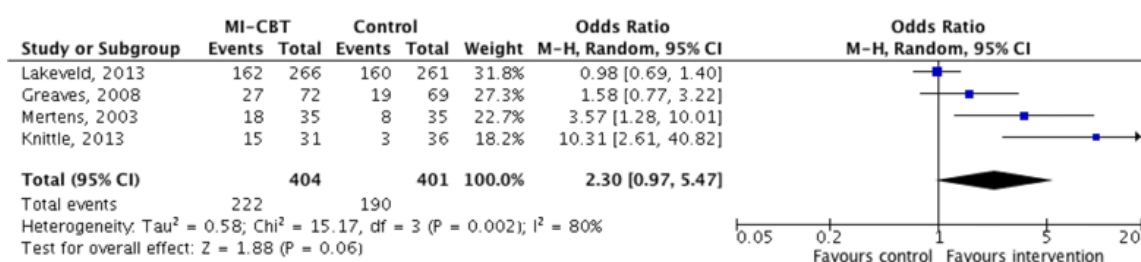


Figure 3.3: Meta-analysis investigating MI-CBT for achieving physical activity guidelines

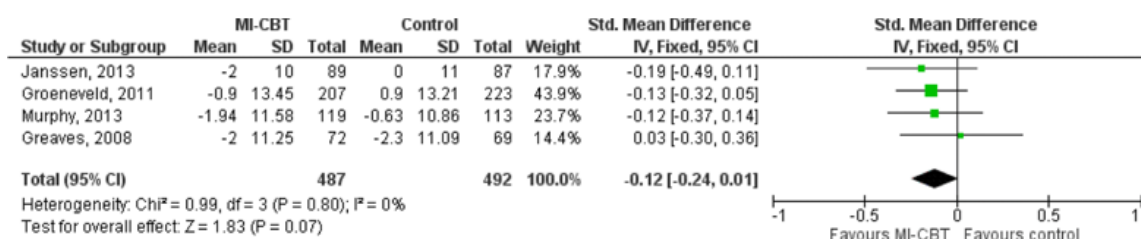


Figure 3.4: Meta-analysis investigating MI-CBT for anthropometric change

3.5 Discussion

This is the first systematic review and meta-analyses to analyse the effectiveness of integrated MI-CBT for lifestyle mediators of overweight and obesity. The results provide moderate quality evidence that integrated MI-CBT has a significant, beneficial effect on PA levels, and a small, beneficial effect on body composition in community-dwelling adults. This has important implications for clinicians looking to address overweight and obesity given that even small increases in PA (Sattelmair et al., 2011) and small changes in body composition (Magkos et al., 2016) can deliver beneficial health outcomes. These findings are consistent with a previous meta-analysis reporting small but clinically significant effects for integrated MI-CBT for changes in alcohol intake (Riper et al., 2014). Stratification of the meta-analysis for MI-CBT versus standard care for change in PA by number of intervention sessions provided low quality of evidence that interventions lasting 5 sessions or more resulted in small, significant effects on PA change (Figure 3.2). Interventions lasting 4 sessions or less demonstrated a 'low' quality of evidence with a non-significant effect in favour of integrated MI-CBT (Figure 3.2). This systematic search failed to yield nutritional data of sufficient quality for inclusion in the synthesis.

The results of the meta-analysis of 7 randomised controlled trials for MI-CBT versus standard care for change in PA demonstrated moderate quality of evidence with a significant effect in favour of the intervention. Incorporating exercise as a regular lifestyle behaviour is difficult for many individuals (Dalle Grave et al., 2010). There are multiple reasons behind this, including low motivation, poor exercise tolerance, and a lack of self-efficacy and coping skills (Dalle Grave et al., 2010). For individuals to positively influence obesity, they must engage regularly in PA, and maintain this behaviour over a prolonged period of time (Dalle Grave et al., 2010; Magkos et al., 2016). The integration of MI-CBT combines evidence informed strategies for motivation and maintenance of PA behaviour change. Of the 7 studies in this meta-analysis, only 4 had a change in PA as the primary outcome (Bennett et al., 2007; Conn et al., 2003; Knittle et al., 2015; Murphy et al., 2013). Behaviour change interventions are most effective when they target single outcomes (Armstrong et al., 2011). The lack of focus on PA change as the primary outcome in the studies included might account for the modest post-treatment effect size. In this meta-analysis, the downgrading of evidence to moderate was primarily due to a lack of sufficient methodological detail around the blinding of participants and personnel involved in the studies, resulting in an unclear risk of bias (Appendix 3.5). Nevertheless, given the complexity and feasibility of blinding participants and personnel in studies using behaviour change techniques,

the moderate level of evidence provides reasonably robust data supporting the use of integrated MI-CBT for PA change in community-dwelling adults.

Subgroup analysis for the effect of MI-CBT versus standard care for change in PA, stratified by number of intervention sessions demonstrated that interventions lasting 5 sessions or more resulted in a small but significant change in PA. Interventions lasting 4 sessions or less did not have a statistically significant effect on PA change. Treatment effect sizes for both MI alone (Lundahl et al., 2010) and CBT alone (Hofmann et al., 2012) have been shown to increase with higher numbers of intervention sessions, though the optimal treatment number remains unclear (Hofmann et al., 2012; Lundahl et al., 2010). Increased number of treatment sessions can strengthen skills around relapse prevention and self-management (Armstrong et al., 2011; Hofmann et al., 2012; Lundahl et al., 2010), which may contribute to the clinically significant outcomes found with 5 sessions or more (Armstrong et al., 2011; Lundahl et al., 2010). The broad application of behaviour change interventions in the community setting has been impeded by the lack of evidence pertaining to the optimal number of treatment sessions (Landry et al., 2015). These meta-analyses indicate that beneficial outcomes can be derived from a small number of sessions, with increasing effect size found with 5 sessions or more.

The meta-analysis of 4 randomised controlled trials investigating MI-CBT versus standard care for achieving PA guidelines indicated that the intervention was effective at increasing PA levels in order to achieve recommended level of PA. For adults, the attainment of PA levels that approximate the recommendations for moderate activity is associated with a lower risk of mortality (Leitzmann et al., 2007) and chronic disease (Sesso et al., 2000). In order to address overweight and obesity, the minimum of 150 min/week of moderate intensity exercise is required (Jakicic et al., 2001). The primary measure of PA in the included studies was standard PA units, minutes per day or steps per day, for example. From this, the authors deduced the binary outcome of attaining or not attaining sufficient PA to meet the guidelines. No study in the meta-analysis investigating MI-CBT versus standard care for achieving PA guidelines provided any indication that participants were set a specific target of achieving the required minutes to meet the PA guidelines. This lack of homogeneity in study design and outcome measures in the included articles might reflect the high degree of heterogeneity found in the meta-analysis. While the meta-analysis indicates a positive effect of the intervention, the high heterogeneity and wide confidence intervals resulted in the downgrading of the quality of the evidence to low. In spite of these inconsistencies, the meta-analysis investigating MI-CBT versus

standard care for achieving PA guidelines further supports the use of integrated MI-CBT for PA change. Future studies looking to measure attainment of PA guidelines should focus on clear outcome identification and uniform measurement.

The results of the meta-analysis of 4 randomised controlled trials for integrated MI-CBT versus standard care for change in anthropometric measures provided moderate quality of evidence that integrated MI-CBT has a small, positive effect on anthropometric measures (Figure 3.4). Achieving long-term, sustainable changes in body composition is difficult (Lundahl et al., 2010). At a minimum, the goal of obesity treatment is to prevent further weight gain (Sharma & Padwal, 2010), while minor changes in body composition are associated with decreased mortality in overweight individuals (Williamson et al., 2000). The beneficial effect on body composition demonstrated by the intervention in our analysis is promising. Positive change in body composition is a primary motivation for PA (Kim & Cho, 2013). Positive changes in body shape have been shown to strengthen self-belief, resulting in PA maintenance (Kim & Cho, 2013). All of the included studies had a 12-month follow-up, and all outcome measures were measured by research assistants. The use of objective measurement strengthens the quality of the evidence, with self-reported body weight and waist circumference measurement being prone to participant measurement error, and participant reporting bias (Stommel & Schoenborn, 2009). Similar to PA, the studies included in this meta-analysis of MI-CBT versus standard care for change in anthropometric measures targeted change in multiple health behaviours, and changes in body composition outcomes was not a primary outcome in any study. When interventions target multiple health behaviours, and changes in body composition is not the primary outcome the application of behavioural change principles to body composition has been shown to decrease in priority (Prochaska & Prochaska, 2011). This downgrading in perceived importance might account for the anthropometric treatment effect size found in the analysis (Prochaska & Prochaska, 2011).

Although the integration of MI and CBT is not a new concept (Haddock et al., 2012), the confirmation and/or measurement of treatment fidelity remains difficult (Haddock et al., 2012). Fidelity scales for integrated MI-CBT have been devised and tested in the literature (Haddock et al., 2012); however none of the studies in our sample used such a fidelity measure. Therefore, the extent to which participants were actually receiving interventions is unclear, which could influence the degree of clinical homogeneity. Measurements of intervention fidelity for MI alone (Moyers et al., 2005; O'Halloran et al., 2014) and for CBT alone (Bellg et al., 2004) indicate

that effect size greatly increases where treatment fidelity is measured. The lack of intervention fidelity measures in the studies included in this review may be a contributory factor to the modest effect size. Of the trials included for PA change, only two trials reported measuring fidelity of the MI component (Bennett et al., 2007; Greaves et al., 2008), with the standardised mean difference for the effect of integrated MI-CBT intervention increasing from 0.18 (95% CI 0.06 - 0.30) to 0.41 (95% CI 0.07 - 0.75) when trials that did not confirm fidelity were excluded from the analysis. This effect of MI fidelity is consistent with results from previous meta-analyses which also demonstrated an increase in the standardised mean difference in trials where treatment fidelity is measured (O'Halloran et al., 2014). Future trials utilising integrated MI-CBT should incorporate a measurement of fidelity into the study design.

3.5.1 Strengths

This is the first systematic review and meta-analysis undertaken that provides evidence to support the use of integrated MI-CBT for changes in PA and body composition in community-dwelling adults. While the demonstrated effect was modest, the combination of MI and CBT is potentially advantageous for a number of reasons. With evidence suggesting that even small increases in PA and body composition change can deliver positive health benefits, a modest effect size, as demonstrated in this review, is likely to deliver important health outcomes (Magkos et al., 2016). The integration of MI-CBT might overcome the documented shortcomings in both interventions delivered alone, while maintaining a collaborative, directive approach (Naar-King et al., 2013). While interventions incorporating behavioural or psychological components have demonstrated modest efficacy for lifestyle mediators of overweight and obesity overall, these interventions do not result in adverse effects, and generally lead to improvements in psychological well-being (Lasikiewicz et al., 2014). As single intervention studies have indicated that larger post-treatment effect sizes are produced if MI and CBT are delivered with fidelity (Hofmann et al., 2012; Lundahl et al., 2010), it can be hypothesised that integrated MI-CBT interventions adhering to higher rates of fidelity have the potential to produce increased effect sizes (Haddock et al., 2012). Another potential advantage to using integrated MI-CBT for addressing lifestyle mediators of overweight and obesity lies in the range of health professionals that were able to deliver the intervention. This clinical diversity might be advantageous when applying the intervention across multiple sectors of the community-dwelling population, especially given the previously mentioned prevalence of overweight and obesity. For clinical interest and uptake, as indicated by the findings of these meta-analyses, higher quality randomised controlled trials with detailed interventions, extended follow-up

periods, and measures of treatment fidelity are required (Hofmann et al., 2012; Lundahl et al., 2010).

3.5.2 Limitations

There are a number of limitations of our review that need to be considered. The number of included trials was restricted by the use of the rigid search criteria designed to assess the combined effects of MI-CBT on lifestyle mediators of overweight and obesity. Excluding languages other than English may introduce a bias and reduce the precision of estimates of treatment effects. The exhaustive search strategy and low number of included studies may have directly impacted the possibility to extract sufficient data for a meta-analysis for dietary changes. Secondly, self-reported tools were used to measure changes in PA change in 9 of the 10 included trials. This lack of an objectively measured outcomes resulted in a higher risk of bias (Stommel & Schoenborn, 2009). Thirdly, this review and meta-analyses included a number of small trials, undertaken on restrictive populations which may have had an influence on the observed effect sizes (Higgins & Green, 2011). Finally, there may have been an impact on external validity from combining data from studies on participants with diverse health conditions. Nevertheless, for all but one of the meta-analyses, heterogeneity was low, and research continually indicates that increasing PA and positive body composition changes have favourable health effects for the majority of the population (Sattelmair et al., 2011).

3.6 Conclusions

Despite the small number of high quality randomised trials, this analysis indicates that integrated MI-CBT leads to modest improvements in PA and body composition changes amongst community-dwelling adults. The emerging evidence for the utility of MI-CBT interventions for promoting the adoption and maintenance of health behaviour change has potential importance in address the rates of obesity worldwide. The intervention can be delivered by a range of health professionals and can be incorporated readily into clinical practice. In order to make stronger recommendations regarding the use of this intervention for lifestyle mediators of overweight and obesity, more high quality randomised controlled trials are required. Such studies should include sufficiently long periods of follow-up to determine the long-term effects of the interventions on health-related outcomes. Finally, intervention trials should also include objective measures of outcomes, longer intervention frequency and clear methods of incorporating and assessing treatment fidelity.

Chapter 4

Integrated motivational interviewing and cognitive behaviour therapy can increase physical activity and improve health of adult ambulatory care patients in a regional hospital: the Healthy4U randomised controlled trial

This chapter is available in published format as follows: Barrett S, Begg S, O'Halloran P, Kingsley M. (2018). Integrated motivational interviewing and cognitive behaviour therapy can increase physical activity and improve health of adult ambulatory care patients in a regional hospital: the Healthy4U randomised controlled trial. *BMC Public Health*; 18(1): 1166. <https://doi.org/10.1186/s12889-018-6064-7>.

4.1 Abstract

Background: The aim of this study was to determine whether a twelve-week, health coaching intervention could result in changes in physical activity, anthropometrics and health-related outcomes in adults presenting to an ambulatory hospital clinic.

Methods: Seventy-two participants who reported being insufficiently active were recruited from an ambulatory hospital clinic and randomised to an intervention group that received an education session and eight 30-min telephone sessions of integrated motivational interviewing and cognitive behaviour therapy (MI-CBT), or to a control group that received the education session only. Actigraph GT3X accelerometers were used to measure moderate-to-vigorous physical activity at baseline, post-intervention (3-months) and follow-up (6-months). Secondary outcome measures (anthropometrics, physical activity self-efficacy, health-related quality of life, type 2 diabetes risk) were also assessed at the three time points.

Results: At baseline, the mean age and body mass index of participants ($n = 72$, 75% females) were 53 ± 8 years and 30.8 ± 4.1 kg/m², respectively. Treatment group influenced the pattern of physical activity over time ($p < 0.001$). The intervention group increased moderate-to-vigorous physical activity from baseline to post-intervention and remained elevated at follow-up by 12.9 min/day (95%CI: 6.5 to 19.5 min/day). In contrast, at follow-up the control group decreased moderate-to-vigorous physical activity by 9.9 min/day (95%CI: -3.7 to -16.0 min/day). Relative to control, at follow-up the intervention group exhibited beneficial changes in body mass ($p < 0.001$), waist circumference ($p < 0.001$), body mass index ($p < 0.001$), physical activity self-efficacy ($p < 0.001$), type 2 diabetes risk ($p < 0.001$), and health-related quality of life ($p < 0.001$).

Conclusions: This study demonstrates that a low contact coaching intervention results in beneficial changes in physical activity, anthropometrics and health-related outcomes that were maintained at follow-up in adults who report being insufficiently active to an ambulatory care clinic.

Keywords: Health promotion; Quality of life; Secondary prevention; Self-efficacy; Type 2 diabetes.

4.2 Background

Chronic diseases such as obesity, type 2 diabetes, and cardiovascular disease are prevalent, costly and largely preventable health conditions (Bodenheimer et al., 2002). Almost 40% of preventable hospital admissions are due to chronic disease (Britt et al., 2008). While the primary role of hospitals is in medical diagnosis and treatment, the increasing prevalence of chronic diseases necessitates that preventative health is included in the scope of practice for many hospital services (Groene et al., 2010). Hospitals are important settings in which to offer health promotion interventions, particularly when delivered opportunistically alongside the provision of secondary care (Groene et al., 2010). Hospitals provide secondary care through the delivery of non-admitted medical consultations in specialities such as general surgery, orthopaedic surgery and endocrinology. A referral from a general practitioner (GP) is required to attend a hospital specialist clinic. Patients attending secondary care hospital clinics are 40% more likely than the general population to have one or more chronic disease (Britt et al., 2008). Therefore, hospitals offer an advantage for health promotion beyond other settings as patients experiencing ill-health are more sensitive to behaviour change contemplation, and show increased responsiveness to health advice (West et al., 2000). Patients have suggested that they would like, and to an extent expect the healthcare system to provide guidance on lifestyle behaviour change and physical activity (PA) (Leijon et al., 2010). Despite the evidence-base underlining the effectiveness of health promotion services in hospitals, preventative health options for increasing self-management or lifestyle counselling around PA have been notably distant from secondary care (Schoen et al., 2005).

Regular PA plays a key role in both primary prevention and management of chronic diseases (Orozco et al., 2008; Shaw et al., 2006; Williams et al., 2007). A dose–response relationship appears to exist for PA, such that individuals with the highest levels of physical activity are at lowest risk of chronic disease (Lollgen et al., 2009). Challenges remain in the translation of established research findings on the health benefits of PA into practical everyday use in the health care system (Eakin et al., 2004). Interventions that deliver prescriptive exercises can increase PA levels in hospital patients (Valkenet et al., 2011); however, PA maintenance over the longer term period has proven more difficult to achieve, with more than 50% of individuals that begin an exercise program dropping out or relapsing (Nigg et al., 2008). As a result, there is an increasing use of non-traditional methods of intervention delivery to influence health behaviour change and maintenance (Teeter & Kavookjian, 2014).

Motivational interviewing (MI) is a behaviour change technique demonstrated to be effective in overcoming ambivalence about behaviour change (Miller & Rollnick, 2012). MI is a person-centered, goal-orientated method of guiding participants to elicit and strengthen personal motivation and commitment to change (Miller & Rollnick, 2012). The collaborative nature between practitioner and client contrasts MI to more prescriptive, expert-driven interventions (Burke et al., 2003). As MI was developed to increase motivation for initial behaviour change, it has been recommended to integrate action-orientated treatments (e.g., behavioural counselling, goal-orientated therapy, cognitive behaviour therapy) to build maintenance skills (Miller & Rollnick, 2012). A meta-analysis indicated that MI was more effective and longer-lasting when combined with another active treatment (Hettema et al., 2005). Cognitive behaviour therapy (CBT) has been increasingly integrated with MI for behaviour change (Naar-King et al., 2013; Westra, 2004). CBT strategies, including, but not limited to barrier identification, problem solving and self-monitoring are more goal-orientated and are used to address behaviour change across multiple health behaviour domains (Westra, 2004). Integrating the theoretical underpinnings of MI and CBT together is theorised to promote long-lasting, sustained behaviour change (Naar-King et al., 2013). Combined MI and CBT (MI-CBT) has resulted in small increases in PA (Groeneveld et al., 2011; Knittle et al., 2015; Murphy et al., 2013). Changes in PA were, however, the primary outcome in only one study (Knittle et al., 2015), and all studies used self-reported outcome measures for PA change (Groeneveld et al., 2011; Knittle et al., 2015; Murphy et al., 2013). Self-reported measures for PA are shown to over-estimate activity when compared to objective measurement (Troiano et al., 2008). Furthermore, none of the studies recruited from outpatient secondary care clinics, where rates of chronic disease are known to be higher than the general population (Hernandez et al., 2009).

Hospitals are important settings from which to advocate for PA as a regular treatment for many of the lifestyle related risk factors and diseases (Börjesson, 2013). Although doctors practicing in hospitals have stated that they do not have sufficient time to spend with patients giving advice on preventive measures (Himmelmann & Weinehall, 1996), brief interventions in the hospital setting, such as recommendations to increase PA from clinical specialists, can have a strong effect on subsequent lifestyle choices by patients (Börjesson, 2013). The Healthy 4U intervention is an augmentation of service, where clinicians under time constraints can direct patients who might benefit from a health behaviour change intervention. This pathway offers a potential method to deliver a preventative health intervention to patients receiving secondary care, permitting hospital specialist to refer patients to a specific service tailored for them. To

the best of our knowledge the Healthy4U study is the first study to examine the change and maintenance of behavioural and physiological outcomes following the integration of a behaviour change intervention into routine care for secondary care patients.

The primary aim of the Healthy4U study was to examine the effectiveness of integrated MI-CBT for change and maintenance of physical activity in insufficiently active patients presenting to an ambulatory outpatient clinic in a public hospital. Additionally, this study investigated the effectiveness of integrated MI-CBT for changes and maintenance in anthropometry, physical activity self-efficacy, type 2 diabetes risk, health-related quality of life in this population.

4.3 Methods

4.3.1 Design

The Healthy4U study was a single-blind randomised controlled trial designed and reported in line with the CONSORT recommendations for reporting (Figure 4.1) (Schulz et al., 2010). The trial was registered with the Australian and New Zealand Clinical Trials Registry (ACTRN12616001331426) prior to patient recruitment.

4.3.2 Participants

Participants were recruited from an ambulatory, secondary care clinic in a major tertiary hospital in regional Victoria. In this clinic, outpatients receive medical care in specialities such as general surgery, orthopaedic surgery and endocrinology. A referral from a GP is required to attend the specialist clinic. Throughout the recruitment phase of the study, recruitment flyers were available at the clinic and patients who were potentially interested in participating made direct contact with the research team using details provided on the flyer.

Participants were included if they were between 18 and 69 years, and reported being insufficiently physically active, defined as obtaining less than 150 minutes/week of moderate-to-vigorous physical activity (MVPA) (Nelson et al., 2007). A single item question “As a rule, do you do at least half an hour of moderate or vigorous exercise (such as walking or a sport) on five or more days of the week?” - was used to identify insufficiently physically active individuals (Rose et al., 2008). The following exclusion criteria were applied: sufficiently physically active

(Nelson et al., 2007); an existing medical condition that contraindicated PA (indicated by the Physical Activity Readiness Questionnaire); a diagnosis of diabetes; deaf/hearing impaired; disabling neurological disorder; severe mental illness such as psychosis; learning disability; dementia; registered blind; housebound or resident in nursing home; non-ambulant; pregnancy; advanced cancer.

4.3.3 Randomisation

Participants who fulfilled the inclusion criteria and consented to take part in the trial were randomised to either the intervention or the control group based on a random number sequence produced by a computer generated program (randomizer.org). Assignments were prepared and sealed in sequentially numbered opaque envelopes. Assignment was made by opening the next envelope in the sequence, after the recruiter had determined eligibility for the study, participants had consented to take part, and baseline measurements were completed.

4.3.4 Procedure

Participants' characteristics and outcome measures were recorded at baseline, after 3 months of intervention (post-intervention) and at 6 months (follow-up) by assessors blinded to the study group assignment. The extension of outcome measures from baseline to 6 months, which included a 3-month period where no contact with participants was made, was designed to investigate behaviour change maintenance using a previously accepted follow-up duration (Fjeldsoe et al., 2011). A recent systematic review highlighted the need for behaviour change interventions to distinguish between initial behaviour change and behaviour change maintenance (Kwasnicka et al., 2016).

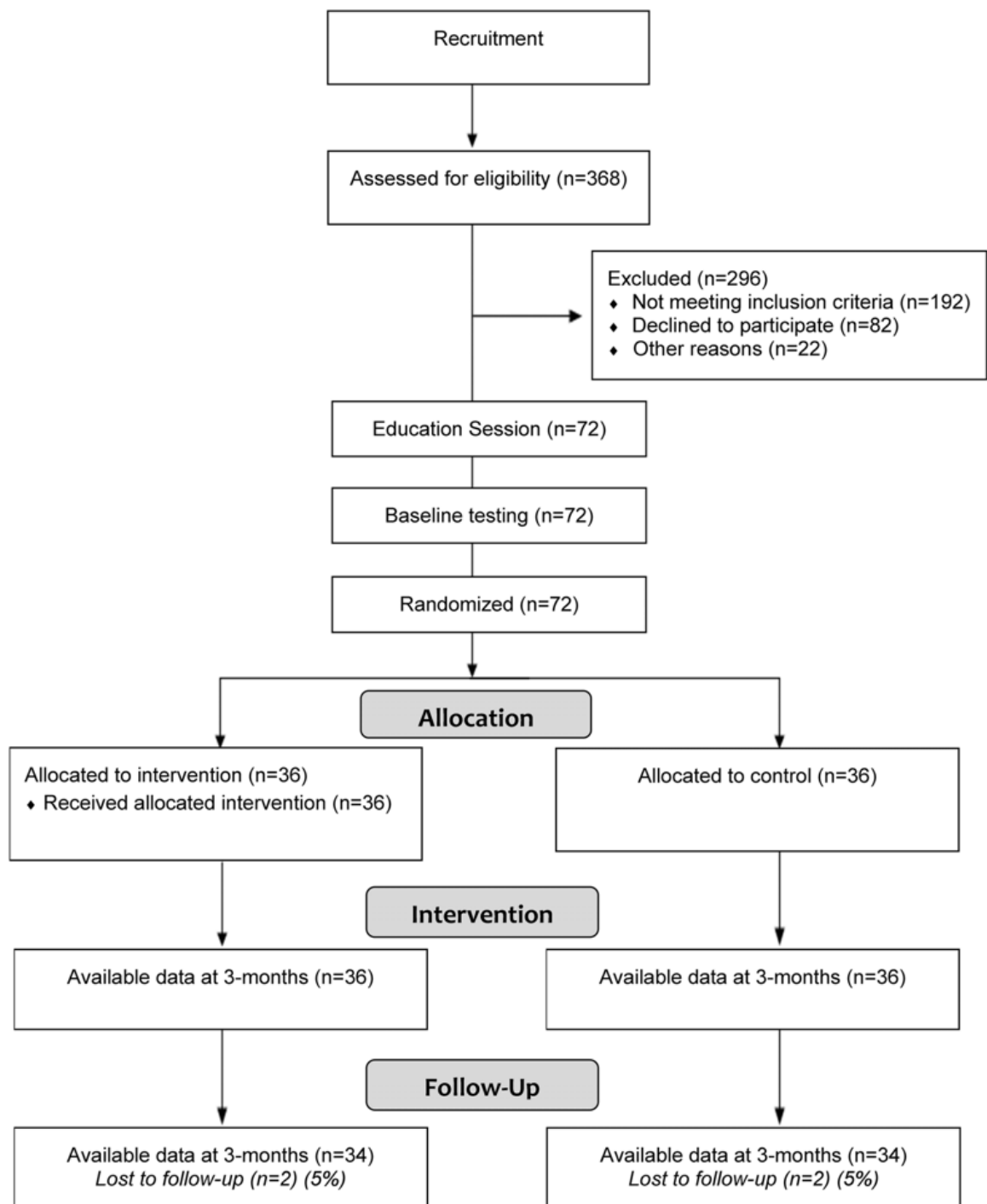


Figure 4.1: Flow of study protocol

4.3.5 Intervention

All enrolled participants attended an education session. The education session was a facilitated learning session based around self-management and lifestyle modification and was carried out using a self-determination theory (SDT) framework (Vansteenkiste & Sheldon, 2006). SDT is a general theory of human motivation that defines motivation as “psychological energy directed at a particular goal” (Ng et al., 2012). Individuals are more likely to engage in certain behaviours, physical activity for example, if they both value that behaviour, and have motivation for change (Ng et al., 2012). SDT was used in this group setting to support, educate and motivate participants around positive lifestyle choices (Vansteenkiste & Sheldon, 2006).

The intervention group completed a telephone-based, integrated MI-CBT intervention, delivered in eight 30-minute sessions over 12 weeks. The intervention was delivered using an MI framework, where MI microskills (open-ended questions, affirmations, reflections and summaries) were used in all sessions to progress participants through the MI processes of change (engagement, focusing, evocation, and planning) (Miller & Rollnick, 2012). Throughout intervention sessions 1 to 4, MI was predominantly delivered in isolation (i.e., without CBT), exploring participants’ feelings about change and evoking intentions to change (Miller & Rollnick, 2012). Where MI was used alone, the person delivering the intervention refrained from discussing any specific change-oriented strategies, and instead focused on exploring participant feelings and specific ambivalence regarding barriers to physical activity (Miller & Rollnick, 2012). In the subsequent sessions, the integrated MI-CBT phase, more specific focus was directed on the identified drivers of ambivalence and resistance, leading to the formulation of goal-directed action plans (Borkovec & Costello, 1993). The CBT treatment built upon a number of evidence-based protocols with adaptations to focus on the goal of change in PA. The CBT component focused more explicitly on individual determinants of PA such as PA experiences, PA outcome expectations, and PA self-efficacy (Borkovec & Costello, 1993). The CBT strategies, which included goal setting, action planning, self-monitoring, personal feedback and relapse prevention, were incorporated within this MI framework for supporting PA change and maintenance (Craske & Barlow, 2006). The intervention used the integration of MI with CBT in two ways: (i) the underlying spirit of MI was used as a foundational platform from which to conduct CBT, and (ii) during more action orientated sessions therapists could switch back to MI in response to identified markers of ambivalence or resistance (Borkovec & Costello, 1993; Craske & Barlow, 2006).

The intervention was delivered by an experienced allied health clinician trained in MI-CBT, including workshop attendances, and one-on-one coaching from an experienced practicing psychologist. The intervener's proficiency in using motivational interviewing was confirmed via role-play sessions, one at the commencement and one at midpoint of the intervention. Proficiency was confirmed by an independent assessor using the validated Motivational Interviewing Integrity scale 3.1.1 (Moyers et al., 2010). The intervener's proficiency in using motivational interviewing was rated as competent on the global clinician rating at both assessments. All participants enrolled into the control arm attended the education session. Apart from contact regarding follow-up outcome measures, participants of the control group received no further contact initiated by the research team.

4.3.6 Outcome measures

The primary outcome, MVPA (minutes/day) was assessed by accelerometry (wGT3X-BT; Actigraph, USA) during all waking hours over 7 days. PA was calculated using the manufacturers software (Actilife; Actigraph, USA) with cut points by Freedson Adult (1998) used to provide daily measures of MVPA (>1951 counts/min) (Freedson et al., 1998). Accelerometer wear time was based on activity counts per minute. Non-wear time was defined as 60 minutes or more of consecutive activity counts of zero, with a spike tolerance of 2 minutes and 100 counts/minute. Accelerometer data were considered valid if the accelerometer was worn >10 hours per day for at least 5 of 7 days including at least 1 weekend day (Eslinger et al., 2005). The accelerometer was worn on a waist band, over the right hip. In adults, the hip-mounted Actigraph has demonstrated high inter-device reliability ($r=0.98$) and validity against indirect calorimetry ($r=0.56$, $p<0.001$) (Hills et al., 2014). Participants used logbooks to report significant PA events (e.g., attending exercise class, going for a walk, heavy gardening) and periods of accelerometer non-wear. Participants returned the PA logbook along with the accelerometer within 48 h of the last accelerometer day. PA data were verified manually against the PA logbooks.

Anthropometric measures were taken objectively in accordance with International Standards for Anthropometric Assessment (Stewart et al., 2011). Waist circumference (WC) was measured to the nearest 0.1 cm using a rigid anthropometric measuring tape (Lufkin, US). Body mass was recorded to the nearest 0.1 kg using a calibrated scale (model 813; Seca, Germany). Free standing stature was recorded to the nearest 0.1 cm using a calibrated equipment with the participant barefoot (Portable stadiometer; Seca, Germany). Body mass index (BMI) was

calculated by dividing body mass by the square of height. Self-efficacy to be physically active was measured using the physical activity self-efficacy survey (Sallis et al., 1988). The survey measures confidence related to undertaking physical activity over a continual timeframe with a higher score indicating a higher degree of self-efficacy. The survey has support for both its reliability and validity (Sallis et al., 1988). Health-related quality of life (HrQoL) was measured using the Medical Outcomes Study Short Form 12 Health Survey (SF-12) (Ware et al., 1996). The SF-12 is a valid and reliable tool with published psychometric support (Sanderson & Andrews, 2002). A single index score on a scale of 0 to 1 was calculated for all participants, with a higher score indicating a more favourable health state (Brazier et al., 2002).

The Australian type 2 diabetes risk assessment tool (AUSDRISK) was used to measure risk of type 2 diabetes (Chen et al., 2010). This 12-item tool has been validated in a number of Australian studies (Chen et al., 2010). The AUSDRISK includes questions on age, gender, waist circumference, and family history of diabetes. Potential scores range from 0–38 and relate to the probability of developing diabetes within the next 5 years (Chen et al., 2010). For scores of 12–15, approximately one person in every 14 will develop diabetes (Chen et al., 2010). For scores of 20 and above, approximately one person in every 3 will develop diabetes (Chen et al., 2010). Demographic data were collected on participant postcode, employment status, smoking status and medical history.

4.3.7 Study size

In order to detect between-group differences of 30 ± 50 (mean \pm SD) minutes, the standardized mean difference, or effect size required is 0.60 (Wilcox et al., 2008). A sample size of 30 participants per arm was calculated to be sufficient to detect an effect size of 0.60 or greater, with the alpha set at 0.05, and the power set at 0.80. Protecting against a drop-out rate of 20% over the 6-month study duration, 36 participants were recruited and randomised into each arm.

4.3.8 Data Analyses

Analyses were carried out using IBM SPSS Statistics for Windows (Version 23.0; IBM Corp., USA) and statistical significance was set at an alpha of 0.05. Data were assessed for normal distribution by Shapiro-Wilk's (Meyers et al., 2006). Homogeneity of variances and covariances were assessed by Levene's test and Box's M test, respectively. Grouped data are presented as

mean \pm standard deviation. For the main analyses, a series of mixed-model ANOVAs (within: time; between: intervention) were used to assess the effects of the integrated MI-CBT intervention on each of the outcome variables separately. Mauchly's test was consulted and Greenhouse–Geisser correction was applied if the assumption of sphericity was violated (Meyers et al., 2006). A significant interaction effect was interpreted to demonstrate that the change in dependent variables was influenced by intervention. Where data were in breach of Shapiro-Wilks test of normality, sensitivity analyses were performed. Data were explored for significant outliers identified and repeat sensitivity analyses were undertaken on data with outliers removed. Repeated sensitivity analyses provided no indication that the outliers had a significant effect on the outcome; therefore, all data were included in analyses.

A full intention-to-treat approach was used. For participants with missing data at 6-month follow-up ($n=2$ in both groups), the last-observation-carried forward approach was adopted (Shao & Zhong, 2003). Repeat sensitivity analyses were undertaken on data with and without imputing the last-observation-carried forward value. The repeated sensitivity analyses provided no indication that the imputed values had a significant effect on the outcome.

4.4 Results

A total of 72 participants (75 % female) completed their baseline and 3-month assessment, and 68 participants completed the 6-month assessment (Figure 4.1). Valid activity monitor data demonstrated wear time per day of 13 ± 1.5 hours at baseline, 12 ± 2.2 hours at 3 months and 13 ± 1.7 hours at 6 months as calculated by using the manufacturer's software (Choi algorithm) and corroborated through participant log diaries. The participants were 53 ± 8 years of age with a mean BMI of 30.8 kg/m^2 , and the majority (86%) had completed either secondary school or tertiary education. At baseline there were statistically significant differences between the groups for MVPA, where the intervention group completed lower daily MVPA than the control group, and for physical activity self-efficacy, where the control group reported higher levels of self-efficacy to be physically active (Table 4.1). All participants enrolled into the intervention arm received their scheduled eight sessions of integrated MI-CBT. The typical length of each session was 30 ± 3 min.

Table 4.1 Characteristics of participants at baseline

Variable	Total	Intervention	Control	p-value
	72	36	36	
Age (years)	53 ± 8	53 ± 8	54 ± 7	0.70 ^a
Sex: female, n (%)	54 (75%)	28 (78%)	26 (72%)	0.58 ^a
Stature (cm)	166 ± 8	165 ± 9	168 ± 7	0.20 ^a
Weight (kg)	84.9 ± 9.4	84.5 ± 9.9	85.3 ± 8.9	0.72 ^a
BMI (kg/m ²)	30.8 ± 4.1	31.1 ± 4.0	30.5 ± 4.2	0.51 ^a
MVPA (min/day)	31.2 ± 10.1	28.1 ± 9.9	33.3 ± 10.3	0.03 ^a
PA Self-efficacy	31 ± 10	28 ± 8	33 ± 10	0.05 ^a
Smoker, n (%)	23 (32%)	12 (33%)	11 (31%)	0.80 ^b
Obesity, n (%)	38 (53%)	22 (61%)	16 (44%)	0.16 ^b
Hypertension, n (%)	14 (20%)	9 (25%)	5 (14%)	0.23 ^b
OA/RA, n (%)	27 (38%)	16 (44%)	11 (31%)	0.22 ^b
Depression/anxiety, n (%)	30 (42%)	16 (44%)	14 (40%)	0.63 ^b
Employment status, n (%)				0.43 ^b
Full time	22 (31%)	10 (28%)	12 (33%)	
Part time	30 (42%)	18 (50%)	12 (33%)	
Unemployed	7 (10%)	4 (11%)	3 (8%)	
Retired	12 (16%)	4 (11%)	8 (22%)	
Other	1 (1%)	0	1 (4%)	
Education, n (%)				0.47 ^b
Year 10/11	10 (14%)	4 (11%)	6 (17%)	
Year 12	22 (31%)	12 (33%)	10 (28%)	
Cert I-IV	18 (25%)	7 (20%)	11 (30%)	
Diploma	13 (18%)	9 (25%)	4 (11%)	
Bachelor or higher	9 (12%)	4 (11%)	5 (14%)	

Group data expressed as means ± standard deviations. Figures in parentheses are proportions. BMI: Body mass index; MVPA: Moderate-to-vigorous physical activity; OA: Osteoarthritis; RA: Rheumatoid arthritis.

^a t-test between intervention and control groups.

^b chi square test between intervention and control groups.

There was a significant group x time interaction indicating that changes in MVPA from baseline through follow-up differed between intervention groups ($p < 0.001$; Figure 4.2). The patterns for groups responded differently over time, where the intervention group significantly increased MVPA at post-intervention by 15.3 min/day (95%CI: 9.7 to 21.0 min/day), and by 12.9 min/day (95%CI: 6.5 to 19.5 min/day) at follow-up. In contrast, MVPA decreased from baseline to follow-up by 9.9 min/day (95%CI: -3.7 to -16.0 min/day) in the control group.

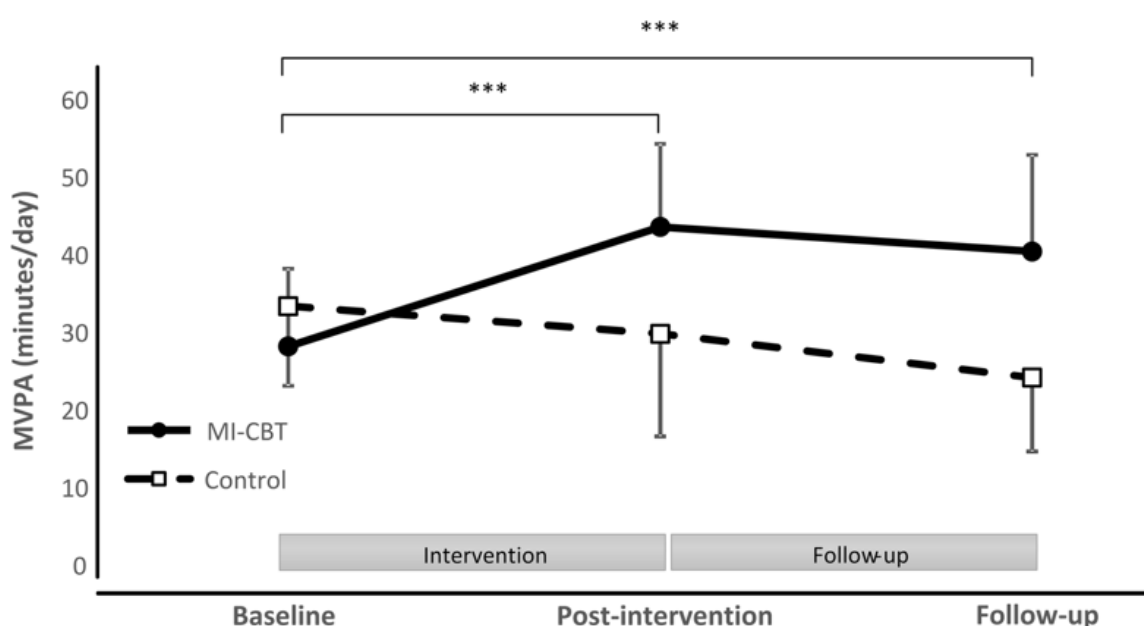


Figure 4.2: Minutes per day of moderate-to-vigorous physical activity (MVPA) for the intervention and control groups at baseline, post-intervention and follow-up. *** $p < 0.001$

Statistically significant group x time interaction effects were also found for all secondary outcomes (Table 4.2). For the intervention group, at follow-up there were significant changes in anthropometrics, resulting in changes in WC (-2.5 cm, 95%CI: -1.8 to -3.1 cm), body mass (-2.7 kg, 95%CI: -2.1 to -3.3 kg), and BMI (-1.0 kg/m², 95%CI: -0.8 to -1.2 kg/m²) indicating sustained changes in these variables. Relative to the control group, the intervention groups also demonstrated significant changes in physical activity self-efficacy (10 points, 95%CI: 6 to 14 points), type 2 diabetes risk (-1 risk point, 95%CI: -1 to 0 risk points) and HrQoL (0.04 units, 95%CI: 0.01 to 0.07 units).

Table 4.2 Means and standard deviations for outcome measures by time and group based on an intent-to-treat analyses.

Outcome	Intervention			Control			Analyses	
	Baseline	Post-Intervention	Follow-up	Baseline	Post-Intervention	Follow-up	Time x Group (F) ^a	Effect size ^b
MVPA (min/day)	28.1 ± 9.9	43.5 ± 10.7	41.1 ± 12.5	33.3 ± 10.3	29.8 ± 13.2	23.4 ± 9.7	23.25*	0.249
Waist circumference (cm)	99.3 ± 11.7	97.2 ± 11.4	96.8 ± 11.3	96.9 ± 11.5	97.2 ± 11.4	97.3 ± 11.3	61.84*	0.469
Body mass (kg)	84.5 ± 9.9	82.5 ± 9.6	81.7 ± 9.4	85.3 ± 8.9	85.6 ± 8.8	85.7 ± 8.7	70.04*	0.500
BMI (kg/m ²)	31.1 ± 4.0	30.4 ± 4.0	30.1 ± 3.9	30.5 ± 4.2	30.6 ± 4.1	30.7 ± 4.1	71.31*	0.505
PA self-efficacy (Risk score)	28 ± 8	36 ± 7	38 ± 7	34 ± 11	33 ± 10	32 ± 6	18.72*	0.211
HrQoL (Scale)	0.63 ± 0.08	0.62 ± 0.08	0.67 ± 0.09	0.65 ± 0.07	0.65 ± 0.08	0.62 ± 0.05	18.08*	0.205
Type 2 diabetes risk (Risk score)	14 ± 5	13 ± 4	13 ± 4	14 ± 5	14 ± 5	14 ± 5	10.91*	0.135

Group data are means ± standard deviations. MVPA: moderate-to-vigorous physical activity; BMI: Body mass index; HrQoL: Health-related quality of life.

* $p < 0.001$. ^a interaction effect of time by group on dependent variable; ^b Partial eta-squared.

4.5 Discussion

Integrated MI-CBT resulted in a meaningful increase in MVPA that was maintained at 6 months follow-up in ambulatory secondary care adults. The intervention also resulted in significant improvements in body mass, WC, BMI, physical activity self-efficacy, type 2 diabetes risk, and HrQoL. These improvements were maintained at 6-months, indicating a lasting effect of the intervention. This is the first study to demonstrate that an integrated MI-CBT intervention, delivered from a secondary care setting can result in significant changes in behavioural and health-related outcomes.

4.5.1 Changes and maintenance in physical activity

The Healthy4U trial recruited participants deemed to be insufficiently active via self-report, and seeking to become more physically active. At baseline, daily MVPA was 31 ± 10 min, indicating moderate levels of PA. All participants completed their baseline measures after attending the education session. Interventions based on SDT has been shown to result in short-term increases in PA (Teixeira et al., 2012). Therefore, it is likely that the education session contributed to moderate amounts of MVPA across all participants at baseline (Teixeira et al., 2012). Despite the moderate level of PA observed at baseline, the intervention group significantly increased MVPA at 3 months (post-intervention) by a further 15.3 min/day (95%CI: 9.7 to 21.0 min/day), with similar MVPA recorded at follow-up (12.9 min/day; 95%CI: 6.5 to 19.5 min/day). These results indicate a positive change in behaviour that was maintained at 6 months. To put this change into perspective, an additional 15 min of PA is associated with a reduction in all-cause mortality of 4%, regardless of age (Wen et al., 2011). In contrast, compared to baseline, the control group decreased MVPA at follow-up by 9.9 min/day (95%CI: -3.7 to -16.0 min/day). This reduction in MVPA in the control group is likely to reflect change from an elevated baseline value resulting from the initial education session. Decreases in PA have been shown to occur following the end of an exercise intervention, demonstrating the challenges of implementing prescriptive exercise interventions into the real world (McNeil et al., 2018). Studies have attempted to address this through the incorporation of self-monitoring strategies to prevent PA recidivism following the completion of exercise interventions (Opdenacker et al, 2011). A recent meta-analysis recommended that lifestyle interventions utilise self-help strategies for health-related behaviour change (Hartmann-et al., 2015). The integration of MI and CBT provides strategies for participants to identify and overcome barriers to initiate and maintain behaviour change (Naar-King et al., 2013). The observed changes in MVPA in the intervention group is

suggestive of the effectiveness of integrated MI-CBT for PA change and maintenance.

4.5.2 Changes and maintenance in anthropometrics

Compared to control, integrated MI-CBT resulted in significant changes in anthropometric outcomes. From baseline to follow-up, body mass reduced by 2.7 kg (95%CI: -2.1 to -3.3 kg) in the intervention group. Although the mean reduction in body mass did not exceed a clinically significant value of 5% (Swift et al., 2016), weight loss over the duration of the study is noteworthy as most middle aged individuals continue to gain weight each year (Williamson, 2004). The average gain in body mass of 0.5 kg (95% CI: -0.3 to 1.0) in the control exemplified the normal pattern of middle-aged weight gain (Williamson, 2004). The 2.5 cm decrease in WC observed in the MI-CBT group (95%CI: -1.8 to -3.1 cm) is also promising, as the baseline value of mean WC suggest an increased risk of obesity related diseases (Zhu et al., 2002). There is limited evidence for what constitutes a minimally important change in WC; however, a clinically relevant change of between 1.8 and 4.1 cm has been proposed as a marker of maintained change (Verweij et al., 2013). Furthermore, high waist circumference is positively associated with mortality rates at all levels of BMI from 20–50 kg/m² (Cerhan et al., 2014). A meta-regression analysis found that a 1cm increase in WC can increase the relative risk of cardiovascular events by 2% (de Koning et al., 2007). The observed decrease in WC in this study is in contrast with longitudinal data on Australian adults, which reported an annualised increase in waist circumference, that did not slow over time (Peeters et al., 2014). The observed pattern of increased WC occurred with a simultaneous decrease in body mass over the period (Peeters et al., 2014). NHANES data also indicated that over time WC increased to a larger extent than expected, relative to changes in body mass over the same period (Walls et al., 2011). These findings suggest that excess body weight over time is resulting in an increase in central adiposity, which is associated with a greater risk of cardiometabolic diseases (Walls et al., 2011). Although recruitment into this study was based upon changing PA, not body composition, the positive changes in anthropometric measures are of clinical importance as these risk factors are strong indicators of metabolic dysfunction, and associated with development and worsening of cardiovascular disease and diabetes (Palaniappan et al., 2004). The changes in both WC and body mass found in this study may strengthen confidence in the MI-CBT intervention for change and maintenance in anthropometric measures.

4.5.3 Changes and maintenance in health-related outcomes

The average baseline scores for PA self-efficacy indicated that the sample had moderate belief in their ability to be physically active. Lack of confidence and self-belief are strongly associated with low rates of PA (Trost et al., 2002). Despite having had higher levels of PA self-efficacy at baseline, the mean PA self-efficacy in the control group decreased at post-intervention and even further at follow-up, which diametrically opposed the trajectory of the intervention group. This increase in PA self-efficacy is a potential mediator for the improvement and maintenance in PA levels among the intervention group. The contrast in patterns of PA self-efficacy between the groups might be explained by the exposure of the intervention group to the MI-CBT treatment. MI-CBT strategies focus on increasing self-efficacy for behaviour change, as well as developing strategies for planning and relapse prevention (Miller & Rollnick, 2012). The changes in self-efficacy found in the study participants exhibited the same pattern of change as PA. The integrated MI-CBT group increased their self-efficacy and physical activity, while the control group demonstrated decreases in these outcomes.

Integrated MI-CBT resulted in small but significant changes in type 2 diabetes risk. The mean baseline AUSDRISK score of 14 indicates that participants are at high risk of developing type 2 diabetes within 5 years (Chen et al, 2010). Early screening for 2 diabetes risk, and subsequent lifestyle modification reduces the risk of type 2 diabetes and other chronic diseases (Blackford et al., 2015). Research indicates that almost 40% of individuals with prediabetes, if left untreated, will progress to diabetes in four years (Tuso, 2014). Lifestyle interventions can decrease the percentage of those with prediabetes who go on to develop diabetes to 20% (Tuso, 2014). The observed increase in PA and reduction in WC in the intervention group contributed to a reduction in risk score, whereas no change in risk score was observed in the control group. At follow-up the intervention group had a mean risk score of 13, which still indicates a high risk developing type 2 diabetes (Chen et al., 2010). The long-term maintenance of behaviour change is important for the effectiveness of lifestyle interventions to prevent type 2 diabetes.

The integrated MI-CBT intervention also resulted in small but significant changes between the groups for HrQoL. A consistent positive association has been demonstrated between PA and HrQoL (Penedo & Dahn, 2005). Changes in HrQoL in the intervention group were significant at follow-up, but not at post-intervention. Changes in multidimensional quality of life measures

have been shown to be less responsive than measures of specific patient outcomes, in this example PA change, particularly where interventions are aimed at achieving a particular outcome (Higginson & Carr, 2001). This might account for the slower degree of change exhibited by the intervention group (Higginson & Carr, 2001).

4.5.4 Strengths

This study was unique in that it enrolled participants from secondary care in a public hospital, integrating preventative health into secondary care. Patients presenting to secondary care have higher rates of chronic disease than the general population, and the targeting of high risk groups is essential to address the rising prevalence of chronic diseases in Australia (Haby et al., 2011). While hospital patients have expressed a desire for health behaviour interventions (Leijon et al., 2010), research from practicing hospitals doctors indicate that they do not have sufficient time to spend giving preventive advice to patients (Himmelmann & Weinehall, 1996). The Healthy 4U intervention was implemented to address this identified gap, to supplement clinical practice in secondary care, facilitating a process where clinicians under time duress were able to direct patients into a health behaviour intervention. With rates of lifestyle related disease projected to continue to rise in the future it is important to develop and evaluate innovative ways to address this concern (Rowley et al., 2017). For a regional hospital the delivery of the health coaching via telephone was important as it can extend reach to both geographically and socially disadvantaged areas, which commonly have higher risk of chronic diseases (O'Hara et al., 2011). In RCT's on behaviour change, the maintenance of physical activity behaviour change is not often reported, influencing the generalisability of findings (Fjeldsoe et al., 2011). The Healthy4U trial was purposely designed to assess the effect of the intervention for behaviour change and maintenance by extending outcome measures to 6 months from baseline. The use of objectively measured PA at all time points was a considerable strength of the study. Objective measures offer more precise estimates of activity intensity while removing many of the issues associated with participant recall and response bias (Prince et al., 2008). A recent meta-analysis on MI for PA change demonstrated that the effect size of the intervention was smaller in trials using objective measures, relative to self-reported data (O'Halloran et al., 2014). The objectively measured changes in PA strengthen the confidence in the findings (Prince et al., 2008).

The participant retention rate in this study was high, with only 4 participants (2 from both groups) lost at follow-up. All participants were required to attend the education session, which was designed to improve motivation. This mandatory attendance at the education session may have had a positive impact on participant adherence. This study used a Manual of Operating Procedures (MOP) to facilitate consistency in protocol implementation and data collection across participants. The MOP transformed the study protocol into a guideline describing the procedure for initial and subsequent contacts with participants. The MOP included standardised procedures for reminding participants of their upcoming commitments in relation to attendance for assessments, and accelerometer use, which may have had a positive influence on adherence rates.

Intervention adherence rate was also high, with 100% of participants receiving all eight sessions of integrated MI-CBT. Intervention-led health behaviour change relies on mutual understanding and trust between the intervener and the participant, which can only emerge when sufficient time is given (Sjöling et al., 2011). The individual delivering the intervention was confirmed as being fidelity proficient.

4.5.5 Limitations

Although the target number of participants was modest, the sample size was large enough to detect significant differences between groups in all outcome measures. Recruitment of volunteers into this study meant that all participants were already interested in becoming more active. Although this might limit the transferability of findings to all community-dwelling adults, it does not influence interpretation about the effectiveness of the intervention when compared against the control, due to the robust nature of the RCT study design. As the study was confined to a 6-month timeframe, it is not clear if improvements were sustained beyond that measurement point. Nevertheless the intervention resulted in increases in MVPA that were sustained at follow-up, which is indicative of behaviour change maintenance (Fjeldsoe et al., 2011), and the exhibited patterns of behaviour change found in the outcomes were not indicative of recidivism following the intervention completion (Bassi et al., 2014). Lastly, the broad generalisability of these findings might be difficult because the study was conducted in one regional location and the majority of participants were female and obese.

4.6 Conclusion

Due to the increased prevalence of chronic disease, addressing the lifestyle behavioural mediators of these preventable diseases is essential. The Healthy4U trial demonstrates that, in comparison to control, integrated MI-CBT resulted in significant improvements in PA, anthropometrics, self-efficacy, type 2 diabetes risk and HrQoL, which were maintained at follow-up. These findings demonstrate that a behaviour change intervention implemented in secondary care is effective for the prevention and management of chronic disease.

Chapter 5

Cost-effectiveness of telephone coaching for physical inactive ambulatory care hospital patients: economic evaluation alongside the Healthy4U randomised controlled trial

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5.1 Abstract

Objective: To assess whether telephone coaching is a cost-effective method for increasing physical activity and health-related quality of life for insufficiently active adults presenting to an ambulatory care clinic in a public hospital.

Design: An economic evaluation was performed alongside a randomised controlled trial.

Setting: Participants were recruited from an ambulatory care clinic in a public hospital in regional Australia.

Participants: Seventy-two adults (aged 18–69) deemed insufficiently physically active via self-report.

Interventions: Participants were randomised to either an intervention group that received an education session and eight sessions of telephone coaching over a 12-week period, or to a control group that received the education session only. The intervention used in the telephone coaching was integrated motivational interviewing and cognitive behavioural therapy.

Outcome measures: The primary health outcome was change in moderate-to-vigorous physical activity (MVPA), objectively measured via accelerometry. The secondary outcome was the quality-adjusted life-year (QALY) determined by the 12-item Short Form Health Survey Questionnaire. Outcome data were measured at baseline, post-intervention (3 months) and follow-up (6 months). Incremental cost-effectiveness ratios (ICERs) were calculated for each outcome. Non-parametric bootstrapping techniques and sensitivity analyses were performed to account for uncertainty.

Results: The mean intervention cost was \$279±\$13 per person. At 6 months follow-up, relative to control, the intervention group undertook 18 more minutes of daily MVPA at an ICER of \$15/min for each additional minute of MVPA. With regard to QALYs, the intervention yielded an ICER of \$36 857 per QALY gained. Sensitivity analyses indicated that results were robust to varied assumptions.

Conclusion: Telephone coaching was a low-cost strategy for increasing MVPA and QALYs in insufficiently physically active ambulatory care hospital patients. Additional research could explore the potential economic impact of the intervention from a broader healthcare perspective.

5.2 Introduction

Insufficient physical activity (PA) is an established risk factor for the development of a number of chronic diseases, including cardiovascular disease, type 2 diabetes and obesity (Warburton et al., 2006). Despite the well-established benefits of PA (Khan et al., 2012), more than half of the population does not attain sufficient levels of PA to derive such benefits (World Health Organization, 2009). The estimated cost of insufficient PA in Australia is AU\$805 million per annum (Ding et al., 2016). Addressing the prevalence of insufficient physical activity is a major public health priority, and necessitates that multiple sectors of the healthcare industry are actively engaged in physical activity promotion (Lambert et al., 2000).

Hospitals are important settings in which to offer health promotion interventions, for both admitted and ambulatory care. In the hospital setting, ambulatory care refers to non-admitted clinics that patients attend for specialist medical care. Patients attending ambulatory care hospital clinics are more likely than the general population to have one or more chronic disease (Britt et al., 2008; Steiner & Friedman, 2009). Hospital patients can be motivated to engage with lifestyle behaviour change as their health is already compromised (Gate et al., 2016; Lawson et al., 2009). Attending a hospital has been identified as a major life event (Allender et al., 2008), and a hospital visit has the potential to initiate health behaviour change (Gate et al., 2016). Ambulatory care settings provide an ideal opportunity for behaviour change interventions (Allender et al., 2008; Gate et al., 2016). Substantial efforts have been made to promote increased engagement in PA using individual and population-based approaches (Foster et al., 2005). This has resulted in an increased use of behaviour change interventions to influence participation in PA (Stephens & Allen, 2013).

A number of studies suggest that telephone coaching results in improved clinical outcomes, self-efficacy and health status (Dennis et al., 2013; Kivelä et al., 2014), as well as increases in physical activity (Eakin et al., 2007; O'Hara et al., 2012). Additional work is required to embed telephone coaching within existing health services (Dennis et al., 2013; Eakin et al., 2007). To make the benefits of telephone coaching more broadly available for hospital outpatients, telephone coaching has been delivered in addition to standard ambulatory care (Barrett et al., 2018a). The addition of telephone coaching to standard care resulted in significant improvements in objectively measured PA and health-related outcomes (Barrett et al., 2018a),

however, the cost to improve these outcomes has not been reported.

Few studies have employed any form of economic analyses on telephone coaching, and little is known about the relative cost-effectiveness of adding telephone coaching to routine care in ambulatory care hospital settings. The purpose of this study was to evaluate the cost-effectiveness of the Healthy4U program for increasing measured PA and the number of quality adjusted life years (QALYs) experienced over a 6-month period from a hospital perspective.

5.3 Methods

5.3.1 Study design

The Healthy4U study was a single-blind randomised controlled trial reported in line with the CHEERS reporting guidelines (Husereau et al., 2013) (Appendix 5.1). The trial design, participants, sample size, intervention, outcomes and ethics approvals have been described in detail elsewhere (Barrett et al., 2018a). Briefly, between October 2016 and December 2017, seventy-two insufficiently physically active adults, aged 18-69 years, were recruited from ambulatory care clinics at a major hospital in a regional town in Victoria, Australia. The primary aim was to promote change in objectively measured physical activity during the trial.

5.3.2 Intervention

All enrolled participants attended a 30-minute group education session. The education session was a facilitated learning session focused on self-management and lifestyle modification, and was carried out using a self-determination theory framework (Vansteenkiste & Sheldon, 2006). The intervention group completed a telephone-based, integrated motivational interviewing and cognitive behaviour therapy (MI-CBT) intervention, delivered in eight 30-minute sessions over 12 weeks. The intervention was delivered by an experienced allied health clinician trained in MI-CBT. All participants enrolled into the control arm attended the education session. Apart from contact regarding follow-up outcome measures, participants in the control group received no further contact initiated by the research team.

5.3.3 Measurement of effects

Outcome measures were recorded at baseline, after 3 months of intervention (post-intervention) and at 6 months (follow-up) by assessors blinded to the study group assignment. The primary outcome measure was change in moderate-to-vigorous physical activity (MVPA), objectively measured by accelerometry (wGT3X-BT; Actigraph, USA). Daily MVPA was determined using the manufacturers software (Actilife; Actigraph, USA) and the Freedson Adult (1998) cut point (vector magnitude > 1961 cpm) (Freedson et al, 1998). To be included in the analysis, a minimum wear time of ≥ 10 h/day for 5 of the 7-day period was required, including at least 1 weekend day (Olds et al., 2012). Weekly PA totals were summed from the daily totals for persons with 7 valid days of monitoring, or estimated as 7 times the average daily total for persons with 5 to 6 valid days of monitoring. Using the summed weekly totals, participants were classified as either meeting or not meeting the recommended PA guidelines (Nelson et al., 2007).

A secondary outcome was a change in health-related quality of life (HrQoL) and QALYs, which was derived from the Medical Outcomes Study Short Form 12 Health Survey (SF-12) and the standard Brazier algorithm (Brazier et al., 2002; Ware et al., 1996). The SF-12 scores were converted to utility scores on a scale of 0 to 1, with a higher score indicating a more favourable health state (Brazier et al., 2002). These utility estimates were converted to QALYs by calculating the 'area under the curve' utility estimates for the different follow-up time intervals for each participant, weighted by the length of follow-up at that time interval.

5.3.4 Measurement of costs

The cost analysis was designed and conducted from a hospital perspective, which allows health care organisations to gauge the approximate cost of offering this program (Drummond et al., 2015). A bottom-up micro-costing approach was used to calculate the intervention costs (Tan et al., 2009). This approach involves the detailed collection of information regarding the quantities of resources consumed while implementing and executing the interventions, as well as their respective unit prices (Tan et al., 2009). Only those costs involved in implementing the intervention (e.g., training of individuals carrying out and undertaking the intervention) were included. Protocol-driven costs, namely the costs of gathering data as part of the clinical trial were considered to be sunk costs and were therefore excluded from the cost-effectiveness

analysis (Drummond et al., 2015).

The program costs included group facilitator time, intervention time, and supplies. The group facilitator's time that was spent preparing for and facilitating group meetings. The intervention assistant's time was calculated as the time spent undertaking reminder phone calls to participants. The intervention costs were calculated as the time spent in 1:1 consultation with the participants. Both group facilitation and intervention costs were calculated using the annual salary of an experienced allied health clinician as they would most likely to be used in delivering MI-CBT were the intervention to be implemented on a large scale (AU\$82,924). Intervention assistant costs were based upon the annual salary of an Allied Health Assistant (AU\$45,338). Finally, the costs of supplies, including the program manuals were included in the program cost.

The group facilitator's time per group meeting was estimated at 2.5 hours, which included 0.5 hours for the group meeting itself, 1.0 hour to set up before and clean up after the group meeting, and 1.0 hour to prepare for the group meeting (i.e., reviewing meeting notes and presentation material). The group facilitator's cost per meeting per participant was calculated by dividing the facilitator's cost per meeting by the number of participants that attended each meeting. Due to the short time frame in which costs and effects occurred discounting was not necessary (Glick et al., 2014). All program costs were calculated in 2017 Australian dollars (AU\$).

5.3.5 Statistical analysis

Analyses of trial data have been reported elsewhere (Barrett et al., 2018a). In brief, mixed-model ANOVAs were used to assess the effects of the intervention on each of the outcome variables. The mean \pm SD for the overall cost and for the change in each outcome at 6-months was calculated. For each outcome, the incremental cost-effectiveness ratio (ICER) was calculated by dividing the difference in costs by the difference in effects between the intervention and control groups where the difference in effects between the two groups was calculated using a change from baseline approach to control for different baseline utilities. Uncertainty in the ICER estimates was accounted for by generating 1000 bootstrap replicates of the dataset, a widely used method in health economic evaluations. Probabilistic sensitivity analysis was completed by calculating the cost-effectiveness acceptability curve (CEAC) derived from the bootstrap replicates. CEAC indicates the probability that the intervention was cost-effective at different values of willingness to pay for the additional improvement in the outcome

(Appleby et al., 2007).

An additional 4 sensitivity analyses were used to examine how the results changed under different input assumptions. In the first 2 analyses, personnel wages and training costs were varied by 20% in either direction before recalculating the ICERs. The third sensitivity analysis using the summed weekly MVPA totals to estimate the ICER for each additional minute of MVPA per week. The fourth sensitivity analysis considered a different outcome measure for PA, using the summed weekly MVPA totals to estimate the ICER for changing one individual from insufficiently physically active to sufficiently physical activity (≥ 150 minutes MVPA per week) (Nelson et al., 2007).

5.3.6 Patient and public involvement

Patients were not involved in the research question, study design, or the conduction of the study.

5.4 Results

5.4.1 Resource use and costs

Seventy two participants were randomised; the group consisting of 54 females and 18 males, with an average age of 53 ± 8 (Appendix 5.2). A total of 72 participants completed their baseline and 3-month assessment, and 68 participants completed the 6-month assessment. For participants with missing data at 6-month follow-up ($n = 2$ in both groups), the last-observation-carried forward approach was adopted. The program resources and cost per participant are described in Table 5.1. Attendance at the education session was mandatory, with full attendance recorded for both groups. The mean group program time was 34 ± 6 minutes, and the mean total participant time spent in the intervention was 242 ± 14 minutes. The mean cost per participant was $\$279 \pm \10 for intervention versus $\$21 \pm \3 for control. The main component costs of MI-CBT were intervention delivery and training.

Table 5.1 Utilisation and cost of program delivery for intervention and control groups

Item	Provider	Units	Time (h)	Cost/h AU\$	Total AU\$ cost per participant
Intervention group					
Group sessions	Allied Health professional	1	2.5	41.90	17.45
Phone call reminders	Intervention assistant	8	0.25	22.80	45.6
Intervention sessions	Allied Health professional	8	0.5	41.90	167.6
Program manual					3.5
Staff training					44.6
Total cost/participant					279
Control group					
Group sessions	Allied Health professional	1	2.5	41.90	17.45
Program manual					3.5
Total cost/participant					21

5.4.2 Health outcomes

Table 5.2 presents the mean costs and the mean change in each outcome at follow-up for each group, and the corresponding ICERs. The ICER for MVPA was \$15 per each additional minute of MVPA per day. The difference in QALYs between intervention and control groups was 0.007 QALYs over the course of the follow-up period. The ICER for the intervention group in comparison with the control group was \$36,857 per QALY gained. Figures 5.1 and 5.2 illustrate the CEAC for each outcome derived from non-parametric bootstrapping replicates. For physical activity, given a willingness to pay of \$15 per additional minute of MVPA, the probability that the intervention was cost-effective was 67% (Figure 5.1). At a willingness to pay of \$37,000 per QALY gained, the probability that the intervention is cost-effective was 52% (Figure 5.2). If the decision maker was willing to pay \$40,000 per QALY, the probability of cost-effectiveness for the intervention was 70% (Figure 5.2).

In the sensitivity analyses, training and implementation costs were varied 20% in each direction, and the corresponding ICERs were recalculated (Table 5.3). The varied ICERs for MVPA was found to range from \$11 to \$17 per each additional minute of MVPA per day, while the ICER for QALYs ranged from \$29,428 to AU\$44,285 per QALY gained. The third sensitivity analysis demonstrated an ICER of \$2.86 per additional minute of MVPA per week. The final sensitivity analysis found that the intervention group was 33% more likely than control to meet recommended PA guidelines at follow-up, with an ICER of \$781 per PA guideline attained.

Table 5.2 Costs, changes in outcomes and incremental cost-effectiveness ratios at follow-up.

Outcome	Cost AU\$/ Participant	Outcome	Incremental cost AU\$	Incremental outcome	ICER
MVPA					
Control	21	23			
Intervention	279	41	258	18	AU\$15/min MVPA per day
QALYs					
Control	21	-0.005			
Intervention	279	0.002	258	0.007	AU\$36, 857/QALY

ICER: Incremental cost-effectiveness ratio; MVPA: moderate to vigorous physical activity; QALYs: quality adjusted life years.

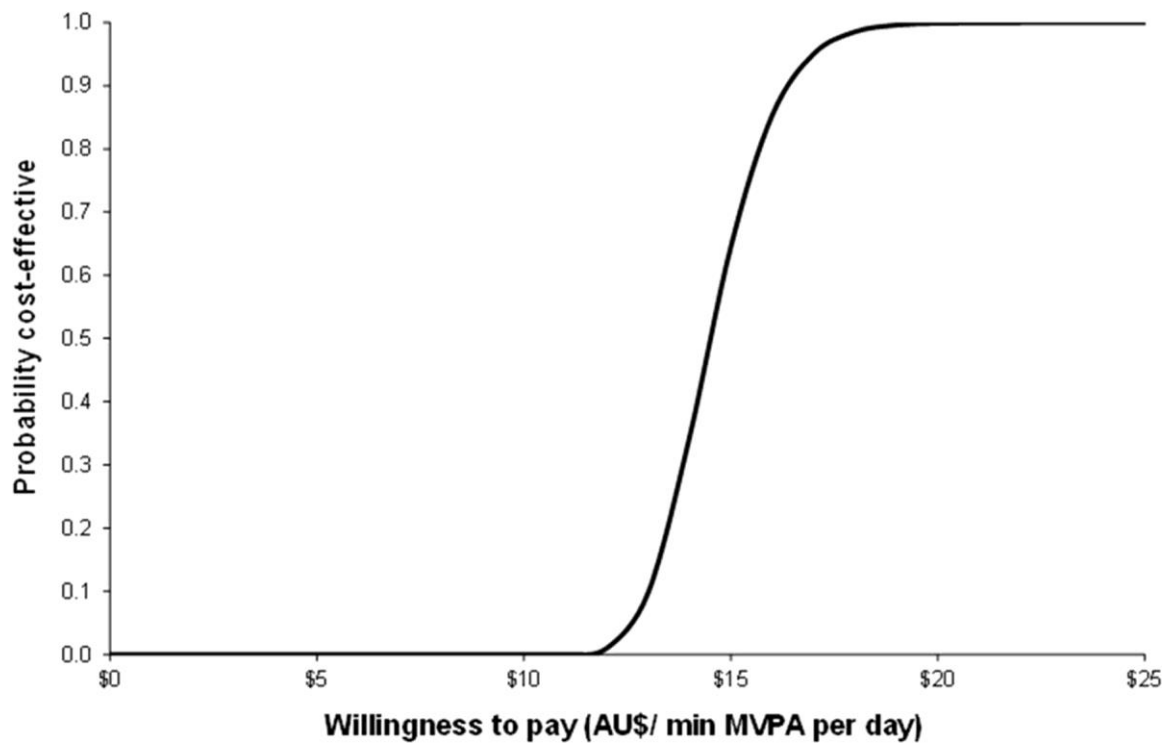


Figure 5.1: Cost-effectiveness acceptability curve showing the probability of the interventions being cost-effective in comparison to control for moderate-to-vigorous physical activity (MVPA)

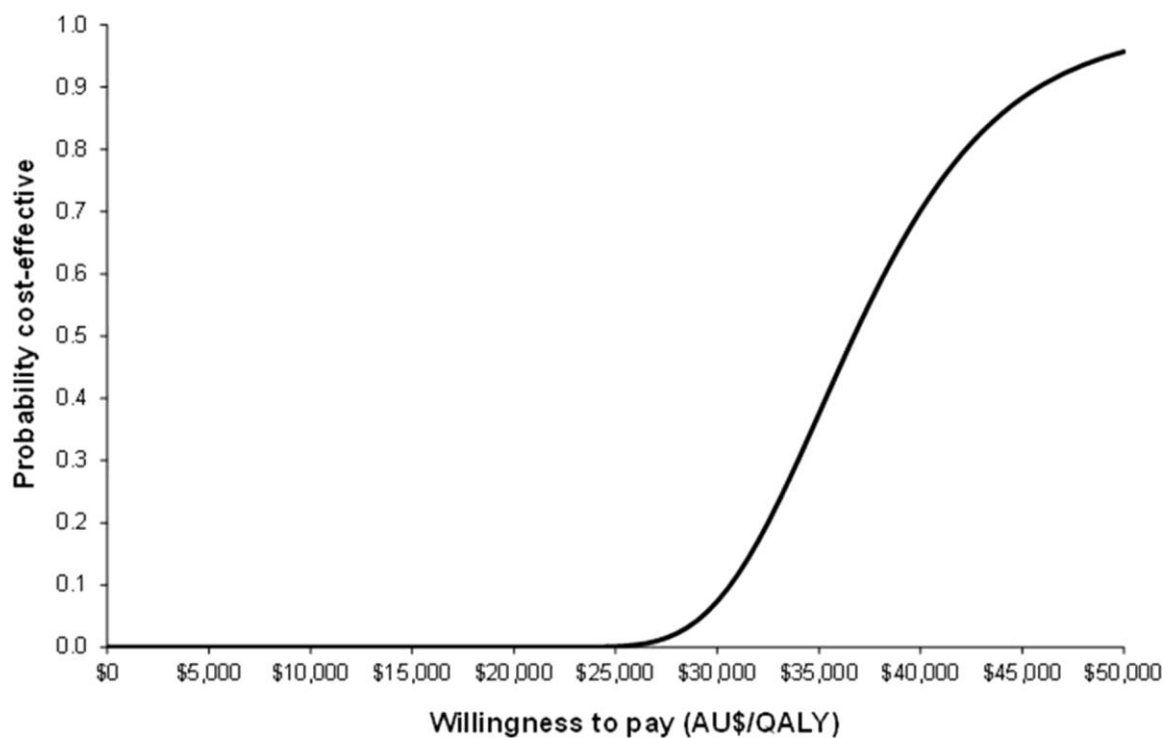


Figure 5.2: Cost-effectiveness acceptability curve showing the probability of the interventions being cost-effective in comparison to control for quality-adjusted life-years (QALYs)

Table 5.3 Sensitivity analyses for costs, changes in outcomes and incremental cost-effectiveness ratios at follow-up

Outcome	Cost AU\$/Participant	Outcome	Incremental cost AU\$	Incremental outcome	ICER
MVPA + 20% variation in cost					
Control	25	23			
Intervention	335	41	310	18	AU\$17/min MVPA per day
QALY + 20% variation in cost					
Control	25	-0.005			
Intervention	335	0.002	310	0.007	AU\$44,285 QALY
MVPA - 20% variation in cost					
Control	17	23			
Intervention	223	41	206	18	AU\$11/min MVPA per day
MVPA min per week					
Control	21	170			
Intervention	279	260	258	90	AU\$2.86/min MVPA per week
PA guidelines attained					
Control	21	20/36 (55%)			
Intervention	279	31/36 (86%)	258	33%	AU\$781/PA guideline achieved

ICER: Incremental cost-effectiveness ratio; MVPA: moderate to vigorous physical activity; PA: Physical activity; QALYs: quality adjusted life years

5.5 Discussion

This study examined the clinical and economic implications of a behaviour change intervention for changes in PA and QALYs for insufficiently physically active adults presenting to an ambulatory care clinic in a regional public hospital setting. Over the follow-up period the MI-CBT intervention was significantly more effective than control in increasing PA and HrQoL. To the best of our knowledge, this is the first study to evaluate the cost-effectiveness and cost-utility of an integrated MI-CBT intervention for health-related behaviour change.

Telephone coaching can be cost-effective for increasing physical activity with patients with or at risk of chronic disease (Hutchison et al., 2011; Varney et al., 2016). However, little is known about the cost-effectiveness of adding preventive interventions to routine hospital care, where implementing an intervention requires an upfront investment of money. The total estimated cost of delivering the MI-CBT intervention was \$279 per person, resulting in the average attainment of 41 ± 12 minutes of MVPA per day at follow-up. The per person cost was similar to the \$245 per person found in recent primary care intervention for PA change (Ewald et al., 2018), while both are considerably lower than costs of \$1,756/person (Groessl et al., 2016) and \$1,562/person (Groessl et al., 2009) reported in other lifestyle interventions aiming at changes in PA.

The cost-effective analysis for measured MVPA indicated a cost of \$15 per each additional minute of MVPA per day. Over the 6-month follow-up period this can be translated to a total cost of \$9 per day, or \$63 per week to increase MVPA by 150 minutes. Sensitivity analysis indicated a one-time cost of \$2.86 per each additional minute of MVPA per week, or \$8.25 per week to increase MVPA to 150 minutes a week over the 6-month follow up. The cost of \$8.25 per week to increase MVPA to 150 minutes is comparable to the \$4.99 (Johnson et al., 2016), \$8.13 (Elley et al., 2011) and \$10.19 (Sevick et al., 2007) per week found in other interventions aimed at increasing physical activity. Increases in PA result in decreased healthcare use, even in the short term, which result in net savings to society over time (Martinson et al., 2003). Determining the cost-effectiveness of integrating telephone coaching into routine care from a hospital perspective is dependent on the willingness-to-pay for each additional minute of MVPA. Interpreting the ICER of \$15 per additional minute of MVPA found here is difficult as there is no standard value for how much policy-makers are willing to pay per additional minute of MVPA (Johnson et al., 2016). The CEAC indicated a probability of 67% that \$15 per additional

minute of MVPA was cost-effective (Figure 5.1).

The intervention group was 33% more likely than the control group to undertake sufficient PA at follow-up. Sensitivity analysis demonstrated an ICER of \$781 for converting one insufficiently physically active adult to a sufficiently active state over the 6-month follow-up period. This value falls within the ranges of \$175 to \$1801 (Vijay et al., 2016), and \$521 to \$5790 (Garrett et al., 2011) estimated in systematic reviews investigating the cost-effectiveness of physical activity interventions. Undertaking sufficient PA is strongly associated with decreased risk of chronic disease, morbidity and mortality (Warburton et al., 2006), as well as decreased healthcare expenditure over time (Martinson et al., 2003).

In the cost-utility analysis an incremental change in QALYs of 0.007 was demonstrated between the intervention and control groups, resulting in an ICER of \$36,857 per QALY gained. The ICER of \$36,857 per QALY gained is considerably smaller than the \$58,924 per QALY gained (Groessler et al., 2016) and the \$68,101 per QALY gained (Groessler et al., 2009) found in similar intervention studies. Oskman et al (2017) recently reported an ICER of \$48,000 per QALY gained for a telephone-based health coaching intervention for chronic disease patients. Direct comparison with the results from the aforementioned studies is challenging because different cost perspectives were considered in these analyses. Nonetheless, the ICER of \$36,857 per QALY falls under the commonly used threshold of \$50,000 per QALY gained proposed for medical treatments and procedures (Hirth et al., 2000). Sensitivity analysis demonstrated that costs for the Healthy4U study are only mildly sensitive to typical variation in the cost input values. A variation in hourly wage costs had the largest impact on the ICERs, however, the ICERs remained well below the threshold of \$50,000 per QALY gained at all imputed values. The CEAC provided a probability of 52% that the intervention was cost-effective at a willingness to pay of \$37,000 per QALY gained (Figure 5.2).

Behaviour change interventions are typically used to modify specific lifestyle factors known to predispose individuals to increased risk of chronic disease over the longer term (Goyder et al., 2014). The long-term impact of such interventions on overall quality of life is less established. While the follow-up period in this study was too short for the mediating effect of physical activity on broader health outcomes to become fully apparent (Goyder et al., 2014), the relatively small observed change in QALYs over 6 months was a combination of the -0.005 fall in

the control group and the 0.002 increase in the intervention group. This finding supports the suggestion that an important impact of behavioural interventions on quality-of-life over the longer-term might be to attenuate expected declines in health-related quality-of-life (Cutler, 2004).

This study was unique in that we enrolled participants from an ambulatory care clinic in a public hospital, integrating preventative health into secondary care. It is important to note that this intervention was carried out in addition to standard care, not as a substitution, and as such an economic evaluation costed from a hospital perspective offers healthcare providers an estimate of the costs and effects of adding a preventative health intervention to clinical care. This study is one of the few economic evaluations of telephone coaching carried out in real-life settings using an RCT design. The addition of preventive health measures is likely to cost hospitals more, however, these preventive measures might be worthwhile due to the substantial health benefits that they confer, relative to their cost (Martinson et al., 2003). Nevertheless, implementation remains a challenge for hospitals (Eakin et al., 2007), and it will be important to engage with key stakeholders, especially clinic leaders, to identify specific patients who can benefit from telephone coaching (Damschroder et al., 2016). Health services with high implementation rates of telephone coaching have used multi-component strategies to engage staff, as they were the most important source of referrals (Damschroder et al., 2016). Investigating hospital clinicians' practice and beliefs around preventive health can also facilitate the development of pathways to increase preventive health practice in the hospital setting (Barrett et al., 2019).

The greatest cost of the intervention was in the delivery, due to the fact that it was delivered individually by trained personnel. These costs could be reduced by decreasing the number of intervention sessions, with a recent meta-analysis indicating that 5 sessions of MI-CBT is significantly effective for physical activity change (Barrett et al., 2018b). Costs could potentially be reduced by incorporating digital technology into the intervention to decrease the time spent by trained professionals in 1:1 sessions. Innovations in digital technologies can assist individuals with health behaviour change, (Sanyal et al., 2018) which can potentially reduce health care expenditure (Jiang et al., 2019; Sanyal et al., 2018). The long-term cost-effectiveness of digital health technologies has not been established (Sanyal et al., 2018).

The use of objectively measured PA at all time points was a considerable strength of the study. Objective measures offer more precise estimates of activity intensity while removing many of the issues associated with participant recall and response bias (Prince et al., 2008). Individuals have been demonstrated to overestimate their PA levels via self-report (Vijay et al, 2016). Overestimation of PA can result in inaccurate estimations of both effectiveness and the cost-effectiveness of interventions (Bizeet et al., 2007). Using objectively measured changes in PA and the collection of full cost data for all participants strengthens our findings (Prince et al., 2008).

This study has a number of limitations. A noteworthy limitation of this study is the restricted perspective used for the economic evaluation. Using a single hospital perspective might have led to the exclusion of important costs and benefits from a societal perspective, including healthcare utilisation and changes in productivity (Jönsson, 2009). Economic analyses from a societal perspective offer the most comprehensive evidence from which to base decisions (Jönsson, 2009). However, due to the relatively short follow-up time of this study it was not feasible to undertake this method. Significant effects on overall healthcare utilisation or productivity loss were not expected over the timeframe of this study (van Keulen et al., 2010). As the intervention was delivered using the telephone, the intervention required relatively small amounts of participant time. With this in mind, the participant opportunity costs were expected to be small and therefore not included in the analyses. Additionally, the study participants included 54 females and 18 males, which might limit the generalisability of the current findings to different populations.

To the best of our knowledge this is the first study comparing the cost-effectiveness and cost-utility of an integrated MI-CBT intervention for health behaviour change amongst community-dwelling adults presenting to a secondary care clinic in a regional public hospital setting. Considering the large group of people who might benefit from such an intervention (i.e., approximately 50% of adults aged 18-69 years in Australia who are currently insufficiently physically active), the widespread adoption and implementation of MI-CBT to increase PA could have important economic implications. However, further research with a more comprehensive economic analysis is needed to investigate whether the long-term benefits of MI-CBT might justify this type of investment.

5.6 Conclusion

The Healthy4U program is a relatively low-cost strategy for increasing physical activity among insufficiently physically active adults presenting to an ambulatory care hospital clinic. The intervention increased measured PA and quality of life at low costs, with positive effects maintained out to 6-months. By increasing physical activity and quality of life at low costs, integrating telephone coaching programs into secondary hospital care offers a potentially cost-effective investment to produce better public health outcomes. The results are however grounded on a short-term follow-up and a restricted economic perspective, and more evidence is needed to explore the potential long-term economic impact of the intervention from a broader healthcare perspective.

Chapter 6

The effect of behaviour change interventions on changes in physical activity and anthropometrics in ambulatory hospital settings: a systematic review and meta-analysis

This chapter is available in published format as follows: Barrett S, Begg S, O'Halloran P, Howlett O, Lawrence J, & Kingsley M. (2021). The effect of behaviour change interventions on changes in physical activity and anthropometrics in ambulatory hospital settings: a systematic review and meta-analysis. *International Journal of Behavioral Nutrition and Physical Activity*. 18, 7. <https://doi.org/10.1186/s12966-020-01076-6>.

6.1 Abstract

Background: The aim of this systematic review and meta-analysis was to investigate whether behaviour change interventions promote changes in physical activity and anthropometrics (body mass, body mass index and waist circumference) in ambulatory hospital populations.

Methods: Randomised controlled trials were collected from five bibliographic databases (MEDLINE, Embase, CINAHL, The Cochrane Central Register of Controlled Trials (CENTRAL) and PsycINFO). Meta-analyses were conducted using change scores from baseline to determine mean differences (MD), standardised mean differences (SMD) and 95% confidence intervals (95% CI). The Grades of Recommendation, Assessment, Development and Evaluation approach was used to evaluate the quality of the evidence.

Results: A total of 29 studies met the eligibility criteria and 21 were included in meta-analyses. Behaviour change interventions significantly increased physical activity (SMD: 1.30; 95% CI: 0.53 to 2.07, $p < 0.01$), and resulted in significant reductions in body mass (MD: -2.74; 95% CI: - 4.42 to - 1.07, $p < 0.01$), body mass index (MD: -0.99; 95% CI: - 1.48 to - 0.50, $p < 0.01$) and waist circumference (MD: -2.21; 95% CI: - 4.01 to - 0.42, $p = 0.02$). The GRADE assessment indicated that the evidence is very uncertain about the effect of behaviour change interventions on changes in physical activity and anthropometrics in ambulatory hospital patients.

Conclusions: Behaviour change interventions initiated in the ambulatory hospital setting significantly increased physical activity and significantly reduced body mass, body mass index and waist circumference. Increased clarity in interventions definitions and assessments of treatment fidelity are factors that need attention in future research.

6.2 Background

Chronic diseases are leading causes of ill health worldwide (World Health Organization, 2014). Modifiable risk factors such as insufficient physical activity (PA), poor diet, and obesity are associated with an increased risk for chronic disease (Strong et al., 2005) but, due to medical improvements, individuals are living with chronic disease for longer periods (Chen et al., 2019; Solé-Auró & Alcañiz, 2015). Increased survival amongst people with chronic disease results in a higher prevalence of morbidity, and lower quality of life (Solé-Auró & Alcañiz, 2015). As a result, secondary prevention has become important for chronic disease management globally (Germano et al., 2012).

Secondary prevention aims to reduce the impact of chronic disease through early detection and treatment. Behaviour change as a secondary prevention strategy is emerging as a way to mitigate the impact of disease and slow down disease progression (Schmidt, 2016). Hospitals are important settings for the delivery of secondary prevention programs given their unique access to members of the local community who might benefit (Gate et al., 2016). Hospital attendees are not necessarily registered with a GP and may not be actively engaged with community health promotion services (Gate et al., 2016), but because their health is already compromised, these individuals can be readily motivated to engage with lifestyle behaviour changes (Lawson et al., 2009). Behaviour change interventions are advocated as the first-line approach to behavioural risk factor management (Lindner et al., 2003).

Results from recent meta-analyses indicate that secondary prevention behaviour change interventions result in positive effects in PA (Lawlor et al., 2018; Sisti et al., 2018), anthropometrics (Sisti et al., 2018) and cardiovascular health (De Waure et al., 2013). These reviews included studies from hospital settings, though many studies recruited patients from the inpatient setting (Lawlor et al., 2018; Sisti et al., 2018). Contextual differences exist in recruiting individuals for behaviour change interventions from the admitted versus ambulatory hospital setting (Bickmore et al., 2009; Mishra et al., 2016).

In the inpatient setting, patients are removed from their home environments, often suffering from a serious condition, and are potentially confined to their bed or the hospital room (Mishra et al., 2016). Being hospitalised has been identified as a major life event, increasing the likelihood of engaging in recommended care (Allender et al., 2008). The inpatient environment

imposes unique constraints on individuals, including their perception of autonomy of their care (Bickmore et al., 2009). Consequently, the decision to initiate health behaviour change is potentially impacted by the inpatient setting (Bickmore et al., 2009).

Ambulatory hospital patients, on the other hand, engage in care under different circumstances. These individuals are community-dwelling, and maintain more autonomy over their care, including decisions regarding the treatment plan, or when they can expect to see the doctor next (Kendall et al., 2015). The delivery of preventive health care in the ambulatory hospital setting should be targeted, patient-centred, and characterised by interventions that support people with chronic disease risk factors and should include self-management support wherever possible (Primary Health Care Advisory Group, 2015). Knowledge of the impact of behaviour change interventions on ambulatory hospital patients might allow prioritising preventive interventions in the ambulatory hospital setting for the prevention and management of chronic disease. To the best of our knowledge, no review has examined the effect of behaviour change interventions that address changes in PA and anthropometrics in non-admitted secondary care patients. Therefore, the aim of this review was to examine the effect of behaviour change interventions on changes and maintenance on PA, and anthropometrics, initiated in the ambulatory hospital setting only.

6.2.1 Research question

Do behaviour change interventions result in positive changes and maintenance in PA and anthropometrics in adults attending ambulatory hospital clinics?

6.3 Methods

A systematic review and meta-analysis was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) (Liberati et al., 2009). This review was registered with PROSPERO (registration ID: CRD42020172140).

6.3.1 Data sources and search strategies

To avoid duplication, a search was undertaken in the Cochrane Database of Systematic Reviews, PubMed Clinical Queries and PROSPERO International prospective register of systematic reviews

to confirm that no similar systematic reviews or protocols have been conducted. Eligible studies were collected (from inception until May 2020) using computer-based searches in MEDLINE, Embase, CINAHL, Web of Science, PsycINFO and The Cochrane Central Register of Controlled Trials (CENTRAL) electronic databases. Database-specific search strategies were developed with the guidance of professional clinical librarians. The database searches were performed using three main concepts: ambulatory secondary hospital care, lifestyle behaviour change interventions and outcomes (PA and anthropometric measures). For each main concept relevant related terms and keywords were included in the sensitive search (search details for MEDLINE are presented in Appendix 6.1).

Two additional steps were undertaken to ensure the comprehensiveness of our search. Firstly, searches were undertaken in clinical trial registries, including ClinicalTrials.gov, EU Clinical Trials Register, Australian New Zealand Clinical Trials Registry and the World Health Organization International Clinical Trial Registry Platform to source relevant ongoing and unpublished trials. Secondly, we performed a snowball search on reference lists, and grey literature databases.

6.3.2 Eligibility criteria

The term behaviour change interventions is used to define coordinated activities designed to change specified behaviour outcomes (Michie et al., 2011a). For the purpose of this review, we included behaviour change interventions that specifically aimed to elicit changes in anthropometrics and/or physical activity changes through the use of behaviour modification components and strategies. Inclusion criteria to select studies were: 1) Study population: adult (aged 18 or older) ambulatory hospital patients; 2) Types of studies: peer-reviewed randomised controlled trials regarding a behaviour change intervention compared to a control intervention or usual care comparison group. The behaviour change intervention could be a single intervention or a multi-component intervention, but needed to include at least one session that was delivered in a 1:1 format (delivered in person, via the phone or telehealth) because of the importance of an individualised approach to self-management (Pearson et al., 2007); 3) Primary outcomes: PA, anthropometric measures – body mass, body mass index (BMI) and waist circumference (WC). Due to the clinical relevance of changes in body mass, BMI and WC, an a priori decision was made to undertake a meta-analysis on each outcome individually (Huxley et al., 2010; Ryan & Yockey, 2017). Behavioural science highlights the need to draw the distinction between initial behaviour change and behaviour change maintenance (Kwasnicka et

al., 2016). To establish the maintenance effect of interventions, studies that included a follow-up duration of less than 12 weeks were excluded.

Studies were included that reported any of the following physical activity outcome measures: changes in daily steps, METs per week (METs/wk) or minutes per day/week of moderate to vigorous physical activity (MVPA) measured subjectively (e.g., self-report) or objectively at baseline and post intervention.

6.3.3 Study selection

Studies were entered into Review Manager (Version 5.3; The Cochrane Collaboration, Denmark) and duplicates were removed. Screening was carried out using Covidence (Covidence Systematic Review Software, Veritas Health Innovation, Melbourne, Australia). Two authors independently screened title/abstracts and full text. Studies were systematically excluded when they did not meet the pre-specified inclusion criteria. Disagreements between reviewers were resolved by discussion, or where required with consensus of a third reviewer.

6.3.4 Data extraction

Data were independently extracted by two reviewers. Data extraction was performed with the aid of a predesigned and piloted data collection form. For each study, the reviewers extracted information with respect to study characteristics (type of study, population description, focused disease or condition); study participants (sample size, demographics); methods (intervention duration, type and frequency, fidelity blinding, amount of intervention groups, number of included participants, the number of individuals that were randomised and analysed); the professional background of the person delivering the intervention); and outcome variables (outcome definition, unit of measurement, time points measured and reported). Continuous data including, means, standard deviations and the sample size numbers were extracted. When information was unclear, insufficient or missing, the authors of trials were contacted for clarifications and additional results. Where standard deviations were not available, measures of variance were estimated from the standard error of a mean, confidence intervals or p-values according to the Cochrane Handbook for Systematic Reviews of Interventions the Cochrane Collaboration (Cochrane Collaboration, 2014). When data were presented as median and interquartile range, the mean and standard deviation were estimated using the formula from

Hozo et al (2005).

6.3.5 Study quality assessment

The risk of bias of the included studies was assessed by two reviewers independently using the Cochrane Risk of Bias assessment tool (Higgins and Green, 2011). The following methodological criteria were assessed: sequence generation; allocation concealment; blinding of participants, personnel and outcome assessors; incomplete outcome data; selective outcome reporting; and other potential threats to validity (Higgins and Green, 2011). Each of these criteria were judged and classified as 'low risk', 'high risk' or 'unclear risk' of bias.

The overall strength of the evidence was assessed using the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) (Andrews et al., 2013) system through the GRADEpro 3.6 software (GRADEpro GDT: GRADEpro Guideline Development Tool [Software]; McMaster University, USA). Quality of evidence for meta-analyses began at the high level and was downgraded to lower levels of evidence when risk of bias, inconsistency, indirectness, imprecision or publication bias were present. Publication bias was examined by Egger test (Egger et al., 1997).

6.3.6 Statistical analysis

Means and standard deviations of change scores for both intervention and control groups were included in one of the extracted studies (Alsaleh et al., 2016). Using these change data, the correlation coefficients were calculated for the intervention group ($r = 0.81$) and control group ($r = 0.80$), with an average r of 0.80 (Alsaleh et al., 2016). For all included studies, the standard deviation of change scores from baseline were calculated using a correlation coefficient of 0.8 (Higgins and Green, 2011), and entered directly into Review Manager 5.3 (Version 5.3; The Cochrane Collaboration, Denmark) for analysis. Analyses based on changes from baseline are more efficient and powerful than comparison of final values through the removal of between-person variability (Higgins and Green, 2011). The mean differences with 95% confidence intervals (CIs) were calculated for anthropometric outcomes. For PA outcomes, standardized mean differences (SMD) with 95% CIs were calculated using Review Manager 5.3 as the mean difference divided by the pooled standard deviation (Higgins and Green, 2011). Due to the heterogeneity in the study interventions and populations, meta-analyses were conducted using

a random effects model (Higgins and Green, 2011). In keeping with recommendations, an effect size of 0.2 was considered small, 0.5 moderate, and 0.8 or more was considered large (Cohen, 2013). The effect of heterogeneity of each summary effect size was quantified using a chi-squared test and the I^2 statistic, in which the boundary limits 25, 50, and 75% were designated as a low, moderate, and high heterogeneity value, respectively (Higgins and Green, 2011).

6.3.7 Sensitivity and subgroup analyses

All analyses were repeated with correlations set at lower (0.50) and higher (1.0) r values than the calculated value of 0.80. Sensitivity analyses were performed to assess heterogeneity of the studies and to evaluate the robustness of the results. Each study was individually removed to evaluate the effect of that study on the summary estimates.

Subgroup analyses were performed to investigate the essential elements in designing effective behaviour change interventions in the ambulatory hospital setting. The subgroup analyses included the study population, follow-up duration, objective or self-reported measurements, the duration of intervention, and the dose of the intervention. The duration of intervention was classified as short term (≤ 3 months) or longer term if ≥ 4 months (Gal et al., 2018). The reporting of the length of intervention sessions was poor in many of the included studies. As a result the intervention dose quantified in this review is through the number of sessions. This intervention dose was categorised as low intensity (≤ 6 sessions), medium intensity (7 - 12 sessions) or high intensity (≥ 13 sessions) (Dusenbury et al., 2003).

6.4 Results

Following de-duplication, 2,984 studies were screened. The PRISMA diagram for the screening is shown in Figure 6.1. Twenty-nine full-text articles fulfilled the inclusion criteria and were included in qualitative ($n = 29$) and quantitative ($n = 21$) syntheses (Table 6.1) (Aas et al., 2005; Ahmadi et al., 2019; Alsaleh et al., 2016; Altenburg et al., 2014; Barrett et al., 2018a; Cakir & Pinar, 2006; Carrasquillo et al., 2017; Cheung et al., 2019; Dogru et al., 2019; Duscha et al., 2018; Elkoustaf et al., 2019; Fappa et al., 2012; Freedland et al., 2015; Gade et al., 2014; Goedendorp et al., 2010; Goodwin et al., 2014; Harting et al., 2006; Ijzelenberg et al., 2012; Kim & Hwang, 2019; Kirk et al., 2004; Kosaka et al., 2005; Lear et al., 2003; Miura et al., 2004; O'Brien et al., 2018; Oldroyd et al., 2006; Rimmer et al., 2009; Sone et al., 2010; Wattanakorn et

al., 2013; Williams et al., 2018). Included studies were published over a 17-year period from 2003 to 2020. The studies were performed in 14 different countries, with the largest representation from the United States (n = 6), Holland (n = 4) and Australia (n = 4). Populations within the included studies represented various health conditions including impaired glucose tolerance (IGT) or type 2 diabetes (T2DM) (n = 10) (Aas et al., 2005; Carrasquillo et al., 2017; Cheung et al., 2019; Dogru et al., 2019; Fappa et al., 2012; Kirk et al., 2004; Kosaka et al., 2005; Oldroyd et al., 2006; Sone et al., 2010; Wattanakorn et al., 2013), cardiovascular diseases (CVD) (n = 10) (Alsaleh et al., 2016; Cakir & Pinar, 2006; Duscha et al., 2018; Elkoustaf et al., 2019; Freedland et al., 2015; Harting et al., 2006; Ijzelenberg et al., 2012; Kim & Hwang, 2019; Lear et al., 2003; Miura et al., 2004), overweight/obesity (n = 5) (Gade et al., 2014; Goodwin et al., 2014; O'Brien et al., 2018; Rimmer et al., 2009; Williams et al., 2018), insufficiently physically active (n = 1) (Barrett et al., 2018a), Chronic Obstructive Pulmonary Disease (COPD) (n = 1) (Altenburg et al., 2014), cerebrovascular disease (n = 1) (Ahmadi et al., 2019), and cancer (n = 1) (Goedendorp et al., 2010).

6.4.1 Study characteristics

The behaviour change interventions in the included studies varied in intervention duration from 4 to 416 weeks. With the exclusion of Sone et al. (2010), which used a low grade intervention over 8 years, the adjusted intervention duration was 32 ± 24 weeks. The intervention duration was 26 weeks or greater in 66% of the included studies. Follow-up duration varied amongst the studies: 5 studies had a 3-month follow-up (Duscha et al., 2018; Gade et al., 2014; Kim & Hwang, 2019; Kirk et al., 2004; Wattanakorn et al., 2013), 1 study had a 4-month follow-up (Dogru et al., 2019), 10 studies had a 6-month follow-up (Barrett et al., 2018a; Cakir & Pinar, 2006; Cheung et al., 2019; Fappa et al., 2012; Goedendorp et al., 2010; Ijzelenberg et al., 2012; Miura et al., 2004; O'Brien et al., 2018; Rimmer et al., 2009; Williams et al., 2018), 2 studies had a 9-month follow-up (Alsaleh et al., 2016; Elkoustaf et al., 2019), 4 studies had a 12-month follow-up, and the remaining 7 studies varied between 15 months and 8 years of follow-up (Ahmadi et al., 2019; Altenburg et al., 2014; Goodwin et al., 2014; Harting et al., 2006; Kosaka et al., 2005; Oldroyd et al., 2006; Sone et al., 2010).

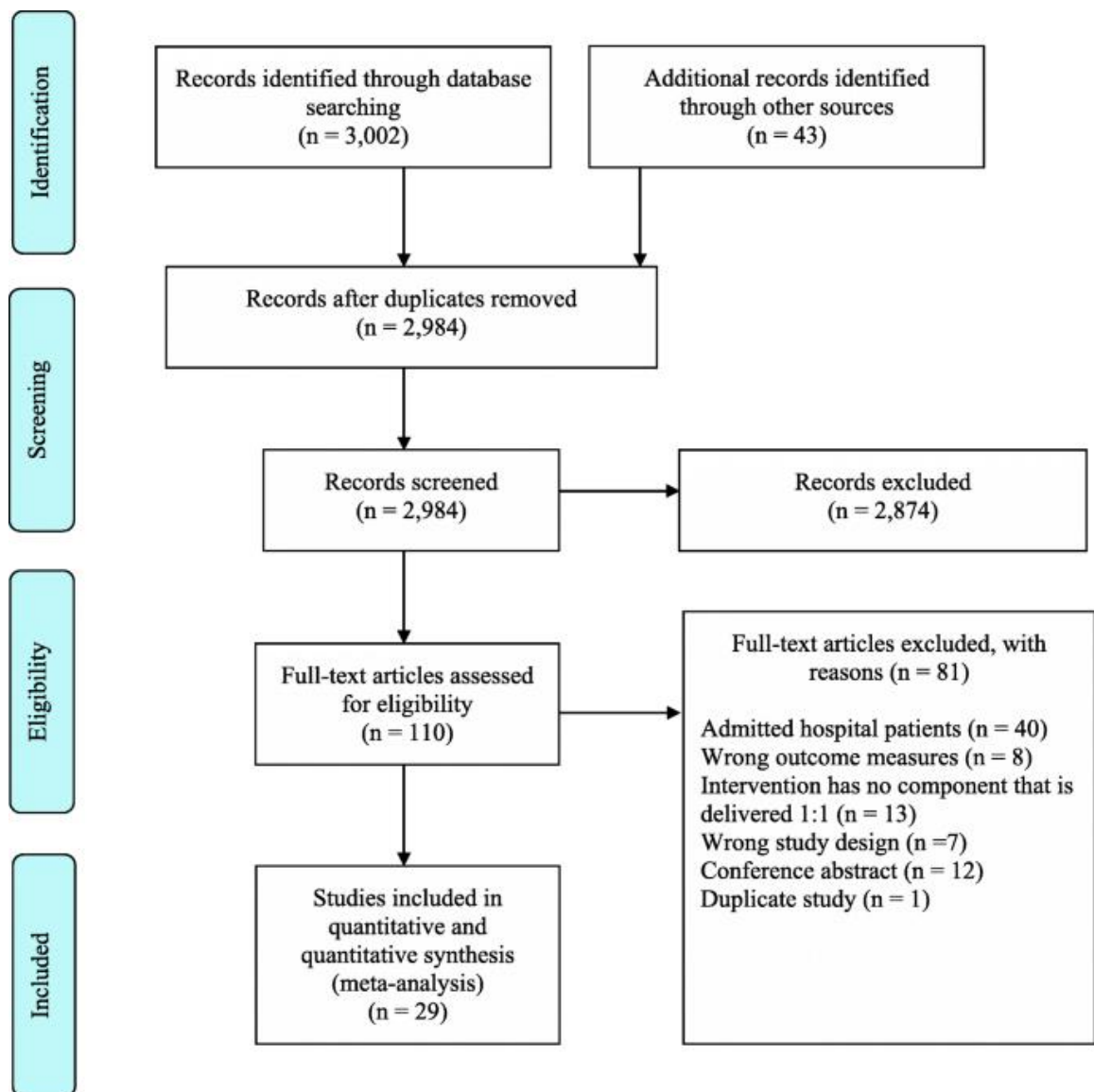


Figure 6.1: PRISMA

The intervention components used in the included studies varied. All of the included studies had at least one component that was delivered 1:1. The underlying theory informing the behaviour change intervention and the behaviour change techniques used are detailed in Table 6.1. For nine studies, the main focus of the intervention was on increasing PA (Alsaleh et al., 2016; Altenburg et al., 2014; Barrett et al., 2018a; Duscha et al., 2018; Goedendorp et al., 2010; Kim & Hwang, 2019; Kirk et al., 2004; Miura et al., 2004; Rimmer et al., 2009). Changes in anthropometrics was the primary focus in four studies (Fappa et al., 2012; Goodwin et al., 2014; O'Brien et al., 2018; Rimmer et al., 2009).

For PA outcomes, objective measurement was used in 8 studies using accelerometers, pedometers and objective measurement of exercise capacity (Altenburg et al., 2014; Barrett et al., 2018a; Cheung et al., 2019; Duscha et al., 2018; Elkoustaf et al., 2019; Freedland et al., 2015; Goedendorp et al., 2010; Miura et al., 2004). Self-reported instruments were used in the other 18 studies (Ahmadi et al., 2019; Alsaleh et al., 2016; Cakir & Pinar, 2006; Carrasquillo et al., 2017; Fappa et al., 2012; Freedland et al., 2015; Goodwin et al., 2014; Harting et al., 2006; Ijzelenberg et al., 2012; Kim & Hwang, 2019; Kirk et al., 2004; Lear et al., 2003; O'Brien et al., 2018; Oldroyd et al., 2006; Rimmer et al., 2009; Sone et al., 2010; Wattanakorn et al., 2013; Williams et al., 2018). The measures of anthropometrics in the studies included body mass (Aas et al., 2005; Alsaleh et al., 2016; Barrett et al., 2018a; Cakir & Pinar, 2006; Goodwin et al., 2014; O'Brien et al., 2018; Oldroyd et al., 2006; Rimmer et al., 2009; Williams et al., 2018), BMI (Aas et al., 2005; Ahmadi et al., 2019; Alsaleh et al., 2016; Barrett et al., 2018a; Cakir & Pinar, 2006; Carrasquillo et al., 2017; Dogru et al., 2019; Elkoustaf et al., 2019; Fappa et al., 2012; Lear et al., 2003; O'Brien et al., 2018; Oldroyd et al., 2006; Rimmer et al., 2009; Sone et al., 2010; Williams et al., 2018) and WC (Barrett et al., 2018a; Cakir & Pinar, 2006; Fappa et al., 2012; Lear et al., 2003; Oldroyd et al., 2006). Objective measurement of anthropometrics was used in 15 of the studies (Aas et al., 2005; Barrett et al., 2018a; Elkoustaf et al., 2019; Goodwin et al., 2014; Ijzelenberg et al., 2012; Kim & Hwang, 2019; Kosaka et al., 2005; Lear et al., 2003; Miura et al., 2004; O'Brien et al., 2018; Oldroyd et al., 2006; Rimmer et al., 2009; Sone et al., 2010; Wattanakorn et al., 2013; Williams et al., 2018), with self-reported methods used in the remaining 3 studies (Cheung et al., 2019; Dogru et al., 2019; Harting et al., 2006).

The professional background of the persons delivering the interventions included community health workers (Carrasquillo et al., 2017), dietitians (Cheung et al., 2019; Duscha et al., 2018; Fappa et al., 2012; Lear et al., 2003; Oldroyd et al., 2006; Sone et al., 2010), exercise counsellors (Altenburg et al., 2014; Miura et al., 2004), exercise scientists (Kirk et al., 2004; Lear et al., 2003), graduate level therapists (Freedland et al., 2015), health professionals (Aas et al., 2005), health educators (Duscha et al., 2018; Elkoustaf et al., 2019), lifestyle coaches (Goodwin et al., 2014), nurses (Ahmadi et al., 2019; Alsaleh et al., 2016; Cakir & Pinar, 2006; Harting et al., 2006; Sone et al., 2010), physicians (Ahmadi et al., 2019; Sone et al., 2010), physiotherapists (Barrett et al., 2018a; Oldroyd et al., 2006; Sone et al., 2010), psychologists (Ijzelenberg et al., 2012), researchers (Dogru et al., 2019; Wattanakorn et al., 2013; Williams et al., 2018), and therapists (Goedendorp et al., 2010).

Table 6.1 Characteristics of the included studies

Study	Country	Study Population	N (% male)	Mean age (SD)	Intervention delivery	Underlying Theory *	Behaviour change techniques *	Length of intervention	Length of follow-up	Outcome measures
Aas, 2005	Norway	Overweight patients with T2DM	38 (63%)	57 ± 6	14 x group education sessions; 2 x counselling sessions over 12 months, delivered in person; Group exercise sessions delivered twice a week	Not stated	Goal setting	12 months	12 months	Anthropometric: Objective measurement
Ahmadi, 2020	Germany & Denmark	Patients with cerebrovascular disease	2098 (33%)	67 ± 10	8 x individual counselling sessions over 24 months, delivered in person	MI	Feedback on behaviour; Feedback on outcome	2 years	3 years	Anthropometric: NS; Physical Activity: Self-reported
Alseleh, 2016	Jordan	Patients with CVD	156 (53%)	58 ± 9	6 x 15-20 minute counselling sessions over 6 months delivered via telephone; Educational text messages were provided 2 per week for first 3 months, and 1 per week for last 3 months	Social Cognitive Theory; Self-Efficacy Theory	Feedback; Goal setting; Self-monitoring; MI techniques			
Altenburg, 2014	Netherlands	Patients with COPD	155 (65%)	62 ± 4	5 x 30 minute counselling sessions over 12 weeks delivered in person	Goal setting and task performance	Goal setting; MI techniques	3 months	15 months	Physical Activity: Pedometer

Barrett, 2018	Australia	Insufficiently physically active adults	72 (25%)	53 ± 8	1 x group education session; 8 x 30-minute individual sessions over 12 weeks, delivered via telephone	Integrated MI and CBT	Goal setting, action planning, self-monitoring, personal feedback; relapse prevention	3 months	6 months	Anthropometric: Objective measurement; Physical Activity: Actigraph Accelerometer
Cakir, 2006	Turkey	Patients with hypertension	70 (58%)	52 ± 8	1 x 30-minute group lecture; 4 x 60-minute group education classes; 4 x individual counselling sessions, delivered in person	Not stated	Education; Stress management; Coping strategies	3 months	6 months	Anthropometric: NS; Physical Activity: Self-reported using Health Promoting Lifestyle Profile.
Carrasquillo, 2017	USA	Latinos with T2DM	300 (45%)	55 ± 7	4 x individual counselling sessions over 12 months, delivered in person; 12 x individual counselling sessions over 12 months, delivered via telephone; Intervention participants were invited to monthly educational groups and bimonthly exercise groups in parks located within a convenient proximity to their homes.	Not stated	MI skills; Education	12 months	12 months	Anthropometric: NS; Physical Activity: Self-reported using IPAQ

Cheung, 2019	Australia	Post-partum women with GD	60 (0%)	34 ± 4	2 x 30 minute individual counselling sessions over 6 months, delivered in person; 1 x follow-up session, up to 12-weeks post-partum, delivered via phone	Focused on the adoption phase of behaviour change	Not stated	6 months	6 months	Anthropometric: Self-reported; Physical Activity: Fitbit
Dogru, 2018	Turkey	Patients with T2DM	60 (32%)	NS	4 x 15-20m individual counselling sessions, delivered once a month for 4-months via telephone	MI	MI techniques	4 months	4 months	Anthropometric: Self-reported
Duscha, 2018	USA	Patients with CVD	25 (76%)	64 ± 8	24 x 30-60 minute telephone coaching sessions over 12 weeks delivered in person; In addition, coaches sent educational material via email and sent text messages to remind them to practice healthy lifestyle habits.	Health Coaching	Planning; Motivation	3 months	3 months	Physical Activity: Fitbit
Elkoustaf , 2019	USA	Patients with CVD	79 (57%)	66 ± 9	1 x groups introduction session; 18 x group sessions over 6 months; 1:1 individual coaching sessions, delivered via phone (unspecified number)	Wellness coaching	Not stated	9 months	9 months	Anthropometric: Objective measurement; Physical Activity: Objective functional measurement

Table 6.1 continued

Fappa, 2012	Greece	Patients with Metabolic Syndrome	87 (42%)	49 ± 12	7 x 60-minute counselling sessions over 6 months, delivered in person	Goal setting theory	Self-monitoring; Problem-solving techniques; Relapse prevention	6 months	6 months	Anthropometric: Objective measurement; Physical Activity: Self-reported using Harokopio PA Questionnaire
Freedland, 2015	USA	Patients with CVD	158 (54%)	56 ± 11	1 x 60-minute counselling sessions weekly for the first 6 months, delivered in person; 4 x 30-minute counselling sessions in the final 6 months, delivered via phone	CBT	Problem-solving; Goal setting	12 months	12 months	Physical Activity: Objective functional measures
Gade, 2014	Norway	Patients who were morbidly obese	102 (68%)	43 ± 10	4 x individual counselling session over 10 weeks delivered in person; 6 x individual counselling session over 10 weeks delivered via telephone	CBT	Psychoeducation; Homework; Self-monitoring; Relapse prevention	10 weeks	3 months	Anthropometric: NS
Goedendorp, 2010	Netherlands	Patients with cancer undergoing curative treatment	240 (34%)	57 ± 11	10 x 60-minute counselling sessions over 6 months, delivered in person	CBT	Restructuring of cognitions and beliefs; education; Behavioral instructions	6 months	6 months	Physical Activity: Actometer

Goodwin , 2014	Canada & USA	Overweight postmenopausal women	338 (0%)	61 ± 7	19 x 30-60m coaching sessions over 2 years delivered via telephone	Not stated	Lifestyle coaching; Motivation; Relapse prevention; Overcoming barriers	24 months	24 months	Anthropometric: Objective measurement; Physical Activity: Self-reported using IPAQ
Harting, 2006	Netherla nds	Patients with CVD risk	1270 (69%)	61 ± 9	6 x 30-45mins counselling sessions over 4 months, delivered in person	Health Counselling based on stage of behavioural change	Not stated	4 months	18 months	Anthropometric: Objective measurement; Physical Activity: Self-reported using a 'short validated survey'
Ijzelenbe rg, 2012	Netherla nds	Patients with CVD	146 (77%)	60 ± 11	22 x group exercise sessions over 6 months; 3 x individual exercise sessions over 6 months; 7 x group counselling sessions over 6 months; Individually counselling sessions over 6 months, delivered in person (unspecified number)	Lifestyle counselling	Motivation; Goal setting; Stress managemen t	6 months	6 months	Anthropometric: Objective measurement; Physical Activity: Self-reported using the SQUASH survey
Kim, 2019	Korea	Women at risk of CVD	58 (0%)	57 ± 6	12 x individual counselling session over 3 months, delivered in person; 1 x education text message delivered weekly for 3 months	Theory of planned behaviour; Theory of self- regulation	Education; goal setting, self- monitoring; feedback	3 months	3 months	Anthropometric: Objective measurement; Physical Activity: Self-reported using the IPAQ

Kirk, 2004	UK	Inactive patients with T2DM	70 (50%)	58 ± 8	2 x 30-minute individual counselling sessions over 9 months delivered in person; 4 x individual counselling sessions over 9 months delivered via telephone	Transtheoret ical model	Problem solving; Social support; Goal setting	9 months	12 months	Physical Activity: Self-reported
Kosaka, 2005	Japan	Men with IGT	458 (100%)	NS	6 x individual counselling sessions over 12 months, delivered in person	Not stated	Education; Self-monitoring; Social support	12 months	48 months	Anthropometric: Objective measurement.
Lear, 2003	Canada	Patients with CVD	302 (82%)	64 ± 9	6 x group exercise sessions over 12 months; 2 x lifestyle and risk-factor assessments; 6 x individual counselling sessions over 12 months, delivered in person	Counselling based on principles of behavioural change	Feedback (outcomes); Counsel on lifestyle behaviours and risk factors	12 months	12 months	Anthropometric: Objective measurement; Physical Activity: Self-reported using MLTPA questionnaire.
Miura, 2004	Japan	Patients with HTN	57 (51%)	62 ± 10	6 x individual counselling sessions over 6 months, delivered in person	Behaviour theory; Social cognitive theory	Not stated	6 months	6 months	Anthropometric: Objective measurement; Physical Activity: Actigraph Accelerometer
O'Brien, 2018	Australia	Overweight patients with OA	120 (36%)	62 ± 12	1 x brief group education session; 10 x individual counselling session over 6-months, delivered in person	MI; Self-regulation principles	Problem solving; Goal setting	6 months	6 months	Anthropometric: Objective measurement; Physical Activity: Self-reported using AAS

Oldroyd, 2006	UK	Patients with IGT	78 (50%)	58 ± 10	12 x 15-20 minutes individual counselling sessions over 24 months, delivered in person	Stages of change model of behaviour change	MI techniques; Action planning; Goal setting	24 months	24 months	Anthropometric: Objective measurement; Physical Activity: Self-reported using a 'lifestyle questionnaire'
Rimmer, 2009	USA	Women with morbid obesity & mobility issues	92 (0%)	59 ± 11	1 x individual counselling sessions each week over 6 months, delivered in person; Option to attend a monthly exercise support group.	Not stated	Goal Setting; Performance feedback; Overcoming barriers	6 months	6 months	Anthropometric: Objective measurement; Physical Activity: Self-reported using a 'lifestyle questionnaire'
Sone, 2010	Japan	Patients with T2DM	2033 (47%)	59 ± 7	1 x group education session; 2 x 15-minute individual counselling session monthly over 96 months, delivered in person	Not stated	Feedback on behaviour; Feedback on outcomes	96 months	96 months	Anthropometric: Objective measurement; Physical Activity: Self-reported using a 'lifestyle questionnaire'
Wattana korn, 2013	Thailand	Patients with T2DM and obesity	76 (16%)	50 ± 8	4 x 30-45 minute individual counselling sessions over 1 month, delivered in person	MI; Self-regulation theory.	Education; Goal setting; Discrepancy between current behavior and goal	1 month	4 months	Anthropometric: Objective measurement; Physical Activity: Self-reported using the Seven Day PA Recall survey

Williams, 2018	Australia	Overweight patients with chronic LBP	159 (41%)	57 ± 13	10 x individual counselling sessions over 6 months, delivered via telephone	SDT;	Setting graded tasks; Setting specific behaviour goals; Barrier identification Prompting self-monitoring of behaviour and outcomes	6 months	6 months	Anthropometric: Objective measurement; Physical Activity: Self-reported using the AAS
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AAS: Active Australia Survey; CBT: Cognitive Behaviour Therapy; COPD: Chronic Obstructive Pulmonary Disease; CVD: Cardiovascular disease; HTN: Hypertension; IGT: Impaired Glucose Tolerance; IPAQ: International Physical Activity Questionnaire; LMTA: Minnesota Leisure Time Physical Activity; MI: Motivational Interviewing; NS: Not stated; OA: Osteoarthritis; PA: Physical Activity; SDT: Self-determination Theory; SQUASH: Short QUestionnaire to ASsess Health enhancing physical activity; SR: Self-reported; T2DM: Type 2 Diabetes Mellitus.

**as defined by the authors of the studies*

6.4.2 Risk of bias

The risk of bias assessment for all studies is detailed in Figure 6.2. In trials involving behaviour change interventions the blinding of participants is extremely difficult to undertake. As a result, all studies were judged to have a high of risk of performance bias (lack of blinding of participants and personnel). Twelve studies were judged to have a high risk of attrition bias, and four studies were rated as unclear. Seven of the included studies reported blinding of the outcome assessors (detection bias), whereas the majority of the studies did not adequately report blinding of the outcome assessors ($n = 18$). Five of the included studies were judged as a high risk of selection bias due to the lack of detail regarding the allocation concealment. Fifteen studies were judged to have an unclear risk of bias due to the lack of information provided on the random sequence generation. The individual risk of bias assessment is included in Appendix 6.2.

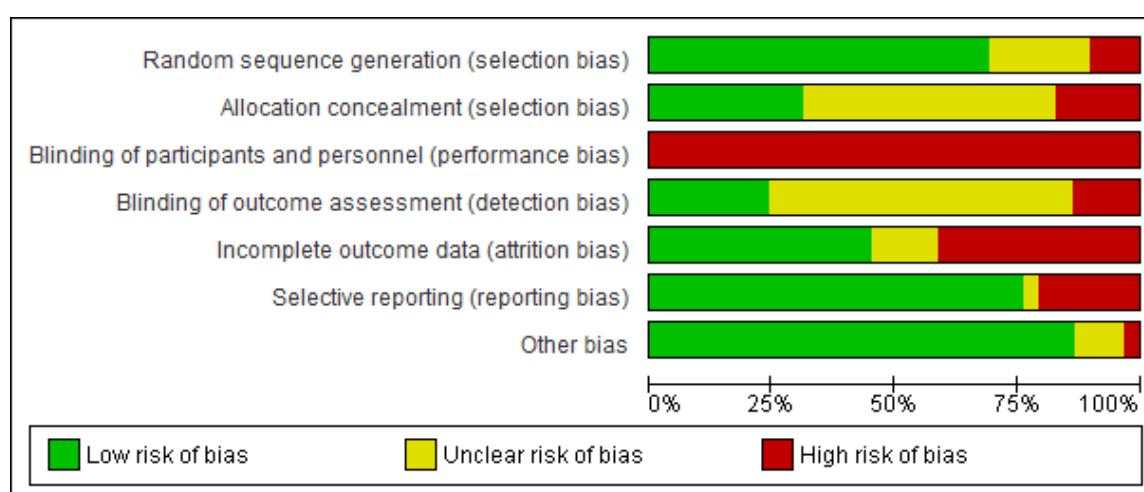


Figure 6.2: Risk of bias of included studies

6.4.3 GRADE Assessment

The overall certainty of evidence for the effectiveness of behaviour change interventions for changes in PA and anthropometrics in adults attending ambulatory hospital clinics is presented in Table 6.2. The certainty of evidence for follow-up duration and studies with low risk of bias overall are presented in Additional file 3. In addition, the GRADE quality assessments are presented in Appendix 6.4

Table 6.2 Summary of findings table

Outcome	Anticipated absolute effects* (95% CI)	No of participants (studies)	Certainty of the evidence (GRADE)	Informative statements
Physical activity	SMD 0.96 higher [0.45 to 1.48]	1454 (13 RCTs)	⊕○○○ VERY LOW ^{a,b,c,d,e}	Behaviour change interventions may increase physical activity in ambulatory hospital patients but the evidence is very uncertain.
Mass (kg)	MD -2.74 lower [-4.42 to -1.07]	872 (9 RCTs)	⊕○○○ VERY LOW ^{a,c,d,e,f}	The evidence is very uncertain about the effect of behaviour change interventions on changes in mass in ambulatory hospital patients.
BMI (kg/m ²)	MD -0.99 lower [-1.48 to -0.50]	4728 (15 RCTs)	⊕○○○ VERY LOW ^{a,b,c,d,e}	Behaviour change interventions may decrease BMI in ambulatory hospital patients but the evidence is very uncertain.
Waist C	MD -2.21 lower [-4.01, -0.42]	530 (5 RCTs)	⊕○○○ VERY LOW ^{a,c,d,f}	The evidence is very uncertain about the effect of behaviour change interventions on changes in waist circumference in ambulatory hospital patients.

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

Explanations

a. Large number of studies with high risk of bias; b. High heterogeneity; c. Differences in population and outcome measures; d. Wide confidence intervals; e. Asymmetry in the pattern of results; f. Moderate heterogeneity

6.4.4 Effects of behaviour change interventions on changes in physical activity

Thirteen of the 29 included studies provided PA data for the intervention and control groups at the post-intervention follow-up, and were included in the meta-analysis. The meta-analysis for behaviour change interventions versus standard care for change in PA demonstrated a significant effect in favour of the intervention (SMD: 0.96; 95% CI: 0.45 to 1.48, $p < 0.01$, Figure 6.3) (Alsaleh et al., 2016; Altenburg et al., 2014; Barrett et al., 2018a; Duscha et al., 2018; Elkoustaf et al., 2019; Freedland et al., 2015; Goedendorp et al., 2010; Goodwin et al., 2014; Kim & Hwang, 2019; Lear et al., 2003; O'Brien et al., 2018; Rimmer et al., 2009; Williams et al., 2018).

Subgroup analyses indicated that behaviour change interventions resulted in a significant increase in PA when the follow-up lasted for 6 months or less (SMD: 1.30; 95% CI: 0.53 to 2.07, $p < 0.01$, Figure 6.3) (Barrett et al., 2018a; Duscha et al., 2018; Goedendorp et al., 2010; Goodwin et al., 2014; Kim & Hwang, 2019; O'Brien et al., 2018; Rimmer et al., 2009; Williams et al., 2018). Behaviour change interventions with a follow-up of greater than 6 months demonstrated a non-significant effect in favour of the intervention (SMD: 0.43; 95% CI: -0.07 to 0.93, $p = 0.09$, Figure 6.3) (Alsaleh et al., 2016; Altenburg et al., 2014; Elkoustaf et al., 2019; Freedland et al., 2015; Lear et al., 2003). Behaviour change interventions may increase PA in ambulatory hospital patients but the evidence is very uncertain.

6.4.5 Effects of behaviour change interventions on changes in body mass

Nine studies provided data on changes in body mass for the experimental and control groups at the post-intervention follow-up, and were included in the meta-analysis. The meta-analysis for behaviour change interventions versus standard care for change in body mass demonstrated a significant effect in favour of the intervention (MD: -2.74; 95% CI: -4.42 to -1.07, $p < 0.01$, Figure 6.4) (Aas et al., 2005; Alsaleh et al., 2016; Barrett et al., 2018a; Cakir & Pinar, 2006; Goodwin et al., 2014; O'Brien et al., 2018; Oldroyd et al., 2006; Rimmer et al., 2009; Williams et al., 2018).

Subgroup analyses indicated that behaviour change interventions resulted in a significant change in body mass when follow-up measurement was 6 months and under (MD: -3.15; 95% CI: -5.96 to -0.34, $p = 0.03$, Figure 6.4), and greater than 6 months (MD: -2.37; 95% CI: -4.40 to -0.35, $p = 0.02$, Figure 6.4). The evidence is very uncertain about the effect of behaviour change

interventions on changes in mass in ambulatory hospital patients.

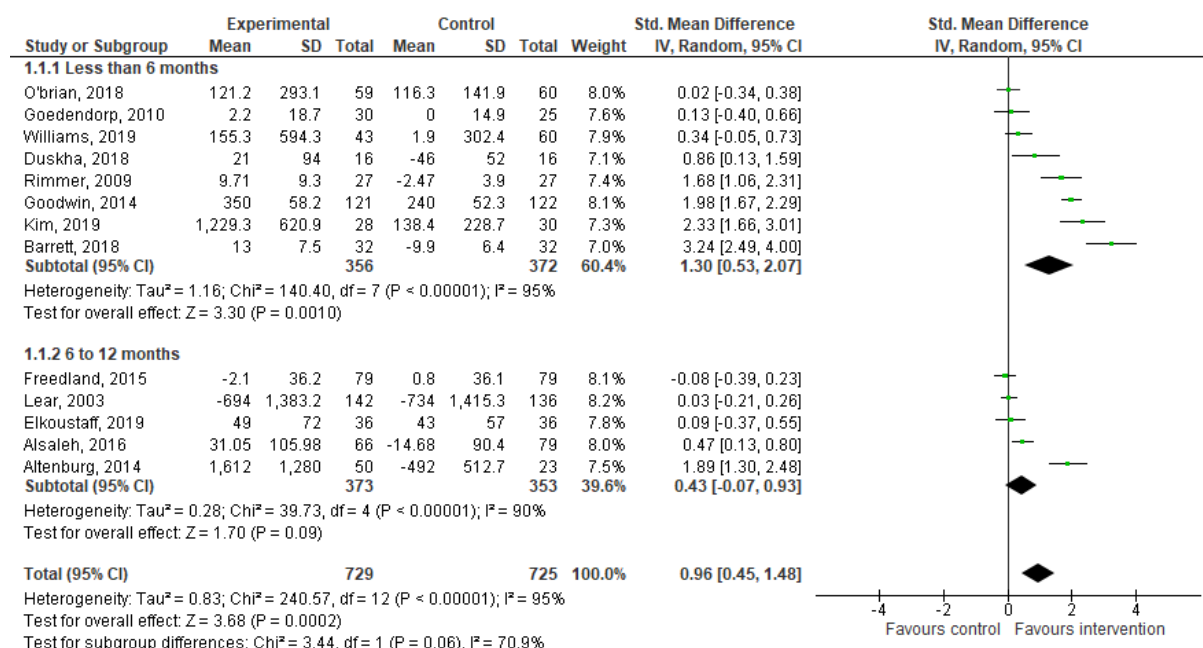


Figure 6.3: Meta-analysis investigating behavioural lifestyle interventions for changes in physical activity

6.4.6 Effects of behaviour change interventions on changes in BMI

Fifteen studies provided data on changes in BMI for the experimental and control groups at the post-intervention follow-up and were included in the meta-analysis. The meta-analysis for behaviour change interventions versus standard care for change in BMI demonstrated a significant effect in favour of the intervention (MD: -0.99; 95% CI: -1.48 to -0.50, $p < 0.01$, Figure 6.5)(Aas et al., 2005; Ahmadi et al., 2019; Alsaleh et al., 2016; Barrett et al., 2018a; Cakir & Pinar, 2006; Carrasquillo et al., 2017; Dogru et al., 2019; Elkoustaf et al., 2019; Fappa et al., 2012; Lear et al., 2003; O'Brien et al., 2018; Oldroyd et al., 2006; Rimmer et al., 2009; Sone et al., 2010; Williams et al., 2018).

The behaviour change interventions demonstrated significant changes in BMI when follow-up measurement was 6 months and under (MD: -1.55; 95% CI: -2.58 to -0.53, $p < 0.01$, Figure 6.5), and greater than 6 months (MD: -0.75; 95% CI: -1.35 to -0.16, $p = 0.01$, Figure 6.5). Behaviour change interventions may decrease BMI in ambulatory hospital patients but the evidence is very uncertain.

6.4.7 Effects of behaviour change interventions on changes in waist circumference

Five studies provided data on changes in WC for the experimental and control groups at the post-intervention follow-up and were included in the meta-analysis. The meta-analysis for behaviour change interventions versus standard care for change in WC demonstrated a significant effect in favour of the intervention (MD: -2.21; 95% CI: -4.01 to -0.42, $p=0.02$, Figure 6.6) (Barrett et al., 2018a; Cakir & Pinar, 2006; Fappa et al., 2012; Lear et al., 2003; Oldroyd et al., 2006).

The behaviour change interventions demonstrated significant changes in WC when follow-up measurement was 6 months and under (3 studies, 194 participants, MD, -3.91, 95% CI, -5.96 to -1.85, $p<0.01$, Figure 6.6), but not when the follow-up was greater than 6 months (MD: -0.66; 95% CI: -2.88 to 0.95, $p=0.42$, Figure 6.6). The evidence is very uncertain about the effect of behaviour change interventions on changes in WC in ambulatory hospital patients. The one exception was the analysis for WC change when follow-up measurement was 6 months and under, in which case the evidence suggests that behaviour change interventions results in a slight reduction in WC in ambulatory hospital patients.

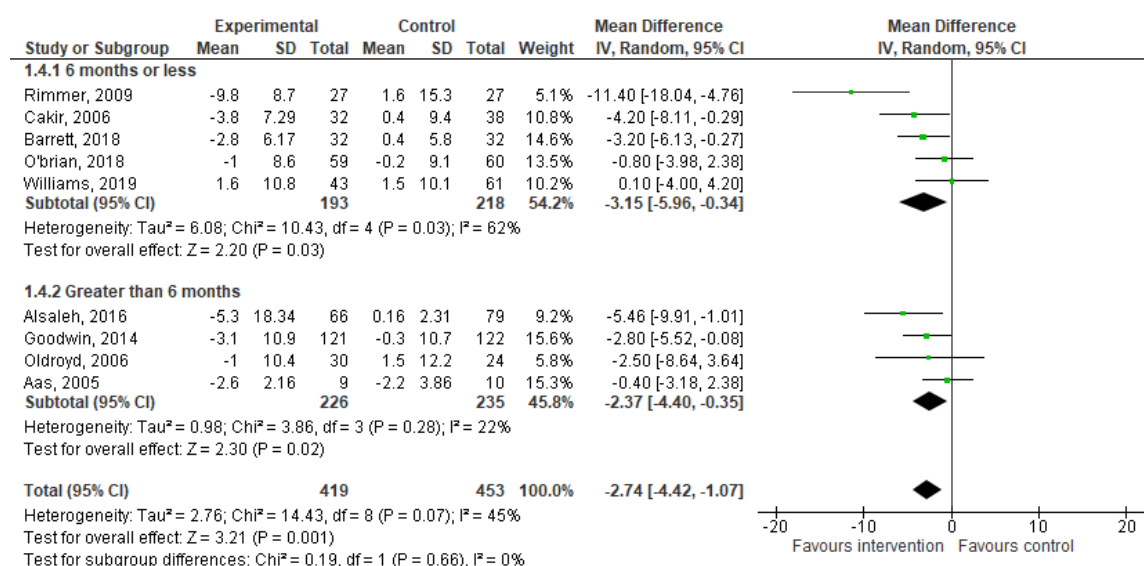


Figure 6.4: Meta-analysis investigating behavioural lifestyle interventions for changes in body mass

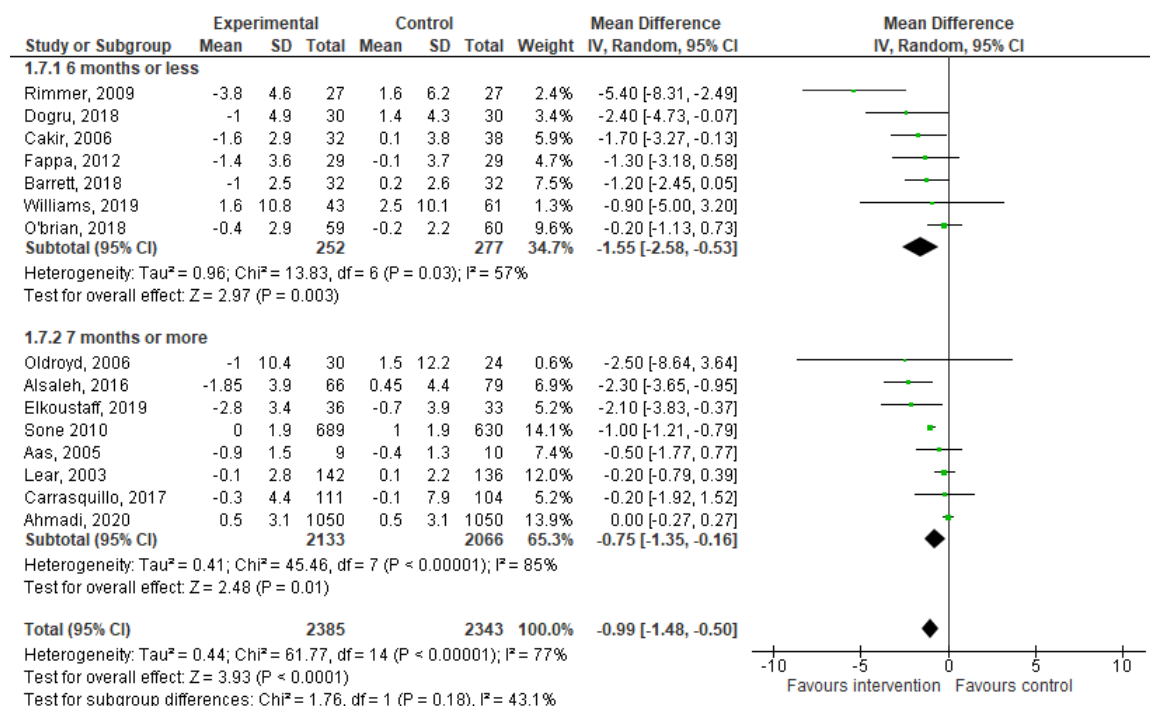


Figure 6.5: Meta-analysis investigating behavioural lifestyle interventions for changes in BMI

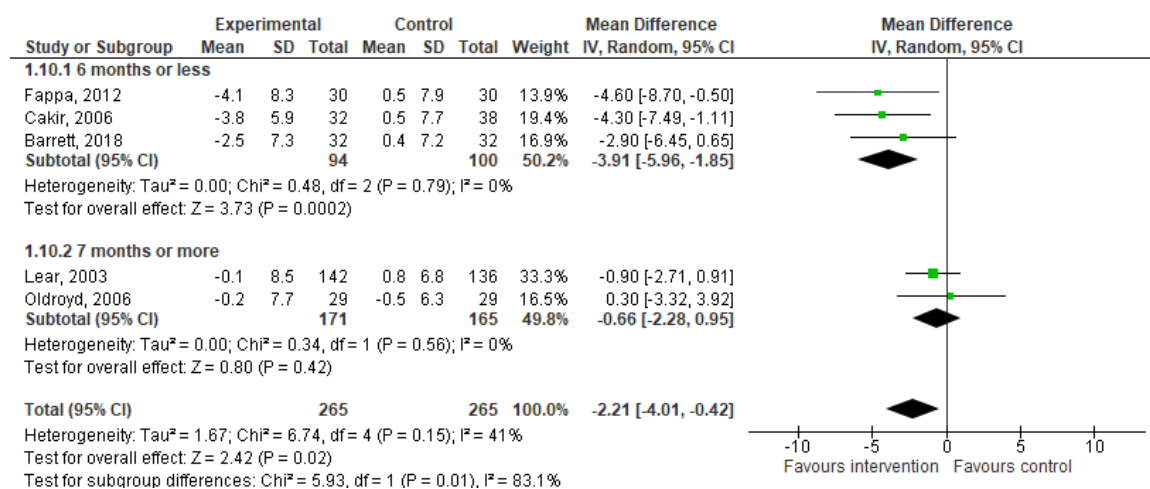


Figure 6.6: Meta-analysis investigating behavioural lifestyle interventions for changes in waist circumference

6.4.8 Sensitivity and subgroup analyses

Sensitivity analyses of the imputed correlation coefficients revealed that effect sizes remained statistically significant, and within the 95% confidence intervals at the imputed r of 0.8 (Table 6.3). Statistically significant changes remained for all outcomes at the inputted r of 1.0 and 0.5. In the low risk of bias analyses, behaviour change interventions exhibited significant beneficial effects in PA, body mass and BMI. Subgroup analyses demonstrated significant changes in body mass and BMI for individuals with cardiovascular diseases, and significant changes in BMI for individuals with type 2 diabetes/impaired glucose tolerance (Table 6.3). Larger effect sizes were observed for PA and BMI changes when objective measurement was used. Larger effect sizes were observed for changes in body mass when self-reported measurement was used. No subgroup analysis could be conducted on changes in WC between objective and self-reported measures.

Interventions with a short-term duration demonstrated significant effects for changes in PA, body mass, BMI and WC (Table 6.3). Interventions with a longer-term duration demonstrated significant effects for changes in body mass and BMI only (Table 6.3). In terms of intervention dose, interventions categorised as low intensity demonstrated significant effects for changes in body mass and WC (Table 6.3). Interventions categorised as medium intensity demonstrated significant effects for changes in PA and body mass (Table 6.3). Interventions categorised as high intensity demonstrated significant effects for changes in BMI (Table 6.3). No subgroup analysis could be conducted on changes in WC between dose of intervention. The moderate to high heterogeneity found in the primary meta-analyses was consistent across the majority of sensitivity and subgroup analyses.

Table 6.3 Sensitivity and subgroup analysis

Characteristics	No. of studies	No. of participants (intervention/control)	Mean change (95% confidence interval)	p-value	Heterogeneity
Physical activity					
Full analysis	13	1454 (729/725)	0.96 [0.45, 1.48]	<0.01	95%
Excluding high risk of bias overall	5	677 (340/337)	1.04 [0.15, 1.92]	0.02	96%
Objective measurement	4	224 (128/96)	1.52 [0.22, 2.81]	0.02	94%
Self-reported measurement	9	1230 (601/629)	0.74 [0.17, 1.30]	0.01	95%
r = 0.5	13	1454 (729/725)	0.72 [0.32, 1.13]	<0.01	92%
r = 1.0	13	1454 (729/725)	1.86 [0.96, 2.76]	<0.01	98%
Short-term intervention duration	4	235 (126/101)	2.08 [1.18, 2.97]	<0.01	86%
Long-term intervention duration	9	1227 (603/624)	0.51 [0.00, 1.02]	0.05	94%
Low intensity intervention	4	654 (337/317)	0.52 [-0.08, 1.12]	0.09	92%
Medium intensity intervention	6	642 (313/329)	1.31 [0.35, 2.28]	<0.01	96%
High intensity intervention	3	158 (79/79)	0.86 [-0.13, 1.85]	0.09	88%
Obese subgroup	4	619 (250/269)	1.00 [0.04, 2.04]	0.06	96%
CVD subgroup	5	675 (339/346)	0.19 [-0.07, 0.45]	0.15	61%

Characteristics	No. of studies	No. of participants (intervention/control)	Mean change (95% confidence interval)	p-value	Heterogeneity
Body Mass (kg)					
Full analysis	9	872 (419/453)	-2.74 [-4.42, -1.07]	<0.01	45%
Excluding high risk of bias overall	3	253 (123/130)	-2.59 [-4.49, -0.68]	<0.01	2%
Objective measurement	7	656 (321/336)	-2.25 [-4.16, -0.34]	0.02	48%
Self-reported measurement	2	226 (98/117)	-4.75 [-7.69, -1.81]	<0.01	0%
r = 0.5	9	872 (419/453)	-2.43 [-4.18, -0.69]	<0.01	0%
r = 1.0	9	872 (419/453)	-2.21 [-3.57, -0.84]	<0.01	98%
Short-term intervention duration	2	134 (64/70)	-3.56 [-5.91, -1.21]	<0.01	0%
Long-term intervention duration	7	738 (355/383)	-2.57 [-4.57, -0.38]	0.04	54%
Low intensity intervention	1	135 (66/79)	-5.46 [-9.91, -1.01]	0.02	N/A
Medium intensity intervention	5	411 (196/215)	-2.14 [-3.80, -0.49]	0.01	0%
High intensity intervention	3	316 (157/159)	-3.82 [-8.26, 0.63]	0.09	78%
Obese subgroup	4	520 (250/270)	-2.85 [-6.27, 0.56]	0.10	68%
CVD subgroup	2	215 (98/117)	-4.75 [-7.69, -1.81]	<0.01	0%
Diabetes/IGT subgroup	2	73 (39/34)	-0.76 [-3.29, 1.77]	0.56	0%

Table 6.3 continued

Characteristics	No. of studies	No. of participants (intervention/control)	Mean change (95% confidence interval)	p-value	Heterogeneity
BMI (kg/m²)					
Full analysis	15	4728 (2385/2343)	-0.99 [-1.48, -0.50]	<0.01	77%
Excluding high risk of bias overall	4	531 (265/266)	-0.57 [-1.20, 0.05]	0.07	37%
Objective measurement	11	2198 (1126/1072)	-0.99 [-1.52, -0.47]	<0.01	55%
Self-reported measurement	4	2530 (1259/1271)	-0.97 [-2.24, 0.29]	0.13	80%
r = 0.5	15	4728 (2385/2343)	-0.88 [-1.43, -0.34]	<0.01	59%
r = 1.0	15	4728 (2385/2343)	-1.38 [-1.88, -0.88]	<0.01	98%
Short-term intervention duration	2	134 (64/70)	-1.39 [-2.37, -0.42]	<0.01	0%
Long-term intervention duration	13	4594 (2321/2273)	-0.93 [-1.47, -0.39]	<0.01	80%
Low intensity intervention	4	698 (349/349)	-1.12 [-2.38, 0.15]	0.02	71%
Medium intensity intervention	7	2569 (1275/1269)	-0.56 [-1.17, 0.04]	0.07	39%
High intensity intervention	4	1461 (761/700)	-1.63 [-2.85, -0.42]	<0.01	72%
Obese subgroup	3	277 (129/148)	-2.08 [-5.56, 1.40]	0.24	82%
CVD subgroup	2	139 (68/71)	-1.88 [-3.04, -0.72]	<0.01	0%
Diabetes/IGT subgroup	6	1725 (898/827)	-0.99 [-1.19, -0.79]	<0.01	0%

Characteristics	No. of studies	No. of participants (intervention/control)	Mean change (95% confidence interval)	p-value	Heterogeneity
Waist Circumference					
Full analysis	5	530 (265/265)	-2.21 [-4.01, -0.42]	0.02	41%
Excluding high risk of bias overall	4	472 (236/236)	-2.34 [-4.49, -0.18]	0.03	45%
Objective measurement	4	460 (233/227)	-1.64 [-3.43, 0.15]	0.07	28%
Self-reported measurement	-	-	-	-	-
r = 0.5	5	530 (265/265)	-2.40 [-4.20, -0.59]	0.02	55%
r = 1.0	5	530 (265/265)	-2.61 [-4.23, -0.99]	<0.01	99%
Short-term intervention duration	2	134 (64/70)	-3.68 [-6.05, -1.30]	<0.01	0%
Long-term intervention duration	3	396 (201/195)	-1.40 [-3.68, 0.88]	0.23	41%
Low intensity intervention	1	278 (142/136)	-0.90 [-2.71, 0.91]	0.33	NA
Medium intensity intervention	4	252 (123/129)	-2.87 [-5.04, -0.70]	0.01	32%
High intensity intervention	-	-	-	-	-
CVD subgroup	2	348 (174/174)	-2.34 [-5.63, 0.96]	0.40	70%
Diabetes/IGT subgroup	2	118 (59/59)	-2.05 [-6.85, 2.75]	0.06	53%
Full analysis	5	530 (265/265)	-2.21 [-4.01, -0.42]	0.02	41%
Excluding high risk of bias overall	4	472 (236/236)	-2.34 [-4.49, -0.18]	0.03	45%

BMI: Body Mass Index; CVD: Cardiovascular Disease; IGT: Impaired Glucose Tolerance; NA: Not applicable

6.5 Discussion

This systematic review and meta-analyses provides evidence to support the use of behaviour change interventions for changes in PA and anthropometrics, initiated in the ambulatory hospital setting. The effect sizes were large for PA and moderate for anthropometric outcomes. These positive results are important as even small positive changes in PA and anthropometrics can deliver beneficial health benefits (Magkos et al., 2016). The moderate to large effect sizes demonstrated here are likely to deliver important health outcomes for ambulatory hospital patients (Magkos et al., 2016). Patients attending secondary care hospital clinics are more likely than the general population to have preventable chronic disease due to risk factors such as insufficient PA or overweight and obesity (Britt et al., 2008). Behaviour change interventions aimed at changes in PA and anthropometrics can go towards addressing health risks in this population (Dean & Söderlund, 2015). Nevertheless, the heterogeneity of results for all outcomes were moderate to high, and the GRADE assessment indicated that the evidence is very uncertain about the effect of behaviour change interventions on changes in PA and anthropometrics.

The meta-analysis of 13 randomised controlled trials for behaviour change interventions versus standard care for changes in PA demonstrated a significant large effect ($d = 0.96$) in favour of the intervention. The effect size is larger than those reported for PA interventions aiming to increase PA in older adults ($d = 0.26$) (Conn et al., 2002), chronically ill adults ($d = 0.45$) (Conn et al., 2008), healthy inactive adults ($d = 0.32$) (Howlett et al., 2019) and young and middle aged adults ($d = 0.32$) (Murray et al., 2017), but similar to that reported for behaviour change interventions targeting individuals at risk of cardiovascular disease (Lawlor et al., 2018; Sisti et al., 2018). The heterogeneity of both interventions and outcome measures, and the wide confidence intervals observed in the included studies contributed to the downgrading of the certainty about the results to very low. Despite the low level of certainty, it is encouraging to see a significant positive intervention effect across the diverse clinical populations with the included measures of PA participation.

When stratified by follow-up duration, the analyses of the effect of behaviour change interventions on changes in PA demonstrated a significant increase in PA when the follow-up lasted for 6 months sessions or less. Interventions with a follow-up of greater than 6 months demonstrated a non-significant effect in favour of the intervention. Samdal et al, (2017) found

that strategies such as motivational interviewing and goal setting are effective for assisting individuals in initiating PA behaviour change. Cognitive strategies such as problem solving and relapse prevention, on the other hand, promote changes in cognition, PA beliefs and influence behaviour change maintenance (Conn et al., 2003). Some of the most common strategies used in the studies included in this review were motivational interviewing, goal setting and general counselling/health coaching. These strategies are all acknowledged as important theoretical constructs for successful behaviour change (Sansano-Nadal et al., 2019); however, very few of the included studies clearly demarcated the use of strategies for PA maintenance, which could have impacted the effect size over the longer term follow-up. Only a small number of the included studies aimed to engage participants in existing community resources. Referrals to specific community programs, such as walking groups, strength training, and exercise for adults, have shown to have a positive effect on longer-term PA behaviour (Sansano-Nadal et al., 2019).

The meta-analyses of behaviour change interventions versus standard care for changes in anthropometric outcomes demonstrated significant positive effects in body mass, BMI and WC. Significant reductions in body mass, BMI and WC were found when the follow-up lasted for 6 months or less. Significant favourable changes in body mass and BMI were found when the follow-up lasted for greater than 6 months. The increasing prevalence of overweight and obesity over recent decades have been a major public health concern (Hruby & Hu, 2015). Overweight and obesity not only have a direct impact on morbidity, but contribute significantly towards further metabolic conditions, including insulin resistance, and type 2 diabetes (Piepoli et al., 2016). Behaviour change interventions, predominantly focusing on changes in PA and anthropometrics, are the central tenets of prevention programs needed to address overweight and obesity prevalence (Claas & Arnett, 2016). This review adds to the evidence base to support the use of behaviour change interventions to influence anthropometric changes in the ambulatory hospital setting.

The 2.74 kg (95% CI: -4.42 to -1.07) reduction in body mass found in this meta-analysis compares to similar reductions of 3.77 kg (95% CI: -4.55 to -2.99) (Mudaliar et al., 2016) and 2.12 kg (95% CI: -2.61 to -1.63) (Dunkley et al., 2014) found in behaviour change interventions for people at high risk for diabetes, and in nutritional education programs with a specific focus on weight loss (-2.07 kg; 95% CI: -1.52 to -2.62). The mean reduction in BMI of 0.99 kg/m² (95% CI: -1.48 to -0.50) found in this meta-analysis lies between the results from studies in secondary prevention behaviour change interventions, being -0.16 kg/m² (95% CI: -0.62 to

0.31) (Lawlor et al., 2018) and -1.80 kg/m^2 (95% CI: -2.62 to -0.99) (Sisti et al., 2018). The significant decrease in body mass and BMI over the longer-term follow-up is noteworthy given the mean age of the individuals in the analyses was 57. High proportions of middle aged individuals continue to gain weight each year (Williamson, 2004). The magnitude of improvements observed for changes in anthropometrics found in this review are likely to be clinically significant. Favourable changes in anthropometrics are associated with decreased risk for cardiovascular events (de Koning et al., 2007), type 2 diabetes (de Koning et al., 2007; Guh et al., 2009) and some cancers (Guh et al., 2009).

6.5.1 Implications for practice

Previous research has shown that experiencing health events such as hospital appointments can be the catalyst for changes in behaviour (Allender et al., 2008; Epiphaniou & Ogden, 2010). Ambulatory hospital patients represent an ideal population to intervene with to lessen the risk of developing serious health conditions. Incorporating the use of behaviour change interventions to increase PA in adults attending ambulatory hospital clinics aligns with the 2020 World Health Organization guidelines on PA and sedentary behaviour, which indicate the importance of PA for individuals with chronic conditions (World Health Organization, 2020). The current analysis incorporates a wide range of participant populations attending ambulatory hospital clinics, ranging from younger to older adults, as well as individuals with health risk factors to individuals with diagnosed chronic conditions. Hospital patients have indicated that they would like the healthcare system to provide guidance on behaviour change and healthy lifestyles (Leijon et al., 2010). Patients and public health at large might benefit from hospitals shifting their focus from predominantly curative care to a position of more holistic health promotion (Börjesson, 2013; Johnson & Baum, 2001).

Hospitals considering integrating behaviour change interventions into routine care may be encouraged that the delivery of short duration interventions results in statistically significant changes in PA, body mass, BMI and WC for hospital patients. The subgroup analyses provide some indication of the effect of intervention dose on PA and anthropometric changes, with significant changes observed for medium and high intensity interventions. Behaviour change interventions providing a higher number of sessions have been demonstrated to increase self-management skills, which may result in the significant outcomes observed for medium and high intensity interventions (Hofmann et al., 2012; Lundahl, et al., 2010). Another potential

advantage highlighted in this review was the range of health professionals that were able to deliver the behaviour change intervention. The diversity in clinicians might be advantageous when applying the intervention across differing sectors of the ambulatory hospital setting.

6.5.2 Limitations

This review has a number of limitations. The wide range of PA measures used within the interventions suggest that caution should be applied when interpreting the translatability of these results. Additionally, only 4 of the studies in the PA meta-analysis used objective measurement (Altenburg et al., 2014; Barrett et al., 2018a; Duscha et al., 2018; Goedendorp et al., 2010). Social desirability bias can lead to over-reporting of PA levels in self-reported measures (Randall & Fernandes, 1991). Although the majority of self-report questionnaires were based on valid and reliable measures, objective measurements have demonstrated a higher degree of reproducibility and validity for quantifying duration and intensity of PA (Corder et al., 2007). The effect size calculated from studies that used objectively measured PA was higher than the overall effect size observed for PA change (Table 6.3), which improves confidence in the effectiveness of behaviour change interventions to increase PA in ambulatory hospital settings.

The meta-analyses included studies with small sample sizes, and differences in the duration of interventions. The review also included studies with heterogeneous intervention components including differences in the frequency and duration of the sessions, and differences in the professionals providing the intervention. The heterogeneity also existed in the delivery format, including face-to-face, telephone calls and group counselling delivery. This heterogeneity makes the independent contribution of any of the intervention components, or a combination of these factors, difficult to establish, and partially explains the moderate to high heterogeneity of the meta-analyses. The moderate to high heterogeneity was reported in the majority of sub-group analyses, indicating a consistency of results across the examination of the different components of the interventions. Behaviour change interventions tend to exhibit both clinical and methodological diversity, often resulting in statistical heterogeneity within the meta-analyses (Higgins et al., 2003). Indeed, almost one third of meta-analyses have been shown to result in moderate to high heterogeneity (Higgins et al., 2003). Finally, only 5 of the 29 included studies reported on intervention fidelity (Ahmadi et al., 2019; Barrett et al., 2018a; Carrasquillo et al., 2017; Freedland et al., 2015; Goodwin et al., 2014). Without a clear measurement of fidelity,

reports of the effectiveness of interventions must be interpreted cautiously, as the possibility that the intervention was not delivered as intended cannot be ruled out (Howlett et al., 2019).

6.6 Conclusion

This review indicates that behaviour change interventions resulted in large improvements in PA, and moderate changes in anthropometric outcomes in adults presenting to ambulatory hospital clinics. The results indicate the value of behaviour change interventions for mitigating chronic disease risk factors, and supports the implementation of behaviour change interventions in ambulatory secondary care clinics. The heterogeneity in study populations, reported outcomes, and intervention components downgraded the certainty of the evidence, and prevents the drawing of firmer conclusions from the evidence provided. In order to improve the translation of these findings into clinical practice, future studies of behaviour change interventions should include clearly defined interventions and assessments of treatment fidelity.

Chapter 7

Surgeons and preventive health: a mixed methods study of current practice, beliefs and attitudes influencing health promotion activities amongst public hospital surgeons

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7.1 Abstract

Background: Little is known about the participation of surgeons in preventative health activities in the non-admitted hospital care setting. The aim of this study was to identify which preventive health activities surgeons practice and to explore their attitudes towards preventive health.

Methods: A mixed methods study was conducted using a sequential explanatory design. Quantitative results were obtained from a self-reported clinician survey (n=16) and a Generalized Estimating Equation was used to assess the relationship between dependent (preventive health practice) and independent (confidence and knowledge in preventive health practice, years of practice, and attitudinal factors) variables. Using a building approach to integration, results from the quantitative analyses informed design of the interview guide. Surgeons' beliefs and attitudes were explored using in-depth, semi structured interviews with a purposeful sample of surgeons (n=14). Responses were collected, independently coded and analysed using a qualitative descriptive approach.

Results: In accordance with a contiguous narrative approach to integration, the quantitative and qualitative findings are reported separately. The clinician survey found that the surgeons carried out preventive health activities at low levels. Preventive health advice was predominantly verbal in nature, and few surgeons provided written material or referred patients to additional services. The GEE analyses indicated that the following factors best predicted the tendency to undertake preventive health activities: years of clinical practice ($p=0.041$), and the perceived work priority placed on preventive health ($p=0.008$). Interviews generated four themes that influenced the tendency of surgeons to undertake preventive health activities: perceptions of their role in preventive health, perceived motivation of patients, hospital structure, and facilitating factors. In regards to enabling factors that are likely to increase preventive health practice, surgeons unanimously advocated for referral pathways into specialist behaviour change programs that they could facilitate within their relatively brief consulting time.

Conclusions: The findings suggests that the majority of public hospital surgeons engage in routine preventive health advice at a low level. The high volume of non-admitted surgical consultations undertaken annually, coupled with medium to high self-reported knowledge and confidence in addressing behavioural risk factors, support an increased involvement of surgeons in preventive health practice.

Keywords: Surgeons, Health promotion, Professional practice, Hospitals, Attitude

7.2 Background

Chronic non-communicable diseases are the foremost cause of preventable illness, disability and death worldwide (Alwan, 2011). Smoking, diet, and insufficient physical activity are the primary behavioural risk factors behind preventable chronic diseases (Bloom et al., 2012). The increased prevalence of chronic diseases has influenced demands on the health system (McPhail 2016), with chronic diseases leading to hospitalisations, long-term disability, and rehabilitation costs (Raghupathi et al., 2018). Accordingly, hospitals need to broaden their role from their primary focus on disease treatment towards a position of more integrated health promotion (Johnson & Baum, 2001).

Hospitals are well situated to play a key role in the delivery of preventive health (Aiello et al., 1990; Johnson & Baum, 2001; McHugh et al., 2010; Ziglio et al., 2011). As hospital clinicians, surgeons have an important role in advocating for behaviour change for patients with, or at risk of, chronic disease (Royal College of Surgeons, 2012). Due to their extensive medical training and specialisation, surgeons are regarded as reliable sources of medical advice, extending beyond their expertise in surgical care (Ziglio et al., 2011). Surgery is considered a major life event (Cohen & Lazarus, 1973), and individuals are more susceptible to behaviour change in the face of such an event (Allender et al., 2008). Surgeons undertake high volumes of non-admitted consultations annually, which provides opportunities to address preventive health directly during routine clinical interactions (Zeev et al., 2017). Surgeons therefore, have potential to be influential in the promotion of lifestyle behaviour change (Jones et al., 2004). In Australian hospitals alone, over 2.2 million elective admissions involving surgery were undertaken in 2015–2016 (Australian Institute of Health and Welfare, 2017; Keyworth et al., 2018). In spite of this, there is a scarcity of research investigating preventive health practice in non-admitted surgical practice.

Studies examining lifestyle risk management (smoking cessation and/or physical activity promotion) delivered by hospital doctors have consisted largely of cross-sectional studies of self-reported practice (Daley et al., 2008; Hardcastle et al., 2018; Jones et al., 2004; Sheill et al., 2018; Williams et al., 2015). Only two of these studies, which both focused on oncology patients, included hospital surgeons (Daley et al., 2008; Williams et al., 2015). Findings in all studies demonstrated low rates of preventive health interventions (Daley et al., 2008; Hardcastle et al., 2018; Jones et al., 2004; Sheill et al., 2018; Williams et al., 2000; Williams et

al., 2015). In addition, hospital doctors report low levels of confidence in their ability to assist patients with health behaviour change (Hardcastle et al., 2018; Williams et al., 2000) and uncertainty over the effectiveness of behaviour change advice (Daley et al., 2008). In the studies (Daley et al., 2008; Hardcastle et al., 2018; Jones et al., 2004; Sheill et al., 2018; Williams et al., 2000; Williams et al., 2015), no interviews were carried out to probe the survey findings and understand the beliefs and attitudes that might explain the low levels of preventive health interventions undertaken.

Given the prevalence of chronic diseases and the necessity for hospitals to move to a position of more integrated preventive health practice (Aiello et al., 1990; Groene et al., 2005; Johnson & Baum, 2001; McHugh et al., 2010), it is important to gain insights from hospital surgeons due to the influence they may exert on patient behaviour (Jones et al., 2004). Surgeons are clinical leaders with responsibility for clinical performance as well as clinical policy and practice (Grove et al., 2016). As such, surgeons maintain autonomy over practice standards (Grove et al., 2016), and little is known about the opinions this professional group concerning preventive health practice. The depth of insight gained from the study of surgeons might offer distinctive perspectives on current preventive health practice, and the attitudes and beliefs of these highly professionalised clinicians relating to implementing preventive health into non-admitted surgical practice. Therefore, the aim of this study was to identify which preventive health activities surgeons carry out in non-admitted public hospital clinics, to explore the attitudes of the profession towards preventive health practice.

7.3 Methods

This study used a mixed-methods design to identify which preventive health activities surgeons carry out in non-admitted public hospital clinics and to explore the attitudes of the profession towards preventive health practice. We integrated mixed-methods at the design level through the use of a sequential explanatory design (Fetters et al., 2013; Ivankova et al., 2006; McCrudden & McTigue, 2018). This two-stage design began with a self-reported clinician survey investigating surgeons' actual participation in preventive health activities (Figure 7.1). This was followed by the subsequent collection and analysis of in-depth interviews with surgeons to gain insight into the attitudes of surgeons towards undertaking preventive health activities in non-admitted settings. The protocol for this study has been detailed previously (Barrett et al., 2018c). Ethical approval for the study was gained from the human research and ethics

committee of the participating hospital and the associated university.

7.3.1 Participants

This study targeted all surgeons and their registrars consulting in an elective outpatient clinic of a major tertiary hospital in regional Australia. Participation was offered to all practicing surgeons (general and orthopaedic; n=20) and registrars (n=11) between June 2017 and August 2018. The recruitment strategy has been described elsewhere (Barrett et al., 2018c). In brief, an email containing the link to the clinician survey was sent to all potential participants by their head of department. Participants were informed prior to commencing the survey that if they continued to complete the survey they agreed to provide informed consent. For the interviews, surgeons were approached individually, in the non-admitted clinic by a project officer to discuss participation. Informed consent was sought from all participants prior to completing the interview.

7.3.2 Clinician Survey

The clinician survey collected detail on surgical practice, including surgical speciality, and number of years of practice. Participants were asked to self-report on proportions of patients who they screened for behavioural risk factors (smoking, diet, physical activity and alcohol), provided verbal and/or written advice and referred to other services for support in changing risk factors (Appendix 7.3). The survey measured surgeons' knowledge and confidence in screening and managing risk factors, as well as attitudinal measures relating to the delivery of preventive health interventions in surgical care. All survey items were measured on a 5-point Likert scale. Data were analysed using IBM SPSS Statistics for Windows (Version 25; IBM Corp., USA).

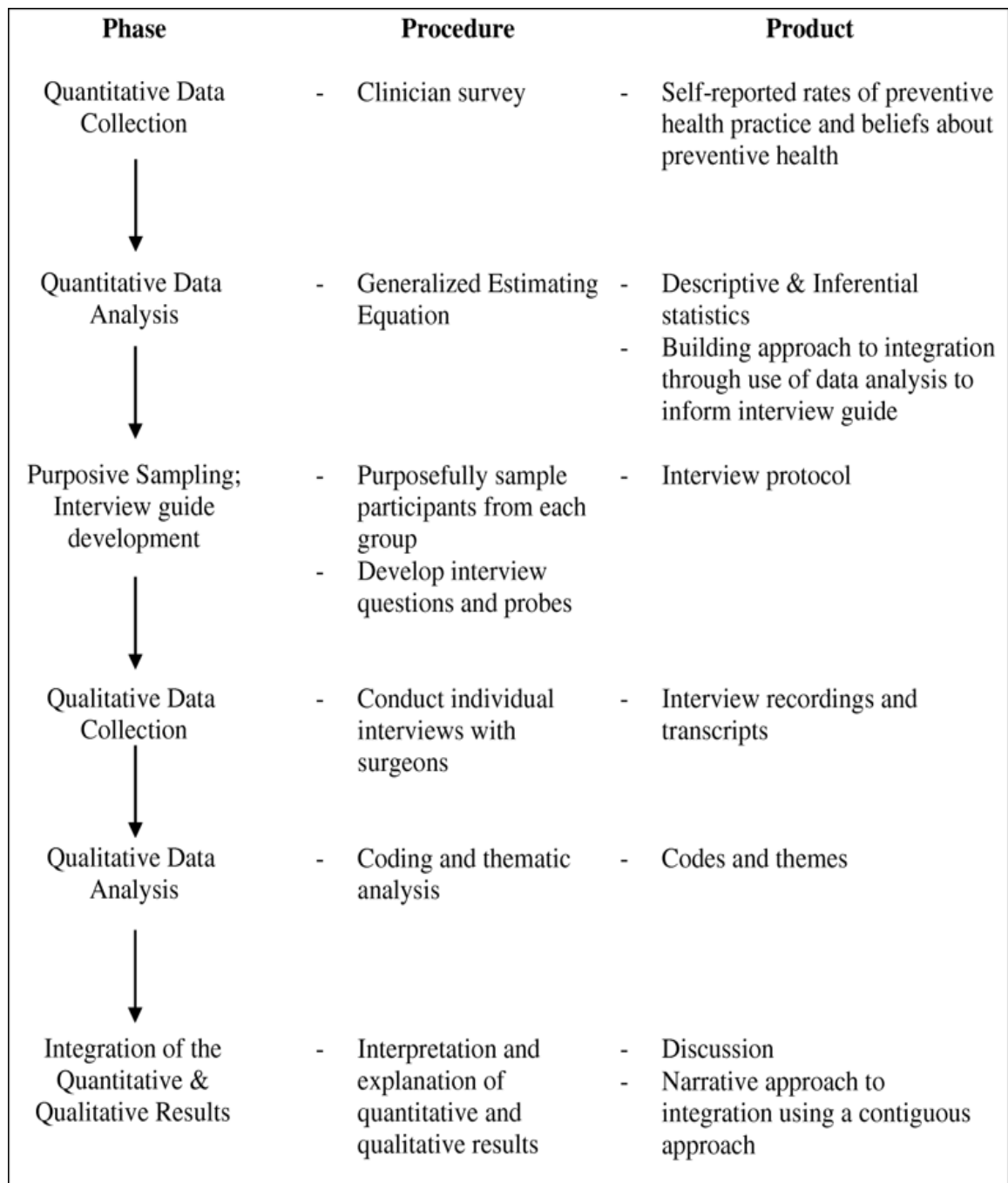


Figure 7.1: Mixed-methods integration flow diagram

7.3.3 Semi-structured interviews

Following analysis of the clinician survey, face-to-face interviews were conducted with a purposeful sample of surgeons and registrars (n=14). Maximum variation sampling was used to ensure that a heterogeneous sample was recruited, to capture the perspective of orthopaedic and general surgeons and registrars to search for variation in perspectives (Palinkas et al., 2015). In total, 21 surgeons were asked to participate in the interviews, with a participation rate of 71%. We employed a building approach to mixed-methods integration, using the results from our quantitative analyses to inform the data collection of the qualitative component (Fetters et al., 2013; McCrudden & McTigue, 2018). The quantitative data was used to develop the interview guide (Table 7.1). Interviews were conducted by the first author and covered issues related to preventive health practice into routine practice and the attitudes of surgeons towards preventive health practice. All interviews were audio-taped with participants' permission and transcribed verbatim by the first author for thematic analysis (Sandelowski, 2000). Field notes were used to supplement the audio and transcripts to inform the iterative development of interview guides and question related probes for subsequent interviews.

7.3.4 Analyses

From the clinician survey, surgeons' implementation rates in preventive health activities (assessing risk factors, providing information; making referrals) were classified as high, medium or low (Laws et al., 2008). High implementation rates defined screening and/or intervention scores in the fourth quartile for responding surgeons. Low implementation rates defined screening and/or intervention scores less than or equal to the first quartile for responding surgeons. Quartile cut-off points are also included for surgeon confidence, knowledge, and attitudinal measures.

Table 7.1: Interview guide for clinician interviews with rationale for questions

Domain	Relevant quantitative findings	Interview question	Rationale for the question
Overview of clinical practice	<ul style="list-style-type: none"> NA 	<ol style="list-style-type: none"> Using a category 2 or 3 patient (expected wait to surgery between 90 and 365 days) as an example, can you please give an overview of a routine clinical consult? We are particularly interested in the steps between telling the patient they need the procedure and the end of the consultation- do you spend any time discussing what the patient could do in this waiting time? 	<ul style="list-style-type: none"> Elicit from the surgeons, in their own words, what constitutes routine practice in the non-admitted setting. Elicit from the surgeons whether preventive health discussions arise with patients in non-admitted practice.
Exploration of survey results	<ul style="list-style-type: none"> How important surgeons felt it was to address lifestyle changes with patients was independently associated with preventive health practice rates ($p=0.006$). This factor did not contribute to the model that best predicted preventive health practice ($p=0.056$). Independent associations were observed between with preventive health practice rates and surgeons' confidence ($p=0.008$) and knowledge ($p=0.029$) at addressing lifestyle changes. Neither confidence ($p=0.184$) and knowledge ($p=0.543$) contributed to the model that best predicted preventive health practice. 	<ol style="list-style-type: none"> From the clinical survey of practicing surgeons, the vast majority of surgeons indicated that addressing behavioural risk factors is important for health. At the same time however, the rates of implementation amongst the sample was low to medium. Have you any thoughts about this? Again from the survey, surgeons indicated medium to high levels of confidence/knowledge in addressing behavioural risk factors; what we found interesting was, despite this perceived confidence/knowledge, a very low number of respondents carried out preventive health interventions. Have you any thoughts about this? 	<ul style="list-style-type: none"> Elicit opinion from surgeons as to why, despite acknowledging the importance of addressing lifestyle changes with patients, preventive health practice was predominantly undertaken at low levels. Elicit opinions from surgeons as to why, despite reporting medium to high levels of confidence/knowledge in addressing behavioural risk factors, preventive health practice is predominantly undertaken at low levels.

Domain	Relevant quantitative findings	Interview question	Rationale for the question
Attitudes to preventive health	<ul style="list-style-type: none"> How much of a work priority surgeons place on addressing lifestyle changes with patients significantly predicted tendency to undertake preventive health interventions ($\beta = 1.22$, $p = 0.008$). The GEE model found two factors that together, significantly predicted tendency to undertake preventive health interventions, including number of years of clinical practice ($\beta = 0.26$, $p = 0.041$) and work priority ($\beta = 1.22$, $p = 0.008$). 	1. Do you think it is an appropriate part of your job to be spending time with patients on preventive health?	○ Elicit opinions from surgeons as to the association between work priority and preventive health practice.
		1. What are some reasons for deciding to engage in preventive health practice with your patients?	○ Elicit rationale from surgeons for their engagement in preventive health.
		2. On the other side, what are some reasons for deciding not to engage in preventive health practice with your patients?	○ Elicit rationale from surgeons for their non-engagement in preventive health.
Working environment	<ul style="list-style-type: none"> NA 	1. Time is a known barrier to undertaking health promotion in routine work, this is well established. The Specialist Clinic is extremely busy, and unlikely to see changes in time demands. At the same time public health institutions continue to call on doctors to do more. In the absence of more time, what can be done to facilitate this?	○ Elicit opinions from surgeons in relation to the call for hospitals to integrated preventive health into routine care.

Domain	Relevant quantitative findings	Interview question	Rationale for the question
Future directions	<ul style="list-style-type: none"> N/A 	<ol style="list-style-type: none"> What might need to be done differently in order to increase delivery of health promotion interventions? We are particularly interested in the steps between telling the patient they need the procedure and the end of the consultation- do you spend any time discussing what the patient could do in this waiting time? 	<ul style="list-style-type: none"> Elicit opinions from surgeons as to the potential to change preventive health practice rates in non-admitted settings. Elicit from the surgeons whether preventive health discussions arise with patients in non-admitted practice.
Exploration of survey results	<ul style="list-style-type: none"> How important surgeons felt it was to address lifestyle changes with patients was independently associated with preventive health practice rates ($p=0.006$). This factor did not contribute to the model that best predicted preventive health practice ($p=0.056$). 	<ol style="list-style-type: none"> From the clinical survey of practicing surgeons, the vast majority of surgeons indicated that addressing behavioural risk factors is important for health. At the same time however, the rates of implementation amongst the sample was low to medium. Have you any thoughts about this? 	<ul style="list-style-type: none"> Elicit opinion from surgeons as to why, despite acknowledging the importance of addressing lifestyle changes with patients, preventive health practice was predominantly undertaken at low levels.

Spearman's rank-order correlations were performed to assess the relationships between the dependent variables [preventive health practice] and independent variables [confidence and knowledge in preventive health practice, years of practice, and attitudinal factors]. Following this, a Generalized Estimating Equation (GEE) was used to model the associations between independent variables and preventive health practice (Ballinger, 2004). The GEE indicates which variables, when added to the model, best predict preventive health practice. Goodness of fit for the GEE model was assessed using the quasi-likelihood under independence model criterion (QIC) (Pan, 2001). The QIC is a statistic for model selection for GEE models, where lower values indicate better model fit to the data (Pan, 2001).

Data from in-depth interviews were collected and analysed concurrently. Qualitative description was used as the theoretical framework for the qualitative component (Sandelowski, 2000). Qualitative description provides straightforward, rich descriptions of experiences or events in a language similar to the participant's own (Sandelowski, 2000). Transcribed transcripts were analysed and coded line-by-line using the qualitative data analysis software NVivo 10.0 (QSR International, Cambridge, MA, USA). Codes were derived from data rather than being determined beforehand, and a coding scheme was applied to the interview text. Coded text was grouped into more general categories, which were reviewed by the research team and merged into themes to help explain the factors that influence surgeons' participation in health promotion activities (Saldaña, 2015; Strauss & Corbin, 1990). Two authors (S Barrett and AS) independently coded and analysed the data. To improve reliability and to reach consensus, two additional authors (MK and S Begg) reviewed the codebook and samples of transcripts. No new information was found between the twelfth and thirteenth interview, providing preliminary indication that data saturation was reached by the twelfth interview (Tønnesen et al., 2009). To ensure data saturation, one additional participant was interviewed. As this additional interview did not bring forward new information, data saturation was deemed to have occurred (Tønnesen et al., 2009), and interviewing was ceased.

7.4 Results

In total, 16 surgeons completed the survey (response rate of 51%) and interviews were carried out with 14 surgeons (participation rate 71%). The surgeons that participated in the interviews were broadly representative of those completing the survey (Table 7.2). The majority of surgeons worked full-time, and three quarters of surgeons in both the survey and interviews

were male. The results of the quantitative and qualitative components are reported on in different sections, utilising a contiguous narrative approach to integration of mixed-methods data (Fetters et al., 2013).

7.4.1 Clinician Survey

Table 7.3 provides preventive health practice rates and attitudes to preventive health amongst the responding surgeons. Overall, all surgeons carried out some preventive health activities, however the majority of surgeons did this at low levels. Asking patients about behavioural risk factors and providing verbal advice were the most undertaken preventive health interventions. Only 2 surgeons reported providing patients with written advice, and 3 surgeons reported having referred patients to other service providers for help with risk factor management. The surgeons self-reported knowledge and confidence in addressing behavioural risk factors was medium to high.

Table 7.2 Characteristics of the surgeons participating in the survey and interview

	Survey (n=16)	Interviews (n=14)
Surgeon Type, No (%)		
General surgeon	5 (31%)	6 (43%)
Orthopaedic surgeon	4 (25%)	4 (29%)
Registrar- general surgery	4 (25%)	3 (21%)
Registrar- orthopaedic surgery	3 (19%)	1 (7%)
Gender, No. (%)		
Female	4 (25%)	5 (36%)
Male	12 (75%)	9 (64%)
Employment, No (%)		
Full time	15 (93%)	14 (100%)
Male	12 (75%)	9 (64%)

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In the Spearman's correlation, significant positive correlations were observed between preventive health practice and clinician confidence ($r = 0.635, p = 0.008$), knowledge ($r = 0.544, p = 0.029$), perceived effectiveness of preventive health practice ($r = 0.710, p = 0.002$), the importance placed on addressing lifestyle changes ($r = 0.655, p = 0.006$), and the work priority placed on addressing lifestyle changes with patients ($r = 0.644, p = 0.007$). The GEE model found two factors that together, significantly predicted tendency to undertake preventive health interventions, including number of years of clinical practice ($\beta = 0.26, p = 0.041$) and work priority ($\beta = 1.22, p = 0.008$) (Table 7.4). The addition of work priority to the model decreased the QIC from 1063 to 736, indicating a more robust fit of data to the model. The lower QIC indicates that the model, with the addition of work priority, contains the best subset of explanatory variables to predict the surgeons undertaking of preventive health interventions.

7.4.3 In-depth interviews

Four themes were found to influence surgeons' preventive health practice. The themes, which all centred around the clinical consultation, included: surgeon's perceptions of their role in preventive health, perceived motivation of patients, the hospital structure, and facilitating factors. The codes, categories and themes are described in Appendix 7.2. These themes are expanded upon below using verbatim quotes from participants for illustrative purposes. Additional verbatim quotes for each theme are provided in Appendix 7.3.

7.4.4 The role of the surgeon in preventive health

All surgeons considered preventive health to be important for health. However, the perceived importance did not translate to high rates of preventive health practice. Surgeons who reported undertaking behaviour change discussions with patients reported that their role was to address behaviour change in relation to specific surgical practice, rather than a holistic wellbeing perspective; for example, smoking cessation was advocated to decrease the risk of infection.

“I’ll be telling them to either cut back on the smoking or try to aim quitting if it’s possible, at least for the surgery, and then after that if they can continue then great; if they can’t then at least for the time period for the surgery if they can do that that would be great” (Surgeon 3).

Some surgeons felt that behaviour change is not part of the role of the surgeon; that surgeons are clinical specialists who have a priority to treat specialist problems, thereby delivering services that no other clinician can, as suggested by the following quote:

“So we know what you need to do, but you know, we are trained to do surgery. And other people can’t do that, and that’s what we need to do. If you make us do all of this other stuff, then it’s not a particularly effective use of surgeon time” (Surgeon 9).

Viewing themselves as specialist practitioners, surgeons believe their role is best suited to focusing on presenting conditions, rather than taking a holistic approach to the person.

“Probably because surgeons don’t feel that it is their job to do that; they are referred a patient for a [specific problem], and they are concentrating on treating that.... they probably zoom in on that pathology rather than looking at the patient as a whole” (Surgeon 13).

7.4.5 The motivation of the patients

Patient motivation, and the acceptance of behaviour change interventions by the patient was another important theme. The surgeons described patient acceptance of lifestyle interventions as an important factor that influenced the surgeon’s participation in preventive health practice. Consistent with existing literature (Haynes, 2008), some surgeons reported that patients are not

opposed to surgeons raising lifestyle discussions during consultations. This advice however, doesn't necessarily translate to actual behaviour change, with surgeons reporting that many patients maintain their behaviours despite the provision of advice.

"I think a good percentage of patients, you say 'you need to quit smoking or if you don't, your risk of infection is higher' and they are like, 'ah yeah, whatever' and you see plenty where you have no response" (Surgeon 1).

Surgeons highlighted that the persistence of risky health behaviour by patients despite health advice was a source of frustration, which might decrease the likelihood of engaging in preventive health activities in the non-admitted setting.

"And we say 'you have to cut down smoking' and every time they come back to clinic and we go 'have you cut down on smoking?' and they are still smoking. I think after a while, you just... you are talking to a brick wall" (Surgeon 3).

"I mean smoking we all know in particular when it comes to wound healing and infection, that's something we all know is not good. However, I don't always advise them to stop because, I don't know, I often don't think they will stop" (Surgeon 6).

The surgeons reported that not all patients are appreciative of discussing their lifestyles during surgical consultations. In the surgeons' experience, many patients attend the consultation seeking specialist advice relating to a particular issue, and are not seeking generalist advice about health behaviours. Previous experience of negative patient reactions may contribute to the surgeons' narrowing the focus of the consultation to that of the presenting condition only.

"... most people don't want to talk to a surgeon in an outpatient clinic about their overall wellbeing. They have come here for a problem, so it [consultation] needs to be problem-focused" (Surgeon 12).

Table 7.3 Self-reported rates of preventive health practice and attitudes to preventive health amongst survey respondents (N = 16)

Variable	High*	Medium*	Low*	No Activity**
	Number (proportion)			
<i>Preventive health activities</i>				
Overall preventive health practice rates	1 (6%)	3 (19%)	12 (75%)	0
Asking patients about behavioural risk factors	2 (12%)	4 (25%)	10 (63%)	0
Assess patients readiness to change their behaviour	0	5 (31%)	9 (56%)	2 (12%)
Provide verbal advice to patients	2 (12%)	4 (25%)	10 (63%)	0
Provide written advice to patients	0	0	2 (12%)	14 (88%)
Refer patients to other service for help in managing their risk factor	0	0	3 (19%)	13 (82%)
<i>Attitudes to preventive health</i>				
Confidence in addressing lifestyle changes	6 (38%)	9 (56%)	1 (6%)	-
Knowledge in addressing lifestyle changes	5 (31%)	10 (63%)	1 (6%)	-
How effective you think your advice is in helping clients with lifestyle changes	0	10 (63%)	6 (37%)	-
Patients find it agreeable for me to raise lifestyle changes as part of consultation	0	12 (75%)	4 (25%)	-
How important lifestyle changes are for health	11 (69%)	5 (31%)	0	-
How important it is to address lifestyle changes with patients	7 (44%)	9 (56%)	0	-
How much of a work priority is it to address lifestyle changes with patients	1 (6%)	13 (82%)	2 (12%)	-

* High implementation rates defined screening and/or intervention scores in the fourth quartile for responding surgeons. Low implementation rates defined screening and/or intervention scores less than or equal to the first quartile for responding surgeons. The same quartile cut-off points are used for attitudes to preventive health. ** Scores of 0 for rates of preventive health activities

Table 7.4 Statistical analyses for variables predicting tendency to undertake preventive health activities (N = 16)

Variable	Spearman's <i>Bivariate correlations</i>		Generalized Estimating Equation <i>Parameter Estimates</i>	
	<i>RO</i>	<i>p</i>	<i>β</i>	<i>p</i>
Confidence in addressing lifestyle changes	0.635	0.008	0.386	0.184
Knowledge in addressing lifestyle changes	0.544	0.029	-0.193	0.543
How effective you think your advice is in helping clients with lifestyle changes	0.710	0.002	0.254	0.747
Clients I see find it agreeable for me to raise lifestyle changes as part of consultation	0.180	0.505	-0.305	0.261
How important lifestyle changes are for health	0.134	0.620	-0.008	0.990
How important it is to address lifestyle changes with patients	0.655	0.006	1.159	0.057
How much of a work priority is it to address lifestyle changes with patients	0.644	0.007	1.217	0.008
How many years of clinical practice have you undertaken?	0.368	0.164	0.258	0.041
Confidence in addressing lifestyle changes	0.635	0.008	0.386	0.184

Dependent Variable: Implementation of preventive health interventions

GEE Model: (Intercept), Time, Confidence, Knowledge, Effectiveness, Agreeable, Important for health, Important to address, Work priority, Years of clinical practice.

Quasi-likelihood under independence model criterion (QIC) = 736

7.4.6 The hospital structure

Surgeons work in busy public hospital clinics that have extensive waiting lists. Surgeons are responsible for clinic throughput, and are accountable to management on such performance indicators. The pressure for volume is a barrier to holistic care. Working under time pressure, curative care is prioritised over preventive health. This issue is compounded by the complexity of the hospital system where there is a disconnect between the absence of preventive health in outpatient clinics and sub-optimal post-operative surgical outcomes.

“...the holistic approach, then probably my extra 5 minutes doing that referral is in the patient’s best interest, I get that. But hospitals don’t always look at the whole picture, they look at the bottom line for them; so the people in clinic here, running the clinic, will be looking at their targets... they don’t really care what they spend up on the surgical ward when the patient gets a wound infection that might be preventable if they weren’t a smoker” (Surgeon 13).

One surgeon changed their practice by limiting the number of patients seen in the clinic, allowing increased time with patients.

“We have limited it to 18 patients between the 2 of us, and so it’s good, there is enough time if you have enough reviews which are quick, and ‘new’ which are not. Yes, there is enough time [for preventive health]” (Surgeon 7).

This surgeon acknowledged that, as a senior hospital clinician, the clinical and institutional influence afforded to him may have permitted such a policy change, but this is ultimately at the discretion of hospital administrators.

With respect to generating referrals, surgeons highlighted an absence of specific programs for general behaviour change in the hospital, as well as poor awareness of behaviour change programs in the community.

“For people who have been inpatients there [are] options, but there aren’t a lot of things for just young inactive people unfortunately” (Surgeon 12).

“I don’t know how you would actually make the referral [to community programs] (Surgeon 2).

Surgeons who refer to internal services, such as exercise physiologists and physiotherapy, use this pathway to address issues that relate to surgical outcomes, increasing muscle strength before surgery for example, rather than increasing physical activity for general health. Surgeons also forego preventive referrals to allied health practitioners due to the demand for rehabilitation services.

“...from a public health system, it’s hard to get them involved in exercise programs.

Physiotherapists are often very busy and overworked, and they can’t just be doing exercises with them” (Surgeon 11).

7.4.7 Facilitators experienced by surgeons

Surgeons were unanimous in their desire for information to give to patients that are specific to their needs (i.e., smoking specific or physical activity specific). The majority of surgeons felt that a referral pathway into specialist behaviour change services, either internally or externally is required to facilitate successful behaviour change.

“A flyer would be good.... and I say put that on your fridge, something like that, where you see it every day, and you think ‘oh, the specialist gave it to me’” (Surgeon 8)

The surgeons felt that if they had dedicated resources, or referral pathways to offer to patients, then they could then use their clinical influence to stress the importance of behaviour change, which may increase the likelihood of patients utilising these services.

“I think a clinician handing it [referral] to them, and underlying who they need to see would be much more effective” (Surgeon 13).

“We need to be able to say ‘you need to make this change, here is someone who can help’. But it comes from the surgeon as the authorizing environment” (Surgeon 12).

7.5 Discussion

This mixed-methods study identified which preventive health activities surgeons carry out in non-admitted public hospital clinics, and explored the attitudes of these professionals towards preventive health practice. The quantitative data suggests that surgeons carried out preventive health interventions at low levels. Face-to-face conversations with patients about behavioural risk factors was the most commonly undertaken intervention. Surgeons were unlikely to provide written advice or refer patients to additional health behaviour change services. Although a number of attitudinal factors individually correlated with rates of preventive health practice undertaken, collectively, years of practice and the work priority placed on addressing lifestyle change were the strongest predictors of preventive health practice identified in the quantitative analyses. The qualitative analysis identified several individual and institutional topics that influenced surgeons undertaking of preventive health practice in non-admitted clinical care, with surgeons preferencing referral pathways into specialist programs to assist patients with behaviour change.

In contrast to previous research (Daley et al., 2008; Hardcastle et al., 2018; Williams et al., 2000), lack of knowledge or confidence were not identified as barriers to preventive health practice. Although surgeons' knowledge and confidence were independently associated with levels of preventive health practice in the quantitative analyses, these variables did not contribute to the model that best predicted preventive health practice rates. The quantitative analysis also highlighted that how important surgeons believe it is to address lifestyle changes with patients was independently associated with preventive health practice in the quantitative analyses, though this did not contribute to the model that best predicted preventive health practice rates either. Quantitative data suggests that although surgeons believe it is important to address lifestyle changes with patients, and are confident and knowledgeable in doing so, these factors do not predict actual rates of preventive health practice. This might reflect the medically oriented work of surgeons, and that surgeons, rather than lacking confidence or knowledge, do not see preventive health as core to their role (Johansson et al., 2010), which was probed in the subsequent qualitative interviews. The surgeons endorsed this biomedical perspective in the qualitative interviews, preferring to practice under a scope of vision restricted to the presenting issue. Surgeons' engagement in health discussions predominantly relate to surgical outcomes; they did not consider it part of the surgical role to discuss general wellbeing.

In the qualitative interviews, discussions with patients about smoking cessation was the most commonly noted preventive health topic; however, as exemplified by the quotes, smoking cessation was advised due to the operative risk, not for general health. Surgeons' engagement in risk mitigation through smoking cessation advice is likely to be influenced by the well-publicised literature relating to smoking and post-operative risks (Thomsen et al., 2009; Tønnesen et al., 2009). Despite unequivocal evidence that behaviour change interventions are effective in multiple settings (Hopkins et al., 2001; Johnson et al., 2010), few interventions have targeted hospital surgical patients (Goldstein et al., 1998) and very few studies have addressed behaviour change in non-admitted surgical clinics (Warner et al., 2004). The lack of published literature on surgeons' preventive health practice might influence the surgeons' perception that preventive health does not fit within their role.

In the quantitative analyses, surgeons' perceptions regarding patient acceptance of lifestyle interventions in non-admitted care was not significantly correlated with preventive health practice rates. The acceptance of lifestyle interventions on the part of the patients, and the patients' motivation to undertake behaviour change was however, repeatedly brought up in the qualitative interviews. Many surgeons reported that although patients are agreeable to receiving lifestyle advice during a non-admitted surgical consult, the provision of advice did not translate to actual behaviour change on the part of the patient. On the other hand, surgeons noted that many patients attend specialist appointments seeking specialist advice, and are not interested in, or motivated by the provision of preventive health in non-admitted surgical care. From the interviews, differences were observed between surgeons as to whether they attempted to use the consultation to illicit patients' motivation to change. Discussion of risk factors is standard practice for surgeons (Neuman & Bosk, 2012) and in the interviews some surgeons reported using the consultation as an opportunity to link behavioural risk factors to the presenting health issue. Opportunistic health promotion is strongly advocated in chronic disease prevention and management (Beaglehole et al., 2008). The quantitative analyses indicated that surgeons who prioritised preventive health were significantly more likely to use the clinical opportunity to undertake preventive health interventions.

Not all surgeons however, approached the consultation as a chance to motivate patients, with some surgeons expressing concern about engaging in preventive health discussions with patients in the non-admitted setting. These concerns might reflect a didactic understanding of preventive health, where the passive patient is expected to adhere to the prescriptions of the

healthcare expert (Walkeden & Walker, 2015). Alternative models exist, however, where emphasis is placed on empowering patients over their own health, rather than delivering purely instructive messages (Walkeden & Walker, 2015). The interviewed surgeons, ambivalent about engaging in behaviour change discussions should be encouraged by research indicating that the majority of patients view hospitals as an appropriate setting for health promotion (Haynes, 2008).

Consistent with existing literature, insufficient time was identified as a major barrier to preventive health (Daley et al., 2008; Williams et al., 2000). Time pressure is institutionally driven, with surgeons under pressure for clinical performance. Surgeons were cognisant of the waiting lists for public services, and the pressure that this places on clinical throughput. Performing under a fixed amount of time, surgeons largely felt that they could not afford to forego time spent in their expert role. In the quantitative analyses, work priority afforded to preventive health was the strongest predictive factor for engaging in preventive health practice, and this finding was subsequently probed in the qualitative interviews. It is important that the surgical profession recognises the role that surgeons can play in preventive health, even in the face of time demands. As little as 3 min of advice can markedly increase a patient's chance of smoking cessation (Hughes, 2003). The number of years of practice was also a significant predictive factor for engaging in preventive health practice. The qualitative interviews highlighted that one senior surgeon chose to decrease clinical volume, even in the face of service demand. This attests to the aforementioned influence that surgeons might have over institutional practice, and strengthens the argument to engage with surgeons on health promotion policies in the future.

The facilitative topics raised by surgeons in the qualitative interviews were unanimous, with surgeons' preferencing pathways to refer patients into specific programs tailored for health behaviour change as a means to facilitate preventive health interventions in non-admitted clinical care. The interviewed surgeons believe that information fliers and standardised referral pathways would allow them to engage, in a time-efficient manner, in preventive health with patients, and subsequently offer follow-on services. The provision of dedicated information, as well as referral pathways could offer avenues for surgeons to integrate preventive health into non-admitted care. Further to this, the development of linkages to community-based aftercare resources is likely to improve continuity of patient care (Williams et al., 2000), particularly when

initiation of behaviour change is driven from the surgical consult (Williams et al., 2000).

7.5.1 Limitations

This study is subject to a number of limitations. First, preventive practices were assessed via self-report. This approach is consistent with numerous previous studies, however, the accuracy in assessing actual behaviour is unclear. Second, although our response rate of 51% was higher than other preventive health research with hospital doctors (Daley et al., 2008; Williams et al., 2000), the response rate is lower than observed in studies of surgeons' clinical decision making (Urquhart et al., 2016). While low response rates can increase the possibility of response bias, significant differences were not observed between responding and non-responding doctors in cross-sectional studies (Kellerman & Herold, 2001). The doctors studied by Kellerman et al (2011), were physicians, and not surgeons, which may limit the generalizability of the finding. Third, the GEE model might be underpowered to show statistical significance in the majority of measured variables (Williams et al., 2015). Further research with a larger cohort of participants may result in differing models that best predict preventive health practice by surgeons (Williams et al., 2015). Fourth, a degree of selection bias could have resulted from the survey non-response rates and interview non-participation rates, with the participating surgeons potentially more engaged in preventive health than non-responders (Geense et al., 2013). However, surgeons were purposefully sampled for the interviews to ensure a variation in the types of speciality areas and experience to providing insights from multiple perspectives. Finally, this study was undertaken in a single hospital. While single-site studies might limit generalizability, the primary aim of this research was to acquire detailed knowledge about context and processes of the studied phenomenon. Steps were taken to maximize rigour and attain theoretical saturation (Barrett et al., 2018c) and these should ensure the broad applicability of the findings to other non-admitted, public hospital services.

7.5.2 Implications for clinical practice and future research

Surgeons' undertaking of preventive health activities is influenced by a multitude of factors, with the working structure of the hospital most likely to influence preventive health practice rates (McHugh et al., 2010; Ziglio et al., 2011). Heavy workload emerged as a core barrier that cannot be ignored (Johansson et al., 2010; Richardson, 2012). The interviewed surgeons were cognisant of the demands of the clinic, and report practising under a narrow specialist approach, foregoing holistic care. Management support is critical for the availability of time and

resources required for surgeons to broaden their practice to increase preventive health practice rates (Johansson et al., 2010).

The interviewed surgeons suggested that to increase engagement in preventive health activities in non-admitted care, while managing consultation time, their preference was for the creation of information fliers on behaviour change to give to patients, and for referral pathways that link patients to specialist behaviour change programs available either in-house or in the community.

The sheer volume of non-admitted surgical consultations provided annually offer vast potential for opportunistic preventive health in the non-admitted clinical setting (Australian Institute of Health and Welfare, 2017). Due to the influence surgeons can exert over patients, it would be valuable to examine how surgeon-initiated referrals to tailored behaviour change programs could be implemented into routine practice, as well as health-related outcomes derived from this pathway.

7.6 Conclusion

This mixed-methods study revealed that the majority of surgeons discuss lifestyle risk factors with their patients at low levels. Surgeons were unlikely to provide written advice or refer patients to ancillary preventive health services. The surgeons largely expressed positive attitudes towards preventive health, and the surgeons who placed the greatest work priority on preventive health were most likely to undertake preventive health practice. To increase preventive health practice, surgeons indicated a preference for pathways to enable referrals into dedicated behaviour change programs that could fit within the scope of non-admitted surgical consultations. Due to the high volume of ambulatory surgical consultations annually, it is important that surgeons remain active participants in preventive health policy.

Chapter 8

A physical activity coaching intervention can improve and maintain physical activity and health-related outcomes in adult ambulatory hospital patients: the Healthy4U-2 randomised controlled trial

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8.1 Abstract

Background: The Healthy 4U-2 study sought to evaluate the effect of a twelve-week, physical activity (PA) coaching intervention for changes and maintenance in PA, anthropometrics and health-related outcomes in adults presenting to an ambulatory hospital clinic.

Methods: One hundred and twenty insufficiently active adults were recruited from an ambulatory hospital clinic and randomised to an intervention group that received an education session and five 20-min telephone sessions of PA coaching, or to a control group that received the education session only. Actigraph GT3X accelerometers were used to measure moderate-to-vigorous physical activity (MVPA) at baseline, post-intervention (3-months) and follow-up (9-months). Secondary outcome measures (anthropometrics, PA self-efficacy, and health-related quality of life) were also assessed at the three time points.

Results: At baseline, the mean age and body mass index of participants were 53 ± 8 years and 31 ± 4 kg/m², respectively. Relative to control, the intervention group increased objectively measured MVPA at post-intervention ($p < 0.001$) and 9 months follow-up ($p < 0.001$). At the 9-month follow-up the intervention group completed 22 min/day of MVPA (95% CI: 20 to 25 min/day), which is sufficient to meet the recommended PA guidelines. The intervention group exhibited beneficial changes in body mass ($p < 0.001$), waist circumference ($p < 0.001$), body mass index ($p < 0.001$), PA self-efficacy ($p < 0.001$), and health-related quality of life ($p < 0.001$) at the 9-month follow-up.

Conclusions: This study demonstrates that a low contact PA coaching intervention **results** in beneficial changes in PA, anthropometrics and health-related outcomes in insufficiently active adults presenting to an ambulatory care clinic. The significant beneficial changes were measured at post-intervention and the 9-month follow-up, demonstrating a maintenance effect of the intervention.

Keywords: Physical activity, Exercise motivation, Accelerometry, Public health

8.2 Background

Insufficient physical activity (PA) is a major public health problem (Bauer et al., 2014; Booth et al., 2011), and is associated with a range of chronic diseases (Lee et al., 2012), decreased quality of life (Brown et al., 2003) and morbidity (Garcia-Aymerich et al., 2006). Individuals with chronic diseases are frequent users of complex hospital services (Fradgley et al., 2015). This care is often delivered at ambulatory secondary care clinics through medical consultations in specialties such as general surgery, orthopaedic surgery and endocrinology. Non-emergency ambulatory services for chronic diseases account for a large proportion of healthcare expenditures (Fradgley et al., 2015). Due to the increasing demands of managing chronic diseases (Ding et al., 2016), hospitals need effective and accessible prevention programs targeting high-risk individuals to increase PA and promote individual self-management (Holman, 2020).

Ambulatory secondary care is an important setting to target high-risk individuals to facilitate changes in PA, and may be an effective strategy for increasing PA (Börjesson, 2013). Patients seek lifestyle advice from their health-care providers, and anticipate discussions on lifestyle choices such as PA as part of their medical care (Albright et al., 2000; Leijon et al., 2010). Patients believe that doctors are credible sources of preventive health information, and are likely to accept doctors' advice and instigate behaviour change (Kreuter et al., 2000; Lewis & Lynch, 1993). Surgeons can identify individuals who are likely to benefit from increasing PA, and facilitate referral pathways into specialist behaviour change interventions as a method for increasing PA (Barrett et al., 2019).

Individually tailored behaviour change interventions are effective at improving PA (Foster et al., 2013). Key components of PA behaviour change include increasing motivation, goal setting, problem solving, social support, and performance feedback (Howlett et al., 2019). Telephone coaching is a well-recognised method of delivering PA behaviour change interventions (Foster et al., 2013). PA telephone coaching enables a remote but personal relationship, and repeated contacts to promote behaviour change (Foster et al., 2013). PA telephone coaching is also favourable due to its low cost, potential for wide dissemination and accessibility across geographical regions.

Research assessing the effects of telephone coaching for changes in PA has shown promise (Eakin et al., 2007; Goode et al., 2012; Howlett et al., 2019; Kivelä et al., 2014). There is

however, a lack of research investigating telephone coaching for changes in PA in the ambulatory secondary care setting. In a previous study (Healthy4U), we assessed the efficacy of telephone coaching for changes in PA in a self-selected sample of insufficiently active ambulatory secondary care patients (Barrett et al., 2018a). At 3-month post-intervention, participants in the intervention group demonstrated significant increases in PA and health-related outcomes compared to controls (Barrett et al., 2018a). The present study builds upon the H4U study in a number of ways, including the use of referrals by hospital surgeons as the recruitment strategy to better integrate the PA coaching into routine secondary care. This present study also extended the follow-up measures to include a six-month post-intervention period to assess behaviour change maintenance (Prochaska & DiClemente, 1982). Although PA coaching has demonstrated effectiveness in maintaining PA changes (Eakin et al., 2010; Howlett et al., 2019; Kivelä et al., 2014), studies that confirm long-term PA behaviour change in ambulatory secondary care are scarce. The assessment of outcomes at least six-month post-intervention, where no contact with participants has been made since the intervention has ceased are required to provide a more robust measure of behaviour change maintenance in ambulatory secondary care (Prochaska & DiClemente, 1982).

The primary aim, therefore, was to examine the effectiveness of the PA telephone coaching intervention for change and maintenance of PA in insufficiently active secondary care patients referred by consulting hospital surgeons. Secondary aims were to investigate the effectiveness of the telephone coaching for changes and maintenance in anthropometry, PA self-efficacy, and health-related quality of life in this population.

8.3 Methods

8.3.1 Design

The study was a single-blind RCT designed and reported in line with the CONSORT statement and checklist (Fig. 8.1) (Moher et al., 2001), and the TIDieR checklist (Hoffmann et al., 2014). The completed CONSORT and TIDieR checklists are included in Appendix 8.1 and 8.2. The trial was registered with the Australian and New Zealand Clinical Trials Registry (ACTRN12619000036112) prior to participant recruitment.

8.3.2 Participants

Participants were recruited from an ambulatory, secondary care clinic in a major tertiary hospital in regional Victoria between January 2019 and September 2019. Recruitment involved consulting orthopaedic and general surgeons providing, during the normal course of the consultation, a verbal recommendation to engage in PA coaching and a sequentially numbered research flier (Appendix 8.3) to adult patients who, in their view, would benefit from increased PA. Potential participants contacted the research team of their own volition using information on the flyer. Sequential numbering allowed the research team to quantify both the number of individuals referred by surgeons and the number who subsequently acted on this referral.

Participants were included if they were between 18 and 69 years, and did not meet the recommended PA guidelines (Australian Department of Health, 2018). A single item question “As a rule, do you do at least half an hour of moderate or vigorous exercise (such as walking or a sport) on five or more days of the week?” was used to identify insufficiently physically active individuals (Rose et al., 2008). The question has demonstrated good sensitivity (76.7%), high specificity (81.1%), and a high positive predictive value (86.7%) for identifying those not achieving the recommended 150 minutes of MVPA per week (Rose et al., 2008). Exclusion criteria included: sufficiently physically active; an existing medical condition that contraindicated PA (indicated by the Physical Activity Readiness Questionnaire); deaf/hearing impaired; poor comprehension of English language; disabling neurological disorder; severe mental illness such as psychosis; learning disability; dementia and cognitive impairment; registered blind; housebound or resident in nursing home; non-ambulant; pregnancy; advanced cancer; and scheduled for surgery within 30 days of the clinic presentation.

8.3.3 Procedure

Participants who were eligible and consented to take part were randomly allocated to either the intervention or the control group based using block randomization generated by a computer generated random number sequence (randomizer.org). The allocation sequence was generated by a research assistant who was not involved in the data collection process. Assignments were prepared and sealed in sequentially numbered opaque envelopes. Intervention assignment was made by opening the next envelope in the sequence, after: (1) the recruiter had determined eligibility for the study; (2) participants had consented to take part; (3) attendance at an education session was confirmed; and (4) baseline measurements were completed.

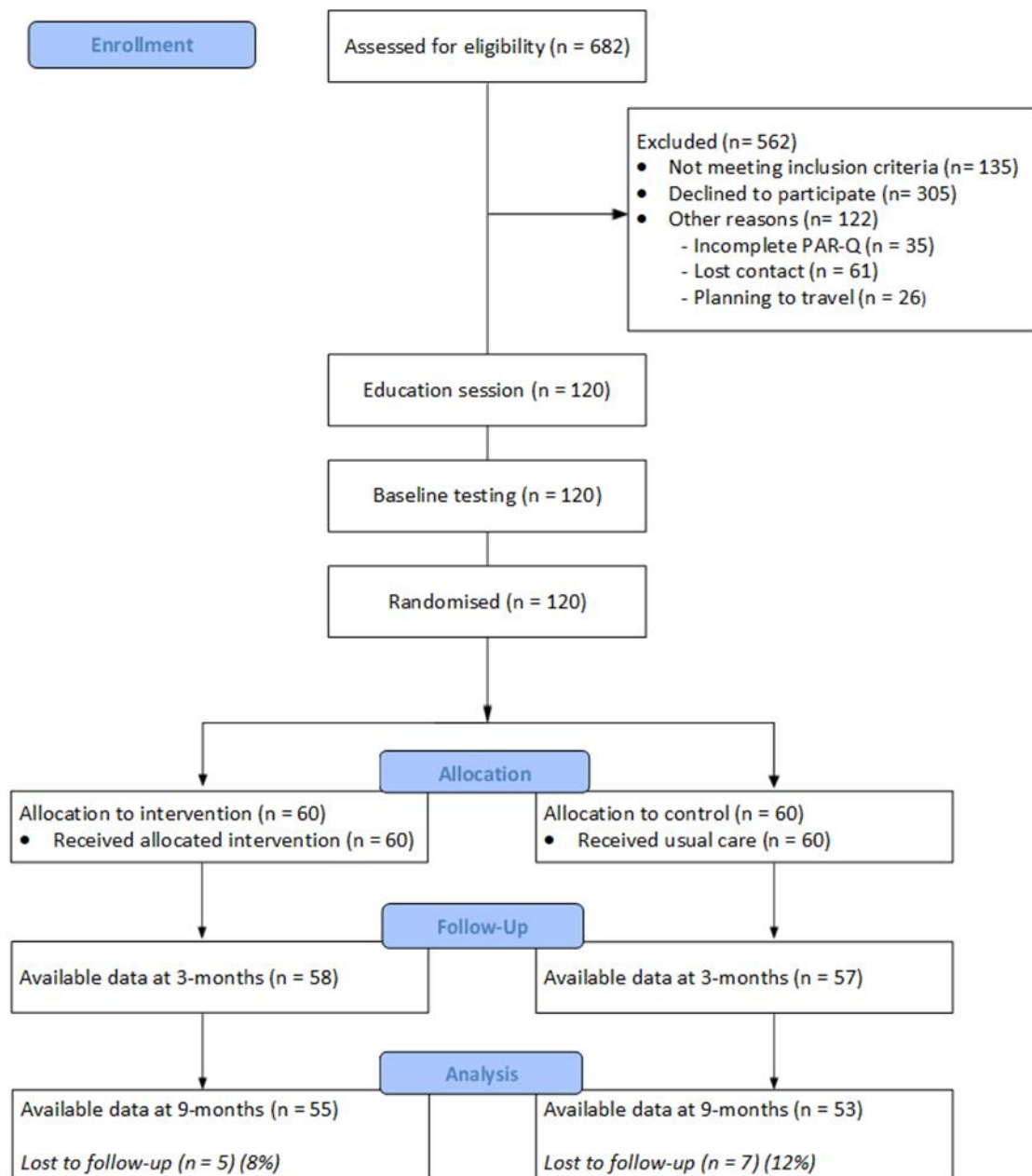


Figure 8.1: CONSORT flow diagram of the study

8.3.4 Intervention

All enrolled participants attended an education session prior to group allocation. The education session was a facilitated learning session based around PA self-management and was carried out using a self-determination theory (SDT) framework (Vansteenkiste & Sheldon, 2006). Self-determination theory is a motivational theory commonly used to illicit changes in PA (Fortier et al., 2012). Self-determination theory was used in this group setting to support, educate and motivate participants around PA changes (Vansteenkiste & Sheldon, 2006).

The intervention group completed a telephone-based coaching intervention that comprised integrated motivational interviewing and cognitive behaviour therapy (MI-CBT). The coaching was delivered in five by 20-min sessions over 12 weeks. The intervention schedule, theories and techniques are displayed in Table 8.1. The intervention was delivered using a motivational interviewing (MI) framework, with MI used as the underpinning approach to influence motivation, ambivalence and self-efficacy to be physically active (Miller & Rollnick, 2012). Motivational interviewing microskills (open-ended questions, affirmations, reflections and summaries) were utilised in all sessions (Miller & Rollnick, 2012). The CBT coaching focused on six theory-derived determinants of PA: PA outcome expectations, PA outcome experiences, PA values, PA barrier self-efficacy, social support and relapse prevention (Michie et al., 2011a). The CBT strategies were incorporated within a MI framework to support PA change and maintenance (Naar-King et al., 2013). The intervention was delivered by an experienced Australian Health Practitioner Regulating Authority registered physiotherapist. The clinician was trained in MI-CBT, including workshop attendances, and one-on-one coaching from an experienced practicing psychologist. The clinician previously delivered 145 hours of MI-CBT in the H4U study (Barrett et al., 2018a). Fidelity was assessed using the MI-CBT fidelity scale (Haddock et al., 2012) using audio-recorded sessions.

Table 8.1 Physical activity coaching schedule, content, theory, determinants and behaviour change techniques.

Session	Week	Session determinants	Content	Techniques
1	1	Physical activity expectations; Physical activity past experiences; Physical activity self-efficacy; Physical activity values.	<ul style="list-style-type: none"> • Exploration of current and historical physical activity behaviours; • Identify telephone coaching outcome expectations; • Identify physical activity outcome expectations; • Determine level of motivation for increasing physical activity (e.g. how motivated are you to increase physical activity on a scale of 1–10? Why did you give it a 3, as opposed to a 4 or 5?); • Identify and address unrealistic physical activity expectations; • Assess barriers to physical activity; • Discuss goals and action plans. 	<p>Motivational interviewing strategies:</p> <ul style="list-style-type: none"> • Open ended questions; • Affirmations; • Reflections; • Summaries; • Develop discrepancy; and • Illicit change talk. <p>Cognitive-behavioural techniques:</p> <ul style="list-style-type: none"> • Elicit PA outcome expectations and experiences; • Elicit values and physical activity priorities; • Identify physical activity barriers and problem solving; • Goal setting –behavioural; • Action planning.
2	2	Physical activity outcome expectations; Experience regarding goal setting.	<ul style="list-style-type: none"> • Review of goal progress from session 1; • Barrier identification and determine level of self-efficacy for overcoming barriers (e.g. how confident are you to overcome barrier X on a scale of 1–10? Why did you give it a 3, as opposed to a 4 or 5?); • Progress and amend action-plan and goals; • If physical activity goals involve program based activities (e.g. strength training, walking groups) individual to source contact details. 	<p>Motivational interviewing strategies as above.</p> <ul style="list-style-type: none"> • Illicit and explore change talk. <p>Cognitive-behavioural techniques:</p> <ul style="list-style-type: none"> • Problem solving; • Goal setting; • Focus on past success; • Prompt experiential learning through trial and error.

3	4	Outcome expectations and experiences in relation to physical activity goal progress.	<ul style="list-style-type: none"> • Review of goals and progress from session 2; • Explore current experiences of physical activity; • Barrier identification and self-efficacy strategies for overcoming barriers; • Discuss self-monitoring strategies to monitor goal (e.g. physical activity tracking); • Discuss intervention timelines and action plan for the next two weeks. 	<p>Motivational interviewing strategies as above.</p> <p>Cognitive-behavioural techniques:</p> <ul style="list-style-type: none"> • Review of physical activity behaviour and outcome goal(s); • Elicit current physical activity outcome experiences; • Goal planning, and what-then plans; • Education regarding self-monitoring of behaviour or outcomes; • Relapse prevention.
4	6	Physical activity outcome expectations; Exercise self-efficacy; Coping strategies; Future planning.	<ul style="list-style-type: none"> • Review of progress from session 3; • Explore current experiences of physical activity; • Relapse prevention - tailored to individual needs; • Discuss intervention timelines and action plan for the next six weeks. 	<p>Motivational interviewing strategies as above.</p> <p>Cognitive-behavioural techniques:</p> <ul style="list-style-type: none"> • Elicit current physical activity outcome experiences; • Coping strategies (e.g. physical activity pacing, planning); • Engaging social support; • Relapse prevention.
5	12	Theory of behavioural maintenance; Relapse prevention;	<ul style="list-style-type: none"> • Intervention recap; • Review of progress from previous session and intervention as a whole; • Identify what has helped PA changes; • Identify what can help PA maintenance; • Relapse prevention – identification of potential future scenarios, and what-then plans for overcoming issues (e.g. if I experience X, then I will do Y); • Additional follow-on services – community health promotion services/exercise services. 	<p>Motivational interviewing strategies as outlined above.</p> <p>Cognitive-behavioural techniques:</p> <ul style="list-style-type: none"> • Action planning - focus on past and current success; • Problem solving – what-if planning. • Relapse prevention.

8.3.5 Outcome Measures

Participants' outcome measures were recorded at baseline, after 3 months of intervention (post-intervention) and at 9 months (follow-up) by assessors blinded to the study group assignment. Information on treatment allocation was not provided to data collectors. The data collection forms only contained unique identifier codes assigned to each participant.

Primary outcome

The primary outcome of interest was the change in MVPA (minutes/day) over time. MVPA was objectively assessed using a tri-axial accelerometer (wGT3X-BT; Actigraph, USA). Participants were instructed to wear the accelerometer on their hip at all times over 7 consecutive days, excluding sleep and water-based activities. PA was calculated using the manufacturers software (Actilife; Actigraph, USA) with cut points by Freedson Adult (1998) used to provide daily measures of MVPA (> 1951 cpm). Accelerometer wear time was based on activity counts per minute (CPM). Non-wear time was defined as 60 minutes or more of consecutive activity counts of zero, with a spike tolerance of 2 min and 100 cpm. Participants used logbooks to report activities and periods of accelerometer non-wear. Non-wear time was compared to participants' notes on their logbook. A minimum of 10 h per day was used as the cut-off for a valid day of measurement and a minimum of 5 days of data were required including at least 1 weekend day (Esliger et al., 2005). Weekly MVPA was computed based on the average of all valid days per person. A daily average of 21 mins of MVPA over a 7 day period is sufficient to meet the recommended PA guidelines (Australian Department of Health, 2018).

Secondary outcomes

Change over time for the following secondary outcomes was also assessed. Waist circumference was measured to the nearest 0.1 cm using a rigid anthropometric measuring tape. Body mass was recorded to the nearest 0.1 kg using a calibrated scale (model 813; Seca, Germany). Free standing stature was recorded to the nearest 0.1 cm using a calibrated equipment with the participant barefoot (Stadiometer; Seca, Germany). Body mass index (BMI) was calculated by dividing body mass by the square of height. Self-efficacy to be physically active was measured using a validated PA self-efficacy survey (Sallis et al., 1988). Health-related quality of life (HrQoL) was measured using the Medical Outcomes Study Short Form 12 Health Survey (SF-12) which is a reliable tool with published psychometric support (Sanderson et al., 2002).

8.3.6 Study size

Utilising data from the H4U study (Barrett et al., 2018a), a sample size of 50 participants per arm was calculated to be sufficient to detect a between group difference of 30 ± 13 (mean \pm SD) mins/week MVPA, with the alpha set at 0.05, and the power set at 0.80. Protecting against a drop-out rate of 20% over the 9-month study duration, 60 participants were recruited and randomised into each arm

8.3.7 Data analyses

Analyses were carried out using IBM SPSS Statistics for Windows (Version 26.0; IBM Corp., USA) and statistical significance was set at an alpha of 0.05. Data were assessed for normal distribution by Shapiro-Wilk tests. Homogeneity of variances and covariances were assessed by Levene's test and Box's M test, respectively. Grouped data are presented as mean \pm standard deviation. For the main analyses, a series of mixed-model ANOVAs (within: time; between: intervention) were used to assess the effects of the PA coaching intervention on each of the outcome variables separately. Mauchly's test was consulted and Greenhouse–Geisser correction was applied if the assumption of sphericity was violated. A significant interaction effect was interpreted to demonstrate that the change in dependent variables was influenced by intervention. Where statistically significant interactions were observed simple main effects analyses were carried out. Where data were in breach of Shapiro-Wilks test of normality, sensitivity analyses were performed. Data were explored for significant outliers and repeat sensitivity analyses were undertaken on data with outliers removed. Repeated sensitivity analyses provided no indication that the outliers had a significant effect on the outcome; therefore, all data were included in analyses. Intention-to-treat analysis was used for missing data using the last observation carried forward approach (Shao & Zhong, 2003). Repeat sensitivity analyses were undertaken on data with and without imputing the last-observation-carried forward value and provided no indication that the imputed values had a significant effect on the outcome.

8.4 Results

Utilising the sequentially numbered study fliers, we know that 2076 individuals were provided with the study information and a recommendation to engage with the PA coaching service. The H4U-2 study team were contacted by 682 individuals (33%), of which 120 consented and were

eligible to participate in the study (Figure 8.1). Of the 305 individuals who chose not to participate, 282 did not want to enroll in the study but did want support to be more physically active; these individuals proceeded to enroll in the hospital's standard PA health promotion program. These data indicate that when ambulatory hospital patients are recommended by a surgeon to participate in a PA coaching intervention, 33% demonstrate sufficient interest to enquire about the service, and almost 20% will take up a PA coaching intervention.

One hundred and twenty (68% female) completed baseline assessment and were subsequently randomised into the intervention or control groups. Baseline demographic and clinical characteristics between the intervention and control groups were similar (Table 8.2). Drop-out rates were low with 115 participants completing their 3-month assessment, and 108 participants completed their 9-month assessment (Figure 8.1)

Mean accelerometer wear time was 14 ± 3 hours per day and 6.1 ± 0.8 days per week (out of 7 days per week). Almost all participants (96%) enrolled into the intervention arm received their scheduled 5 sessions of PA telephone coaching. The mean duration of each intervention session was 18 ± 4 min. Results from the assessment of intervention fidelity revealed that the intervention provider demonstrated competence during the delivery of MI-CBT structure and core skills.

Table 8.2. Characteristics of participants at baseline.

Variable	Total	Intervention	Control
	120	60	60
Age (years)	53 ± 8	54 ± 8	53 ± 7
Sex: female, n (%)	81 (68%)	40 (67%)	41 (68%)
Stature (cm)	166 ± 8	165 ± 9	167 ± 7
Weight (kg)	84.4 ± 9.4	84.5 ± 9.9	84.3 ± 9.1
BMI (kg/m ²)	30.5 ± 4.3	31.0 ± 4.4	30.0 ± 4.2
MVPA (min/day)	14.5 ± 4.9	14.7 ± 5.2	14.3 ± 4.7
PA Self-efficacy	25 ± 4	24 ± 4	25 ± 4
Smoker, n (%)	12 (10%)	7 (10%)	5 (10%)
Obesity, n (%)	62 (52%)	30 (50%)	32 (53%)
Hypertension, n (%)	38 (32%)	20 (33%)	18 (30%)
OA/RA, n (%)	42 (35%)	22 (37%)	20 (33%)
Depression/anxiety, n (%)	25 (21%)	12 (20%)	13 (22%)
Employment status, n (%)			
Full time	48 (40%)	25 (42%)	21 (35%)
Part time	39 (32%)	19 (32%)	22 (37%)
Unemployed	11 (10%)	5 (8%)	8 (13%)
Retired	22 (18%)	11 (18%)	9 (15%)
Education, n (%)			
Year 10/11	3 (3%)	1 (2%)	2 (3%)
Year 12	31 (26%)	13 (22%)	17 (28%)
Cert I-IV	42 (35%)	24 (40%)	19 (32%)
Diploma	26 (21%)	14 (23%)	12 (20%)
Bachelor or higher	18 (15%)	8 (13%)	10 (17%)

Group data expressed as means ± standard deviations. Figures in parentheses are proportions. BMI: Body mass index; MVPA: Moderate-to-vigorous physical activity; OA: Osteoarthritis; RA: Rheumatoid arthritis. ^a t-test between intervention and control groups.

^b chi square test between intervention and control groups.

Repeated measures ANOVAs demonstrated a significant group by time interaction for daily MVPA, indicating that changes from baseline differed between intervention groups ($p < 0.001$; Fig. 8.1). The intervention group significantly increased MVPA over time, undertaking 22 min/day (95%CI: 20 to 25 min/day) at 9-month follow-up. In contrast, the control group significantly decreased MVPA over the same time, undertaking 10 min/day (95%CI: 8 to 13 min/day) at follow-up. This translates to a between group difference for MVPA of 12 min/day (95%CI: 9 to 15 min/day) at 9 months.

Statistically significant group by time interaction effects were found for all secondary outcomes (Table 8.3). For the intervention group, at follow-up there were significant changes body mass (-2.1 kg, 95%CI: -1.6 to -2.7 kg), waist circumference (-1.3 cm, 95%CI: -0.9 to -1.7 cm), and BMI (-0.8 kg/m², 95%CI: -0.6 to -1.0 kg/m²). Relative to the control group, the intervention group also demonstrated significant changes in PA self-efficacy (6 points, 95%CI: 4 to 8 points) and HrQoL (0.02 units, 95%CI: 0.002 to 0.04 units).

The proportion of individuals undertaking sufficient daily MVPA to meet the PA guidelines was similar across both groups at baseline, with 8% (n=5) of the intervention group and 13% (n=8) of control group sufficiently active. In the control group this proportion decreased to 10% (n=6) at 3 months, and decreased further to 3% (n=2) at 9 months. In contrast, the proportion of individuals in the intervention group undertaking sufficient daily MVPA increased to 55% (n=33) at 3 months, and dropped slightly to 52% (n=31) at 9-months.

Table 8.3 Means and standard deviations for outcome measures at 3 months and 9 month follow-up

Outcome	Intervention			Control			Analyses	
	Baseline	Post-Intervention	Follow-up	Baseline	Post-Intervention	Follow-up	Time x Group (F) ^a	Effect size ^b
MVPA (min/day)	15 ± 5	23 ± 10	22 ± 10	14 ± 5	13 ± 6	10 ± 6	28.70*	0.20
Waist circumference (cm)	97.6 ± 11.7	97.6 ± 11.7	96.3 ± 11.4	97.4 ± 11.4	97.8 ± 11.1	98.2 ± 11.1	45.94*	0.28
Body mass (kg)	84.5 ± 9.9	83.2 ± 9.6	82.4 ± 9.4	84.3 ± 9.1	85.3 ± 8.9	85.8 ± 8.8	107.77*	0.48
BMI (kg/m ²)	31.0 ± 4.5	30.6 ± 4.4	30.2 ± 4.3	30.0 ± 4.2	30.4 ± 4.1	30.5 ± 4.2	108.22*	0.49
PA self-efficacy (Risk score)	24 ± 4	28 ± 6	30 ± 6	25 ± 4	25 ± 4	22 ± 4	53.33*	0.31
HrQoL (Scale)	0.63 ± 0.06	0.64 ± 0.06	0.65 ± 0.07	0.63 ± 0.07	0.63 ± 0.07	0.61 ± 0.06	8.72*	0.07

Group data are means ± standard deviations. MVPA: moderate-to-vigorous physical activity; BMI: Body mass index; HrQoL: Health-related quality of life.

* $p < 0.05$.

^a interaction effect of time by group on dependent variable; ^b Partial eta-squared.

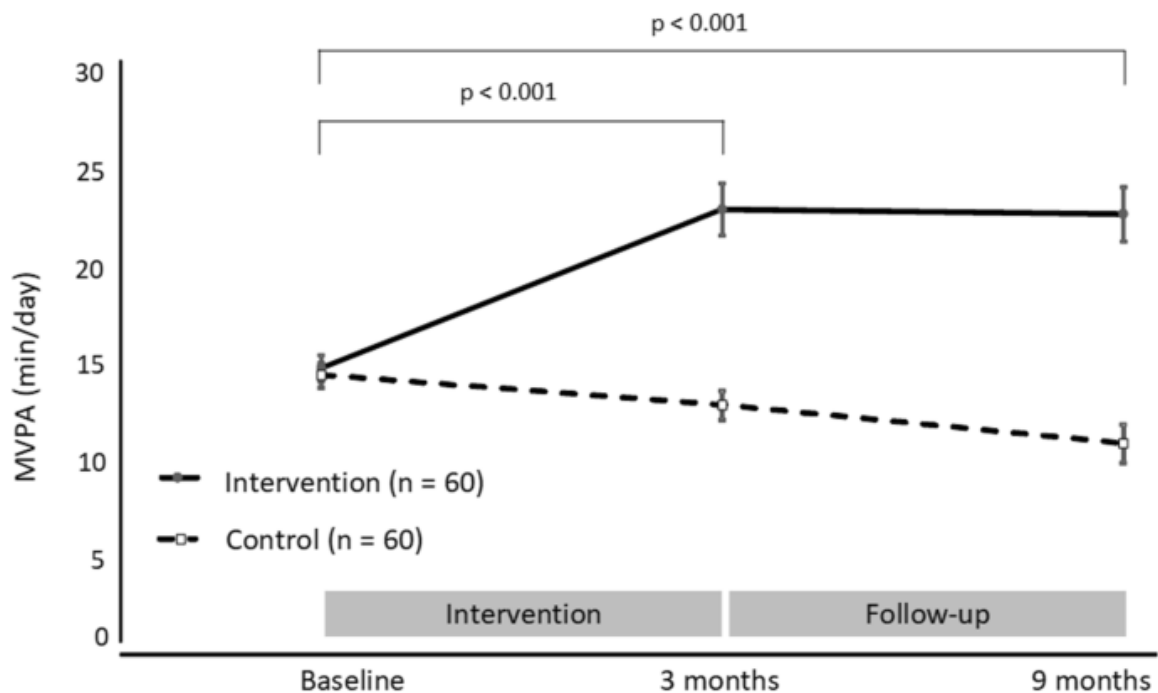


Figure 8.2: Minutes per day of moderate-to-vigorous physical activity (MVPA) for the intervention and control groups at baseline, post-intervention and follow-up

8.5 Discussion

Physical activity telephone coaching resulted in a significant increase in MVPA that was maintained at 9-months in adults attending ambulatory secondary care clinics. The intervention also resulted in significant improvements in body mass, waist circumference, BMI, PA self-efficacy, and HrQoL. The positive changes exhibited in outcomes at 3-months and 9-months indicate short-term and maintenance effects of the intervention. The attrition rate of 10% was low. This study offers important information on the potential effects that can be achieved by a targeted, patient-centred PA lifestyle intervention delivered in an ambulatory hospital setting.

The intervention group significantly increased MVPA at 3 months (post-intervention) and maintained this change at 9-month follow-up. In contrast, the objectively assessed MVPA of the control group declined below baseline at 3 months, and declined further at follow-up. Very few studies have analysed the long-term effects of remotely delivered PA coaching (Foster et al., 2013; Silfee et al., 2018). The effect size observed in this study (0.20) was higher than that found (0.11) in

a meta-analysis of remote PA interventions for self-reported PA change (Cleland et al., 2017). Additionally, following a PA coaching intervention, self-reported PA was maintained after a no-contact follow-up, whereas objectively assessed PA decreased (Van Hoecke et al., 2014). Objectively measured increases in MVPA in the intervention group that were maintained following a 6-month no-contact period indicate that change in behaviour was maintained at 9 months.

The majority of intervention participants undertook sufficient PA to meet the PA guidelines at 3 months and 9 months. This was in stark contrast to the control group where less than 10% of participant we classified as sufficiently active at 3 months and 9 months. The increase in MVPA in the intervention group and the group differences between the control and the intervention group are highly relevant. Previous studies have documented that 15 minutes a day of MVPA can decrease chronic disease risk (Lee et al., 2012), attenuate the risk of sedentary behaviours (Ekelund et al., 2016), and reduce all-cause mortality (Wen et al., 2011).

Compared to control, the intervention participants experienced improvements in their body mass, waist circumference and BMI from baseline to follow-up. The improvements in the intervention group were maintained during the no contact period from the end of coaching sessions for a further 6 months. The magnitude of long-term change in anthropometrics is comparable to changes reported in other studies using telephone coaching interventions, though none of these were conducted in the ambulatory secondary care setting (Eakin et al., 2010; O'Hara et al., 2013). The positive changes in the intervention group and the group differences between the intervention and control group are relevant, and could have important population-health implications for addressing chronic disease risk factors. Even at modest levels, weight loss and decreases in waist circumference are beneficial for chronic disease risk reduction (Byers et al., 2011; Lavie et al., 2009). The recruitment into this study was based upon changing PA, not anthropometrics. Additionally, intervention components only addressed issues relating to PA beliefs, attitudes and plans. The positive results for these secondary outcomes indicates that PA moderately, but significantly induces anthropometric changes, and it is important in the maintenance of these changes (Jakicic, 2009).

Baseline scores for PA self-efficacy indicated that both groups had low-to-moderate confidence in their ability to be physically active. In the control group PA self-efficacy decreased significantly over time. This contrasted with the trajectory of the intervention group, who increased PA self-efficacy at 3 months, and even further at 9 months. The changes in PA self-efficacy potentially mediated the changes in PA amongst the groups (Rhodes et al., 2010). The intervention increased PA self-efficacy and PA, while the control group demonstrated simultaneous decreases in both these outcomes. The MI-CBT intervention demonstrated efficacy in improving psychological determinants in the short and long term, including self-efficacy to overcome exercise barriers and maintain change. Self-monitoring, goal setting, feedback on outcome of behaviour and action planning are known to be effective for behaviour change, and can strengthen autonomy which is important for maintenance of change (Samdal et al., 2017). Integrated MI-CBT strategies can influence the determinants associated with PA maintenance if implemented correctly, and appear to be particularly important for long-term effects (Pavey et al., 2011).

8.5.1 Strengths and limitations

Using consulting surgeons to identify insufficiently physically active individuals was an important strength of this study. Once identified, surgeons discussed the need for PA change with insufficiently active patients and referred them to the study. This approach was based on hospital surgeons' stated preferences, previously ascertained, for clear referral pathways into specialist behaviour change programs (Barrett et al., 2019), and demonstrates how preventive health can be successfully embedded into routine ambulatory hospital care. The use of sequentially numbered study fliers permitted the calculation of the PA intervention interest and uptake. It is encouraging in this respect that one-third of the individuals made contact with the study team after referral by a surgeon, and almost 20% went on to undertake PA coaching of some type.

The uptake of the intervention itself is also promising given the opt-in procedure that was used and the eligibility criteria that were applied. Many insufficiently active people are not ready to change important behaviours and are therefore unlikely to volunteer for a study such as this (Hardcastle et al., 2013). Nevertheless, the individuals who did enroll in the study still needed to make those changes and we were able to demonstrate effectiveness in this group due to the robust nature of the RCT study design. This strengthens confidence in the transferability and scalability of our

findings. In the H4U study we demonstrated the efficacy of PA telephone coaching in self-selected sample of ambulatory care patients (Barrett et al., 2018a); in this study we have demonstrated its effectiveness when used as the end point in a referral pathway starting with consultant surgeons working in ambulatory secondary care.

The participant retention rate in this study was high, with only 12 participants lost to follow-up. Intervention adherence rate was also high, with 96% of participants receiving all 5 sessions of telephone coaching. The use of objectively measured PA at all time points was a considerable strength of the study, offering precise estimates of PA intensity. For a regional hospital, delivering the PA intervention via telephone permitted extending the reach to both geographically and socially disadvantaged areas. A limitation of the study may be the involvement of only one hospital, though this permitted the continuation of a previous body of work towards integrating preventive health in that hospital. Additionally, the broad generalizability of these findings might be difficult because the majority of participants were female and obese.

8.6 Conclusions

Ambulatory hospital appointments provide an important opportunity for initiating PA behaviour change. The H4U-2 trial demonstrates that PA telephone coaching is an efficacious tool for the promotion of a physically active lifestyle in adults and facilitates sustained behaviour change maintenance 6 months post-intervention. Physical activity coaching also resulted in significant sustained improvements in anthropometrics, PA self-efficacy and HrQoL. Telephone coaching interventions in ambulatory hospital care contribute to substantial improvements in participant's health outcomes, and are effective for the prevention and management of chronic disease.

Chapter 9

Discussion, recommendations and concluding remarks

The overarching purpose of this thesis was to investigate the effect of behaviour change interventions on PA and health-related outcomes in ambulatory hospital care in a regional hospital in Australia. A series of studies, using a variety of study designs were completed, culminating in a RCT that evaluated the effect of the behaviour change intervention for changes in and maintenance of PA and health-related outcomes in ambulatory secondary care patients referred by their consulting surgeon. This final study provided a link between the findings of the systematic reviews, the first RCT and the investigation of the hospital surgeons' practice and attitudes to preventive health. Integrating the findings from Chapters 3 to 7 provided strategies to evaluate the effective delivery and implementation of preventive health in ambulatory secondary care. This chapter synthesises the findings from the individual studies included in this thesis, and discusses the findings in relation to practical applications. A more detailed discussion of these studies, including their limitations is presented within the relevant chapters, all of which have undergone external peer review and are available in the published literature (Chapters 3 to 8).

9.1 Integrated discussion of findings

The management of chronic disease and associated morbidity has placed significant demands on the hospital system (Bodenheimer et al., 2009). Hospitals have been encouraged to broaden their role from a primary focus on curative care to a position of more integrated preventive health, and implement pathways that support individual self-management (Haynes, 2008; International Network of Health Promoting Hospitals and Health Services, 2020; Johnson & Baum, 2001; Pelikan et al., 2001). To support self-management, behaviour change interventions need to incorporate strategies to increase motivation and self-efficacy (Dishman et al., 2005; Lawn & Schoo, 2010; Newman et al., 2004). As improvements in behaviour change have been shown to diminish over time, interventions also need to also incorporate strategies to promote behaviour change maintenance (Dunkley et al., 2012; Kaur, 2014). The integration of MI and CBT has been proposed as a framework to promote self-management, and to facilitate lasting behaviour change (Naar-King et al., 2013; Naar & Safren, 2017). The effectiveness of MI-CBT interventions had not been

evaluated in ambulatory secondary care settings, and a significant gap existed regarding the optimum design and delivery of an MI-CBT intervention to change PA and health-related outcomes for this population. To address this, the systematic review and meta-analyses in Chapter 3 was carried out, with the results used to inform the design of the behaviour change interventions used later in this thesis. The systematic review was necessary to evaluate the overall effectiveness of the MI-CBT intervention and, for clinical applications, demonstrate the influence that the number of intervention sessions had on changes in PA and health-related outcomes.

The systematic review and meta-analyses in Chapter 3 provided evidence to support the use of integrated MI-CBT for changes in PA and health-related outcomes. While the observed effects sizes were modest, even small increases in PA and small changes in anthropometric measures can deliver positive health benefits (Magkos et al., 2016). The study provided important information relating to the delivery of the behaviour change intervention that was used in the subsequent RCTs in this thesis. The meta-analysis indicated that interventions lasting 5 sessions or more resulted in significant changes in PA. Interventions lasting 4 sessions or less did not result in significant changes in PA. Telephone delivery was one of the most common modes used, and generally favourable outcomes were associated with this method. This was particularly relevant for Bendigo Health as the Specialist Clinics service a wide geographic area of regional Victoria. Delivering the intervention via the telephone eliminated the need for individuals to travel extended distances and durations to undertake the PA coaching. The use of objective measurement to evaluate PA changes was an important recommendation from Chapter 3, and this was undertaken in both of the RCTs in this thesis through the use of accelerometers. Finally, the conclusion that future studies should include sufficient follow-up durations to determine the maintenance effects of the interventions was also accounted for in the 6 months of follow-up in Chapters 4 and 5, and the 9 months of follow-up in Chapter 8.

The systematic review and meta-analyses in Chapter 3 presented a number of options for consideration in the design of the H4U RCT reported in Chapters 4 and 5. The H4U study was largely concerned with evaluating the efficacy of the behaviour change intervention for changes in PA and health-related outcomes in ambulatory secondary care patients. Assessing intervention efficacy can be summarised into the question, 'can it work?' (Haynes, 1999). If an intervention does not work

under controlled conditions, it is unlikely to work under usual clinical conditions. Indeed, it has been recommended that all interventions are tested for efficacy prior to any larger scale implementation (Gottfredson et al., 2015; Haynes, 1999). The findings from Chapter 3 indicated that MI-CBT interventions lasting 5 sessions or more resulted in significant changes in PA, which was concluded to be the minimal number of sessions that should be used in the RCT. When MI and CBT are delivered as a single intervention, a dose effect has been observed such that more sessions tended to increase behaviour change effect sizes (Lundahl & Burke, 2009; Robinson et al., 2020). As adults attending ambulatory secondary care in Australia are more likely than the general population to have one or more chronic disease (Britt et al., 2008), it was concluded that a higher number of intervention sessions may benefit behaviour change in this population (Newman et al., 2004). These data informed the decision to provide 8 x 30-minute sessions to the intervention group in the H4U study.

The findings from the H4U study in Chapter 4 demonstrated that the intervention resulted in significant, beneficial changes in PA, anthropometrics and health-related outcomes that were maintained at follow-up. For PA changes, the observed effect size of 0.25 was slightly higher than the SMD of 0.18 reported in Chapter 3. This effect size was a positive outcome, given the objective measurement of PA used in the H4U study. The studies included in the meta-analyses in Chapter 3 predominantly used self-reported measures to assess changes in PA. Objective measures of PA typically result in smaller effect sizes compared with self-reported data (O'Halloran et al., 2014), which strengthened confidence in the findings of Chapter 4.

The Specialist Clinic surgeons did not have the capacity to participate in the H4U study in Chapter 4. Recruitment of participants into the study was via self-selection. Recruiting self-selecting participants might have introduced a degree of self-selection bias (Tripepi et al., 2010), meaning that the individuals were already potentially interested in becoming more physically active. An interesting result of this study was the baseline measure of PA for the participants. Despite the use of a well-validated tool (Rose et al., 2008) that screened all participants as insufficiently physically active prior to enrolment, the daily objectively measured MVPA at baseline was 31 ± 10 minutes for the cohort. This raised some questions as to whether this method of recruitment was broad enough to capture individuals who were ambivalent towards, or disinterested in changing PA. The use of

recruitment strategies such as posters can result in potentially biased samples; this remains a challenge for recruitment into PA interventions (Cooke et al., 2017; Mutrie et al., 2010).

Additionally, using posters on the wall to instigate behaviour change contemplation was unlikely to significantly contribute to the longer-term viability of increasing preventive health practice in the Specialist Clinics. These recruitment concerns were addressed in Chapter 8. In spite of these limitations, Chapter 4 provided robust data from a well-designed RCT on the efficacy of the intervention for changes in PA and health-related outcomes for secondary care patients.

Chapter 5 built upon Chapter 4 to provide further relevant information on the potential role of preventive health interventions in ambulatory secondary care. Chapter 5 assessed whether the MI-CBT intervention was a cost-effective method for increasing PA and health-related quality of life (HrQoL) for insufficiently active adults presenting to the Bendigo Health Specialist Clinics. Where Chapter 4 was predominantly concerned with efficacy, Chapter 5 was concerned with the economic implications. Economic analyses measure the effect of an intervention in relation to the resources it consumes, and may be considered through the query, 'is it worth it?' (Haynes, 1999). Little is known about the cost-effectiveness of adding preventive interventions to routine ambulatory hospital care, where implementing an intervention requires an upfront investment of money. By undertaking an economic analysis of this new preventive intervention, I was able to provide robust costing data directly to Bendigo Health management, and more broadly to clinicians and policy makers on the value of preventive health interventions in ambulatory secondary care.

To understand the relative value of an intervention, we need to know if it is cost-effective. The cost-effectiveness threshold is the maximum amount a decision-maker is willing to pay for a unit of a health outcome (Drummond et al., 2015). Cost-effectiveness thresholds are set to help identify interventions that appear to be relatively good, or very good value for money. Applying this to health services, a willingness-to-pay threshold represents an estimate of what healthcare services might be prepared to pay for the health benefit, given other competing demands on that consumer's resources (Bertram et al., 2016). Willingness-to-pay thresholds are clearly defined for measures such as quality adjusted life years (QALYs) and have been increasingly used for economic evaluations on health outcomes. Economic evaluations can inform important decision-making regarding how much health services are willing to pay for changes in specific health measures, for

example a 1 mmHg decrease in systolic blood pressure (Richman et al., 2016).

Evaluating the cost-effectiveness of adding PA interventions was complicated somewhat, because at present there is no standard for how much policymakers are willing to pay per additional minute of PA, or for engagement of at least 150 minutes of MVPA per week (Johnson et al., 2016). To address the lack of established thresholds for changes in PA, this thesis reported on a range of costs for achieving PA improvements. The estimated cost of delivering the intervention was \$279 per person, which represents a relatively low-cost strategy for increasing PA. This cost was comparable to other interventions used to increase PA (Elley et al., 2011; Groessl et al., 2009; Groessl et al., 2016; Johnson et al., 2016; Sevick et al., 2007). The cost of \$279 per person resulted in the average attainment of 41 ± 12 min of MVPA/day at 6 months. Over the 6-month follow-up period this can be translated to a cost of \$8.25 per week to increase MVPA to 150 min a week. This is comparable to the reported costs (\$4.99 - \$10.19) of other interventions aimed at increasing PA (Elley et al., 2011; Johnson et al., 2016; Sevick et al., 2007).

The greatest cost of the intervention was in the delivery, as it was delivered individually by me, a senior Allied Health clinician. This was an important finding given the results of the systematic review in Chapter 3 indicated that 5 sessions or more of MI-CBT were effective for changes in PA. The findings from Chapter 4 demonstrated that 8 sessions of MI-CBT resulted in significant, beneficial changes in PA. Decreasing the number of intervention sessions from 8 to 5 in the H4U-2 study in Chapter 8 provided an opportunity to improve efficiency, while adhering to evidence-based delivery parameters.

The economic evaluation reported in Chapter 5 was undertaken from a hospital perspective, which factored in the costs of delivering the service only (Drummond et al., 2015). One of the recommendations from Chapter 5 was for future studies investigating the cost-effectiveness of behaviour change interventions to consider taking a broader healthcare perspective to capture relevant economic data. In the H4U-2 study, the perspective of the economic analysis was changed from hospital perspective to a health service perspective. A health service perspective includes program and participant costs, and factors in other health service resource use costs associated with managing health conditions, for example GP visits or preventable hospital admissions. The

time-frame required to collect and analyse these data was beyond the scope of this thesis, but the findings may provide further information on the cost-effectiveness of this intervention for changes in PA and health-related outcomes in ambulatory secondary care.

The evidence of the intervention efficacy from Chapter 4 was backed up with economic data from Chapter 5, demonstrating that this low-cost intervention resulted in meaningful outcomes that were maintained at 6 months. The findings from these chapters strengthened the case for the role of preventive interventions in the secondary care setting. To further strengthen the case, the systematic review and meta-analyses reported in Chapter 6 was undertaken to provide high level evidence to support the use of ambulatory hospital appointments as an avenue to initiate behaviour change interventions for changes in PA and health-related outcomes. Evidence-based practice is a key part of decision making for clinicians in daily clinical work (Schnitzbauer et al., 2015). Surgeons are evidence-based practitioners, integrating individual clinical expertise with the best available clinical evidence obtained from systematic research (Hoffmann et al., 2014; Sackett et al., 1996). On a scale from 1 (unimportant) to 10 (very important), surgeons rated evidence-based practice as very important for clinical decision making (7.3 ± 1.9), and for patient care (7.8 ± 1.9) (Schnitzbauer et al., 2015). In addition, on a scale from 1 (unimportant) to 5 (very important), surgeons identified systematic reviews (4.6 ± 0.6) and RCTs (4.6 ± 0.6) as the highest levels of study designs to enhance evidence in clinical practice (Schnitzbauer et al., 2015).

The systematic review in Chapter 6 indicated that hospital-initiated behaviour change interventions resulted in large improvements in PA, and moderate changes in anthropometric outcomes. The results illustrated the value of behaviour change interventions for mitigating chronic disease risk factors, and support the implementation of preventive health interventions in ambulatory secondary care clinics. The systematic review highlights that ambulatory hospital patients represent an ideal population to intervene with to lessen the risk of developing serious health conditions. This finding correlates with the recent WHO (2020) guidelines on PA and sedentary behaviour, which provide recommendations for people living with chronic conditions to engage in regular PA. These results suggest that patients and public health at large might benefit from hospitals shifting their focus from curative care to a position of more integrated health promotion, and strengthen the case for the integration of behaviour change interventions in ambulatory secondary care. The

findings of the studies in Chapters 3 to 6 were presented to the Bendigo Health Specialist Clinic surgeons, demonstrating that if secondary care patients engage in preventive health interventions this can result in lasting, beneficial changes in PA and health-related outcomes. Upon review of the evidence presented to them, the Specialist Clinic surgeons agreed to take a participatory role in the research.

From the outset of the project, I felt that gaining input from the surgeons was essential in understanding the potential role of preventive interventions in the secondary care setting. The individuals attending the Specialist Clinic are there to see the surgeons. Seeing a surgeon is a major life event, and individuals are responsive to behaviour change in the face of such life events (Allender et al., 2008). Surgeons have the potential to be influential in promoting lifestyle behaviour change (Jones et al., 2004). Engaging with surgeons also represented an avenue to potentially address the recruitment limitations found in Chapter 4. I felt that using surgeons as part of the recruitment process might assist with enrolling participants who were ambivalent about changing PA, and help address issues with selection bias (Cooke et al., 2017; Mutrie et al., 2010). I did not know however, if referring patients into preventive health interventions was congruent with the Specialist Clinic surgeons' practice and interest. It is the surgeon who consults with the patients, and it is the surgeon who makes the operational decision to deliver preventive health advice and interventions, or not (Fixsen et al., 2005; Johansson et al., 2010). This is why the surgeons played a key role in the implementation process. If the goal of increasing preventive health in the Specialist Clinics was compatible with the surgeons' values and working norms, the prospects of successful implementation were likely to increase (Greenhalgh et al., 2004). It was therefore vital to explore the practice and opinions of the surgeons regarding preventive health, to further investigate the potential role of preventive health interventions in secondary care.

The findings from the mixed-methods study in Chapter 7 demonstrated that surgeons carried out preventive health interventions at low levels. The most commonly undertaken intervention was face-to-face conversations with patients about behavioural risk factors. Surgeons were unlikely to provide written advice or to refer patients to additional health behaviour change services. In contrast to previous research undertaken with hospital doctors (Daley et al., 2008; Hardcastle et al., 2018), lack of knowledge or confidence were not identified as barriers to preventive health practice

by the Bendigo Health Specialist Clinic surgeons. The quantitative data suggested that although surgeons believe it is important to address lifestyle changes with patients, and are confident and knowledgeable in doing so, these factors did not predict actual rates of preventive health practice.

The most common behaviour change discussions undertaken with patients related to smoking cessation. Conversations about smoking cessation predominantly related to surgical risk, and were not related to the risk of smoking for general health. Surgeons are well versed in risk mitigation, and the provision of smoking cessation advice is likely to be influenced by the well-publicised literature relating to smoking and post-operative risks (Tønnesen et al., 2009). In regard to PA, the surgeons tended to discuss PA in terms of physical strength, where having stronger musculature pre-operatively was correlated with improved recovery post-operatively. This too is consistent with the extant literature relating to preoperative PA and post-surgery recovery (Hoogeboom et al., 2014; Nilsson et al., 2016). There is an absence of studies relating to the provision of non-treatment-based PA advice by surgeons, where the advice relates to general PA levels, and not the presenting condition. The lack of published literature on preventive health practice by surgeons might have influenced the surgeons' perception that spending time on preventive health discussions was not a priority within their role.

The surgeons expressed positive attitudes towards preventive health, and believed that preventive health is relevant within ambulatory secondary care. The surgeons were willing to engage in discussions on avenues to increase preventive health practice in the Specialist Clinics. The surgeons valued facilitating a change in practice to integrate preventive health into practice, which was a vital component for the implementation of practice change (Greenhalgh et al., 2004; Johansson et al., 2010). By asking the surgeons to come up with their own solutions to integrating preventive health into practice, the proposed changes were likely to be compatible with the surgeons' own values, working norms, and perceived needs (Greenhalgh et al., 2004). To increase preventive health practice in the Specialist Clinics, the surgeons' preference was for the creation of specific information fliers on behaviour change to give to patients, and for referral pathways that link patients to specialist behaviour change programs. The surgeons did not have time to spend researching the programs available in the community for changes in lifestyle behaviours such as PA or diet. This likely contributed to the very low rates of referrals to preventive health programs

reported in the clinician survey. Probing this topic in the interviews, it was evident that the only referrals for PA services the surgeons completed were for in-house physiotherapy, and these referrals were specific to an existing physical ailment, namely the reason for presenting at the clinic. The surgeons were cognisant of the demand for rehabilitation services in the hospital, and as a result tended to forego preventive health referrals to allied health practitioners to increase general PA. For the surgeons, information fliers and standardised referral pathways to specialist behaviour change programs would allow them to engage in preventive health with patients in a time-efficient manner, and subsequently offer a referral to follow-on services.

The results of Chapter 7 provided rich data towards the aim of understanding the potential role of preventive health in ambulatory secondary care. Using the findings from Chapters 3 to 6, I was able to illustrate to the surgeons that if secondary care patients engage in behaviour change interventions this can result in lasting beneficial changes in PA and health-related outcomes. Demonstrating the efficacy of the behaviour change intervention in Chapter 4 was important, as referral pathways into a specialist behaviour change program was the very thing that surgeons recommended as a way for them to integrate preventive health interventions into the Specialist Clinic. Adding the findings from Chapter 7 to the previous chapters offered a more complete picture of behaviour change interventions in Specialist Clinic practice, and informed the design of the RCT reported in Chapter 8, the Healthy 4U-2 (H4U-2) study.

While the H4U study was largely concerned with evaluating the efficacy of the intervention for changes in PA and health-related outcomes in ambulatory secondary care patients, H4U-2 was concerned with evaluating the intervention in a more pragmatic delivery, and moving towards an assessment of effectiveness. Assessing effectiveness determines whether an intervention is effective under usual circumstances of healthcare provision, and can be summarised into the question, 'does it work in practice?' (Haynes, 1999). In order to evaluate the intervention under conditions closer to standard clinical practice, a number of changes were made to the design of the H4U-2 study, relative to the H4U study.

The method of study recruitment differed between H4U and H4U-2, with consulting surgeons used in the recruitment for the H4U-2 study. Using direct input from the surgeons, a research flier was

created that the surgeons would provide to individuals (Appendix 9.7). During clinical practice the consulting surgeons identified patients who, in their view, would benefit from increased PA and the surgeons provided patients with a verbal recommendation to engage in PA coaching, and the research flier. Although the surgeons were cognisant of time demands, they felt that this recruitment flier would permit them to undertake a brief conversation, facilitating them to play a role in preventive health. Even this brief intervention had potential to elicit behaviour change contemplation, with as little as 3 minutes of medical advice shown to markedly increase a patient's chance of undertaking behaviour change (Hughes, 2003).

As a result of the findings from Chapters 3 to 6, changes were made to the delivery and reporting of the MI-CBT intervention in Chapter 8. In Chapter 4, the primary objective was to establish the efficacy of the intervention for PA changes in the secondary care patient population. The provision of 8 x 30-minute intervention sessions resulted in a moderate effect size PA change, which supported the efficacy of the intervention. These preventive health interventions were provided in addition to standard care, not as a substitution, therefore determining the effectiveness of a more pragmatic dose was important. As the greatest cost of the intervention was borne from the delivery, decreasing the dose of the intervention would impact the overall cost of adding preventive health intervention into ambulatory secondary care. In the H4U-2 study, the participants were provided with 5 x 20-minute intervention sessions over 12 weeks. The provision of five sessions was supported by the evidence, and could improve the economic efficiency, which was a key recommendation from Chapter 5. In the H4U study, a total of 144 hours of intervention delivery were undertaken, providing coaching support to 36 individuals. In the H4U-2 study, the time spent delivering the intervention decreased to 99 hours, though the number of individuals who received the coaching support increased to 60. Increasing the reach of the intervention was important for the overall viability of the intervention, and is important for strengthening the case for longer-term investments in preventive health by hospitals.

The decision to provide the intervention in 5 x 20-minute sessions in H4U-2 was not informed through consumer consultation, which is a noted limitation of this work. The decision was informed by the evidence from Chapter 3, and the economic analysis in Chapter 5. Given the need to offer services at scale within the fiscal constraints of the public hospital budget, decreasing the number

and duration of sessions was a pragmatic decision. As the H4U-2 study was concerned with effectiveness and a simulated integration of the intervention into clinical practice, a process evaluation including consumer consultation with 18 participants has been undertaken. The results of this evaluation and the timeframe in which to report them fall beyond the scope of this thesis, but they will be used to inform future research and practice.

Despite the proliferation of behaviour change research, the uptake of effective behaviour change interventions into clinical practice settings has been limited (Bacon et al., 2014). Interventions that have demonstrated efficacy in research settings are often less effective once implemented into real-life settings (Feldman et al., 2014). Two of the key methodological inadequacies that pose barriers towards the implementation of interventions into practice are the poor reporting of intervention content and intervention fidelity (Toomey et al, 2020). Beyond research studies seeking to assess the effectiveness of behaviour change interventions, the clear identification of intervention components and measurement of intervention fidelity are important for evaluating, and potentially scaling up of interventions into policy or practice (Bacon et al., 2014). The poor reporting of behaviour change intervention components found in the systematic review in Chapter 6 highlighted the need for more accurate detailing of behaviour change content, determinants, theories and techniques. Clear reporting can help specify the core components of an intervention and link to theories of change (Abry et al., 2014). In Chapter 8, the behaviour change intervention schedule, content, theory, determinants and behaviour change techniques were clearly identified and reported. When evaluating the implementation of behaviour change interventions into real life contexts, it is also important to assess the intervention fidelity as close as possible to the original intervention, while permitting required adaptation for contextual differences (McCrabb et al, 2019). The use of the MI-CBT scale permitted the evaluation of the integrated components of MI and CBT delivered within the contextual framework designed to elicit and maintain changes in PA.

The final key difference between H4U and H4U-2 was the change in timeframe for outcome measures. Both studies were interested in PA change and maintenance. Prochaska & DiClemente (1982) hypothesised that maintenance occurs at a minimum of 6 months after initial behaviour change. More recently, when evaluating maintenance of PA change, Fjeldsoe et al. (2011) used the measure of 3-months following intervention completion to determine behaviour change

maintenance. In the H4U study, outcome measures were recorded at baseline, after 3 months of intervention (post-intervention) and at 6 months (follow-up). The extension of outcome measures from baseline to 6 months included a 3-month period where no contact with participants was made, which was designed to investigate behaviour change maintenance (Fjeldsoe et al., 2011; Prochaska & DiClemente, 1982). In the H4U-2 study, outcome measures were recorded at baseline, after 3 months of intervention (post-intervention) and at 9 months (follow-up). This provided a 6-month no-contact period. This 6-month no-contact period following the intervention satisfied the behaviour change maintenance timeframe proposed by Prochaska & DiClemente (1982) and Fjeldsoe et al. (2011). It also satisfied the more recent recommendations made by Howlett and colleagues (2019), which stated that 6-month post-intervention outcomes, where no contact with participants is made, are preferable to capture behaviour change maintenance.

The results from Chapter 4 demonstrated that 8 x 30-minute sessions of MI-CBT resulted in a significant increase in MVPA that was maintained at 6 months. The effect size for PA change was 0.25 and resulted in the intervention group undertaking an average of 41 ± 13 min/day of MVPA at 6 months. In Chapter 8, the intervention was delivered in 5 x 20-minute sessions, resulting in an effect size for PA change of 0.20. This translated to the intervention group undertaking 22 ± 10 min/day of MVPA at 9 months. While both studies report significant positive findings and in both studies the intervention groups undertook enough objectively measured PA to be deemed sufficiently physically active, there were important differences in the studies that may have influenced the results. Though both studies screened potential participants prior to enrolment to ensure they fulfilled the criteria of insufficiently physically active, there was a marked difference in the baseline MVPA measurement between H4U and H4U-2. In the H4U study, MVPA was 31 ± 10 min/day at baseline. In H4U-2, where the surgeons initially highlighted to patients the need for PA behaviour change and provided patients with the study information, the baseline MVPA of participants was 15 ± 5 min/day. The participants in both studies completed their baseline measures after attending the education session. Education interventions based on self-determination theory (SDT) can result in short-term increases in PA (Teixeira et al., 2012). In the H4U study, it was theorised that the education session contributed somewhat to the high MVPA levels recorded at baseline (Teixeira et al., 2012). This was not observed in H4U-2, despite all participants undergoing the same education session. It is likely that the participants who self-selected into the H4U study were already interested in becoming more physically active and more

motivated to engage in health-promoting behaviours and PA change (Hardcastle et al., 2015). In the H4U-2 study, the surgeons identified and referred patients; this provided a pathway to access individuals who were potentially less inclined to make the necessary changes by themselves. The brief preventive health intervention undertaken by the surgeons may have initiated behaviour change contemplation to the point that the individuals considered being more physically active and were willing to engage with the study team. The brief interaction with the surgeon may not have been enough by itself for the individuals to increase their PA levels.

Behaviour change occurs gradually, with individuals moving from being uninterested, unaware or unwilling to make a change (precontemplation), to considering a change (contemplation), and progressing to a point of deciding and preparing to make a change (Brogan, 1999). Behaviour change is rarely a discrete, single event (Zimmerman et al., 2000). The primary goal to achieve with individuals uninterested in change is to get them to begin to think about changing a behaviour (Grol & Grimshaw, 2003). DiClemente (1991) said *“we cannot make precontemplators change, but we can help motivate them to move to contemplation”*. This was where the surgeons played a key part. The important task for the surgeons was to engage patients in contemplating change (DiClemente, 1991; Zimmerman et al., 2000). Doctors can engage patients in the contemplation process by developing a positive relationship, by personalising risk factors and posing questions that provoke thoughts about risk factors (Zimmerman et al., 2000). The surgeons voiced elements of this in Chapter 7, however, they reported only discussing risk factors as they related to the presenting ailments. For example, they discussed how the patients’ poor muscle strength predisposed them to arthritis related pain. What was not discussed by the surgeons was the personalisation of risk factors beyond the presenting condition. They did not discuss insufficient PA as a risk factor for health; instead, they stuck to the presenting condition. This was influenced by factors other than surgeon beliefs. The surgeons were reticent to refer people to physiotherapy or exercise physiology to increase general PA as they were conscious of the demand for those services for rehabilitation needs. This might have influenced their low rates of preventive health practice in Chapter 7. However, their positive attitudes towards preventive health, and their willingness to engage in discussions on avenues to increase preventive health practice in the Specialist Clinics permitted the co-design of strategies to address these barriers.

The co-design of the recruitment strategy was a real strength of the H4U-2 study. Chapters 4, 5 and 6 demonstrated to the surgeons the significant lasting changes in PA and health-related outcomes that occurred when ambulatory secondary care patients engaged in behaviour change interventions. The in-depth assessment of surgeons' practice and attitudes to preventive health in Chapter 7 led to the co-design of pathways to facilitate preventive health interventions in the Specialist Clinics. While the changes to practice were small, they were co-designed by the proposed implementers themselves, which is vital for practice change implementation (Greenhalgh et al., 2004). The pathway allowed the surgeons to refer into a reputable behaviour change program, which was another preference stated in Chapter 7.

The process resulted in 2076 individuals receiving a preventive health intervention over the duration of the recruitment period. Importantly for the potential ongoing inclusion of preventive health in ambulatory secondary care, this pathway permitted the surgeons to provide the preventive health interventions during the normal course of the consultation. This small change to surgeon practice can be maintained beyond the study timeframe and can facilitate ongoing preventive health practice in ambulatory secondary care. This model of active patient identification and intervention is more effective than passive strategies such as posters displayed in clinics, and also permits the recruitment of samples that are potentially less biased towards PA uptake (Cooke et al., 2017; Mutrie et al., 2010). The influence of the surgeon is likely to provide preventive health interventions to individuals uninterested or ambivalent to making a change (Allender et al., 2008). This is an important step towards the delivery of preventive health interventions to those who may benefit from it most. The integrated findings from Chapters 3 to 8 provide a deeper insight into the effectiveness of behaviour change interventions on PA and health-related outcomes in ambulatory hospital care.

Through the co-design of clinical pathways, surgeons were able to engage with individuals who would benefit from change, make the verbal recommendation and provide information for a follow-on program. The surgeons stated that referring individuals into creditable programs was their preferred method for increasing preventive health practice in the Specialist Clinics. The findings from Chapter 3 and 4 illustrated the efficacy of the MI-CBT intervention, and creating a referral pathway into the H4U-2 intervention satisfied the surgeons' desire to refer into reputable

programs. Surgeons undertake high volumes of non-admitted consultations annually, which provides significant opportunities to engage in preventive health practice (Zeev et al., 2017). In Australian hospitals alone, more than 2.2 million elective admissions involving surgery were undertaken in 2015–2016 (Australian Institute of Health and Welfare, 2017; Keyworth et al., 2018). This pathway could be replicated in other ambulatory care settings and could have positive implications for community health and public health more broadly.

9.2 Recommendations for research and practice

The findings of this thesis highlight a number of areas to be considered when developing, implementing and evaluating behaviour change interventions in ambulatory secondary care. Recommendations for future work are provided in this section.

Recommendation 1: Preventive health interventions should be implemented and evaluated across a broader range of ambulatory secondary care specialties.

Health professionals have been increasingly encouraged to use clinical consultations to engage patients in behaviour change contemplation, with a focus on ‘making every contact count’ (Gates et al., 2016). Clinicians are encouraged to take a holistic view of clinical presentations and behavioural risk factors, and move away from the reductionist approach of managing chronic diseases through pharmacotherapy (Kaur, 2014). Reductionist approaches are likely to remain in practice due to the belief that it is more efficacious to prescribe medication for conditions such as hypertension, hyperglycaemia or dyslipidaemia rather than working towards a longer-term strategy to increase PA, improve dietary intake and lose excess weight as a means to improve chronic disease morbidity (Ahn et al., 2006; Kaur, 2014). There is a broad range of medical specialists working in ambulatory secondary care settings and engaging these professionals in preventive health initiatives could contribute to a deeper understanding of the role that preventive health plays across the continuum of ambulatory secondary care. In the Specialist Clinics at Bendigo Health, this would present an opportunity to increase preventive health practice in medical subspecialties such as endocrinology, renal health and obstetrics. These subspecialties have established links with behavioural risk factors including insufficient PA, poor nutrition, alcohol consumption, and tobacco smoking, and behaviour change interventions offer the potential to mitigate these risk factors. While the findings from Chapter 7 can be broadly generalisable to other clinicians practicing in Specialist Clinics, future research in these subspecialties assessing rates of preventive health practice would provide important data on the role of behaviour change interventions in ambulatory secondary care.

Recommendation 2: Preventive health interventions should be implemented and evaluated at a large scale within a range of public hospitals.

The effectiveness of the interventions used in this thesis to increase and maintain changes in PA and health-related outcomes supports the use of behaviour change interventions that could be added to routine secondary care in public hospitals. Recruiting participants for the RCTs in Chapters 4 and 8 from one hospital site only may have been a limitation of each of the studies, however, it permitted the continuation of this body of work towards the overall aim of understanding the effect of behaviour change interventions on PA and health-related outcomes in ambulatory hospital care. The positive findings from the RCTs in Chapters 4 and 8 are backed up by the findings from the systematic review in Chapter 6 which demonstrated beneficial changes in PA and anthropometrics amongst a wide range of patient populations attending ambulatory hospital clinics. The populations ranged from younger to older adults and included patients with health risk factors to individuals with established chronic diseases. Together these findings indicate that ambulatory hospital care patients represent an ideal population to intervene with to mitigate the risk of developing serious health conditions. This recommendation aligns with that of the 2020 WHO guidelines on PA and sedentary behaviour (World Health Organization, 2020), which indicate the importance of PA for individuals with chronic conditions.

Of the RCTs included in the systematic review in Chapter 6, more than two thirds had an n of less than 200, and almost half of all studies had an n of less than 100. Future research should utilise high quality RCTs with an increased number of participants and multiple recruitment sites to assess the broader generalisability of the findings. Larger-scale trials incorporating additional medical sub-specialties as discussed in Recommendation 1 could identify sub-groups of secondary care patients that respond favourably (or not) to behaviour change interventions. Supporting patient behaviour change in the hospital setting is one of the key sub-standards in the 2020 Standards for Health Promoting Hospitals and Health Services (International Network of Health Promoting Hospitals and Health Services, 2020). These standards highlight the need for hospitals to consider integrating pathways to interventions that address changes in health risk behaviours such as insufficient PA, poor diet and smoking.

Recommendation 3: Cost-effectiveness analysis should be conducted as part of future behaviour change interventions targeting patients presenting to secondary care clinics.

A primary focus of the Australian health system is to improve health outcomes via better prevention and management of chronic diseases (Australian Institute of Health and Welfare, 2014). The goal of improving and maintaining health outcomes is complicated by the ageing population and the impact of lifestyle-related chronic disease and associated morbidity (Australian Institute of Health and Welfare, 2014; Willett et al., 2006). Research and public policy efforts need to focus on effective and cost-effective interventions for lifestyle behaviour change (Cecchini et al., 2010; Ding et al., 2016). Cost-effectiveness is best determined by long-term health benefits rather than the direct cost of treating chronic disease morbidity (Drummond et al., 2015). Despite the clinical value of large studies evaluating behavioural lifestyle interventions, the lack of robust economic data highlights the need to evaluate the cost-effectiveness of these interventions (Drummond et al., 2015; Dunkley et al., 2012). Future research on preventive health and behaviour change interventions in ambulatory secondary care should include long-term follow-up with a robust assessment of economic outcomes from a broad health service or societal perspective.

Recommendation 4: Preventive health interventions in ambulatory secondary care should be implemented and evaluated across a broader range of behavioural risk factors including diet, alcohol consumption, and tobacco.

Chronic diseases and associated morbidity place a significant burden on hospitals. Insufficient PA, poor nutrition, excess alcohol consumption, and tobacco smoking are significant behavioural risk factors for chronic disease development (Bodenheimer et al., 2009). This thesis provides evidence for the potential effectiveness that behaviour change interventions play for changes and maintenance in PA in ambulatory secondary care patients. In addition to changes in PA, a number of important secondary outcomes were found in this thesis. In the RCTs presented in Chapters 4 and 8, the behaviour change interventions resulted in significant beneficial changes in anthropometrics. The beneficial changes in anthropometrics are of clinical importance as these risk factors are strong indicators of metabolic dysfunction, and associated with development and

worsening of issues such as cardiovascular disease and diabetes morbidity (Kannel et al., 1996; Williamson et al., 2000). The significant reductions exhibited in body mass, BMI and waist circumference are important findings given that recruitment into the studies was based upon interest in changing PA, and not in changing anthropometrics. The behaviour change interventions undertaken in Chapters 4 and 8 were also designed and delivered based on determinants of PA, with the sole focus of changing PA behaviours, and did not contain any content specifically related to changes in anthropometrics.

In addition to improvements in anthropometrics, in both Chapter 4 and Chapter 8 the behaviour change interventions resulted in significant differences in HrQoL between intervention and control groups. Although integrated MI-CBT interventions have been used across a range of mental health areas (Westra & Arkowitz, 2011), the improvements in HrQoL found in Chapters 4 and 8 are also important as the strategies used in the interventions were based on determinants of PA change, and not changes in HrQoL. The improvements in multidimensional quality of life measures demonstrate the positive secondary changes elicited through interventions that aim to increase motivation, self-efficacy, and resilience. Future research should investigate the effectiveness of behaviour change interventions in ambulatory secondary care with a primary focus on changes and maintenance in diet, alcohol consumption, and tobacco smoking. This could provide evidence for the effectiveness of preventive health interventions on the primary outcomes, as well as secondary outcomes such as multidimensional quality of life measures.

Recommendation 5: Published research evaluating behaviour change interventions need to clearly detail the content, theories and components of the interventions used.

Behaviour change interventions are a coordinated set of activities designed to change specified behaviour patterns (Michie et al., 2011a). The design of behaviour change interventions generally starts with determining the broad approach that will be used, and then refining the specifics of the intervention design. Despite the recognition that a near indeterminable number of ways of classifying behaviour change interventions exists, the reporting of intervention components, determinants and behaviour change techniques in published research could be much improved (Kok et al., 2016; Michie et al., 2009). Limited description of behaviour change interventions means

the reader is often left knowing very little about intervention components, or the relationship between the intervention components and the results (Michie et al., 2009). The poor description of behaviour change interventions also constrains scientific replication (Kok et al., 2016). Clarity in the intervention details and functional relationships are important for potential widespread implementation and scale-up of effective interventions (Sullivan et al., 2008). The provision of sufficient knowledge assists in the teaching of new practitioners, understanding how to measure fidelity and provides important information to guide implementation into clinical practice (Michie et al., 2009; Mowbary et al., 2003). These are all key components of successful implementation (Mowbary et al., 2003). The ubiquitous publication of supplementary material overcomes traditional issues of journals' space constraints, and permits the publication of detailed intervention content, theory, determinants, behaviour change techniques and fidelity framework. Increased clarity about the functional components of behaviour change interventions can only benefit the field, and public health more broadly.

9.3 Concluding remarks

This thesis has added to the understanding of the effect of behaviour change interventions on PA and health-related outcomes in ambulatory secondary care patients, and contributed to the evidence on the potential role of behaviour change interventions in this setting. Whilst the need for hospitals to broaden their perspective beyond curative care to a position of more health promotion has been well documented, the evidence for the integration of preventive health into clinical practice is scarce. This thesis has demonstrated that engaging adults presenting to secondary care hospital clinics in behaviour change interventions resulted in significant, lasting changes in PA and health-related outcomes. Behaviour change interventions combining MI and CBT together provide strategies to increase motivation, self-efficacy and coping skills, and facilitate behaviour change and maintenance. While these interventions need to be delivered as an addition to secondary care, not a substitution, they can deliver these beneficial outcomes at a low cost. Finally, to facilitate integrating preventive health interventions in routine care, engagement with practicing clinicians is essential. Understating the perspective of clinicians towards preventive health, and the co-design of pathways to increase preventive health practice can enable the integration of preventive health interventions into standard care and is a key component in the ongoing role of preventive health interventions in ambulatory secondary care.

Chapter 10

Appendices

10.1 Appendix 3.1 Search strategy and results Ovid PsycINFO

NOTE - Appendix 3.1 has been published: Barrett S, Begg S, O'Halloran P, & Kingsley M. (2018). Integrated motivational interviewing and cognitive behaviour therapy for lifestyle mediators of overweight and obesity in community-dwelling adults: a systematic review and meta-analyses. *BMC Public Health*. 18(1), 1160. <https://doi.org/10.1186/s12889-018-6062-9>.

#	Searches	Results	Search Type
1	exp Motivational Interviewing/	2066	Advanced
2	motivational interviewing.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]	3458	Advanced
3	motiv* interv*.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]	4074	Advanced
4	motivat* Counsel*.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]	124	Advanced
5	health* coach*.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]	169	Advanced
6	Motivat* change.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]	221	Advanced
7	Motivat* Intervention.mp.	431	Advanced
8	1 or 2 or 3 or 4 or 5 or 6 or 7	4526	Advanced

#	Searches	Results	Search Type
9	exp Cognitive Therapy/ or exp Treatment Outcomes/ or exp Cognitive Behavior Therapy/ or exp Intervention/	145696	Advanced
10	cogni* behav* ther*.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]	25046	Advanced
11	cognitive*.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]	462468	Advanced
12	behavioral.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]	291117	Advanced
13	behavioural.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]	41467	Advanced
14	cogni* behav* strat*.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]	457	Advanced
15	CBT.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]	11453	Advanced
16	CBS.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]	856	Advanced
17	maintenance.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]	55967	Advanced
18	cognitive restructuring.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]	2418	Advanced
19	mindfulness.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]	10106	Advanced
20	relaxation.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]	15660	Advanced
21	RET.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]	779	Advanced
22	9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21	853474	Advanced
23	8 and 22	2553	Advanced

#	Searches	Results	Search Type
24	limit 23 to (human and english language and embase and randomized controlled trial and journal) [Limit not valid in PsycINFO; records were retained]	1799	Advanced
25	health* behav* chang*.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]	1477	Advanced
26	health related behav* change.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]	66	Advanced
27	exercis*.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]	65515	Advanced
28	activity.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]	285535	Advanced
29	prevent* health.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]	1942	Advanced
30	health promotion.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]	27034	Advanced
31	diet*.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]	41632	Advanced
32	nutrition*.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]	26289	Advanced
33	smok* cessat*.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]	14242	Advanced
34	physic* activ*.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]	32442	Advanced
35	alcohol*.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]	125841	Advanced
36	25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35	526058	Advanced
37	24 and 36	942	Advanced

10.2 Appendix 3.2 Sensitivity analyses of imputed correlation coefficients for meta-analyses investigating MI-CBT for physical activity change and anthropometric change

NOTE - Appendix 3.2 has been published: Barrett S, Begg S, O'Halloran P, & Kingsley M. (2018). Integrated motivational interviewing and cognitive behaviour therapy for lifestyle mediators of overweight and obesity in community-dwelling adults: a systematic review and meta-analyses. *BMC Public Health*. 18(1), 1160. <https://doi.org/10.1186/s12889-018-6062-9>.

Outcome Measure	Std. Mean Difference, Fixed (95% CI)		
	Imputed	Imputed	Imputed
	Correlation	Correlation	Correlation
	Coefficient = 0.5	Coefficient = 0.2	Coefficient = 0.8
Physical activity change	0.18 (0.06, 0.31)	0.15 (0.03, 0.26)	0.28 (0.16, 0.39)
Anthropometric change	-0.12 (-0.24,0.01)	-0.09 (-0.22, 0.03)	-0.18 (-0.31, -0.06)

Std. Mean Difference: standardized mean difference; Fixed: fixed-effects model; (95% CI): 95% confidence interval.

10.3 Appendix 3.3 Funnel plots of meta-analyses investigating MI-CBT for physical activity change and anthropometry change

NOTE - Appendix 3.3 has been published: Barrett S, Begg S, O'Halloran P, & Kingsley M. (2018). Integrated motivational interviewing and cognitive behaviour therapy for lifestyle mediators of overweight and obesity in community-dwelling adults: a systematic review and meta-analyses. *BMC Public Health*. 18(1), 1160. <https://doi.org/10.1186/s12889-018-6062-9>.

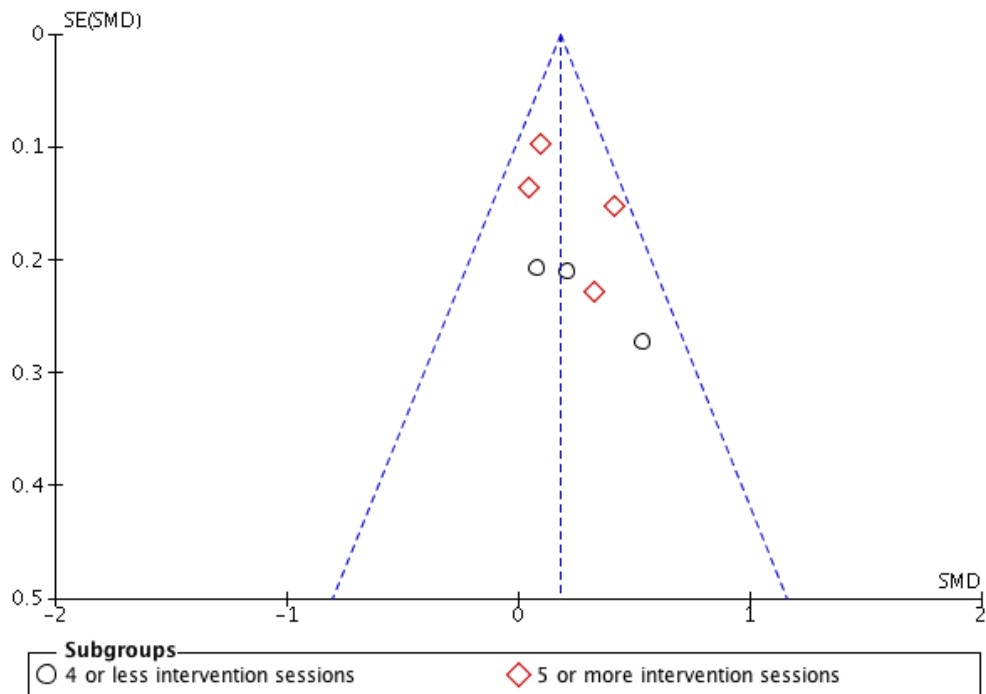


Figure A: Funnel plot for meta-analysis investigating MI-CBT for physical activity change.

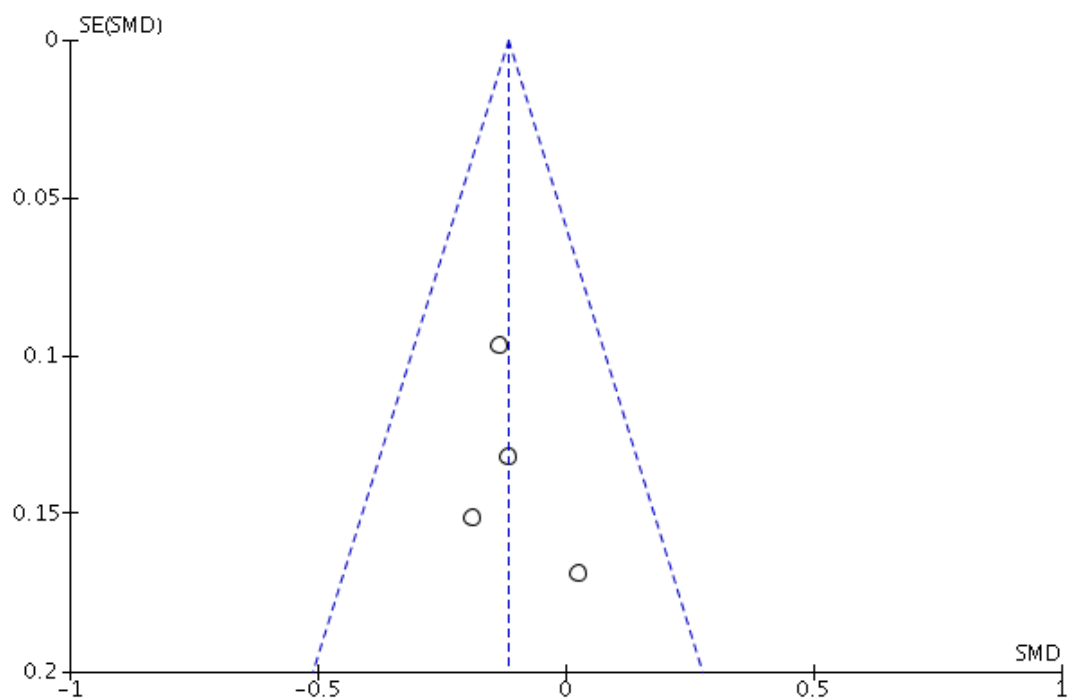


Figure B: Funnel plot for meta-analysis investigating MI-CBT for anthropometric change.

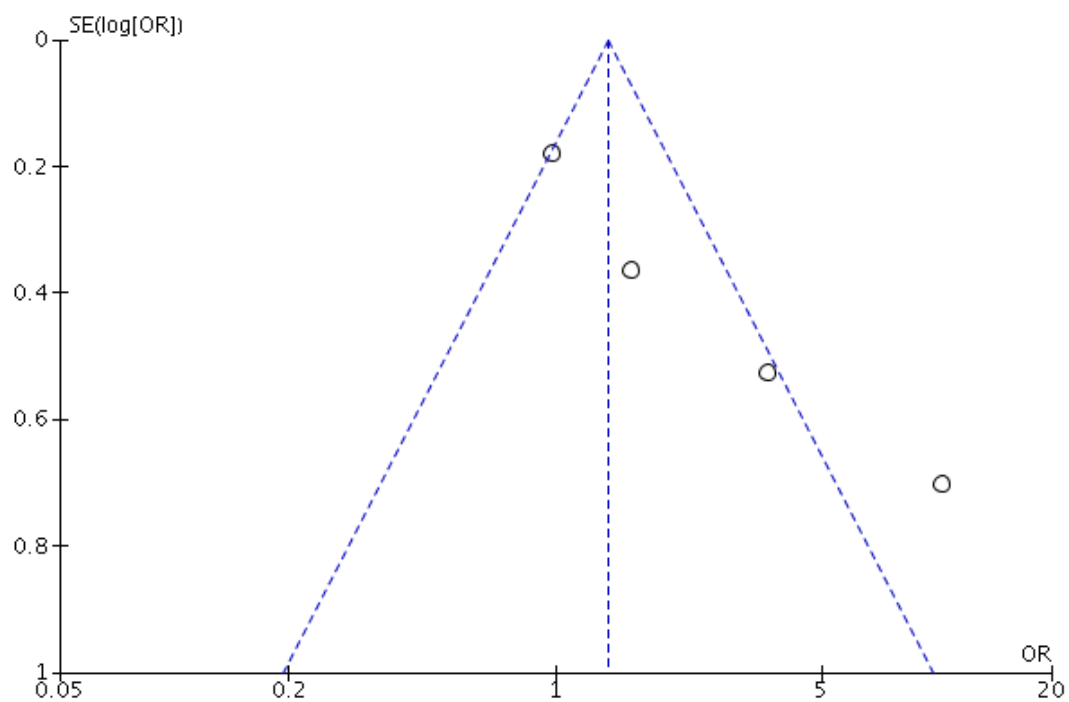


Figure C: Funnel plot for meta-analysis investigating MI-CBT for achieving physical activity guidelines.

10.4 Appendix 3.4 Quality of evidence of Integrated Motivational Interviewing and Cognitive-Behaviour Therapy compared to standard care for physical activity change and anthropometric change

NOTE - Appendix 3.4 has been published: Barrett S, Begg S, O'Halloran P, & Kingsley M. (2018). Integrated motivational interviewing and cognitive behaviour therapy for lifestyle mediators of overweight and obesity in community-dwelling adults: a systematic review and meta-analyses. *BMC Public Health*. 18(1), 1160. <https://doi.org/10.1186/s12889-018-6062-9>.

Quality assessment							№ of patients		Effect		Quality	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	MI-CBT	standard care	Relative (95% CI)	Absolute (95% CI)		
Physical Activity Change												
7	randomised trials	not serious	not serious	not serious	serious ^a	none	560	579	-	SMD 0.18 higher (0.06 higher to 0.31 higher)	⊕⊕⊕○ MODERATE	

Quality assessment							№ of patients		Effect		Quality	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	MI-CBT	standard care	Relative (95% CI)	Absolute (95% CI)		
Meeting physical activity guidelines												
4	randomised trials	not serious	serious ^b	not serious	serious ^a	none	222/404 (55.0%)	190/401 (47.4%)	OR 2.30 (0.97 to 5.57)	77 more per 1,000 (from 5 more to 146 more)	⊕⊕○○ LOW	

Quality assessment							№ of patients		Effect		Quality	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	MI-CBT	standard care	Relative (95% CI)	Absolute (95% CI)		
Physical Activity Change Short term intervention												
3	randomised trials	not serious	not serious	not serious	serious ^a	none	120	121	-	SMD 0.23 higher (0.02 lower to 0.49 higher)	⊕⊕⊕○ MODERATE	

Quality assessment							№ of patients		Effect		Quality	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	MI-CBT	standard care	Relative (95% CI)	Absolute (95% CI)		
Physical Activity Change Long term intervention												
4	randomised trials	not serious	not serious	not serious	serious ^b	none	440	458	-	SMD 0.18 higher (0.01 higher to 0.35 higher)	⊕⊕⊕○ MODERATE	

CI: Confidence interval; SMD: Standardised mean difference; OR: Odds ratio; a. Inadequate sample size; b. Significant Heterogeneity

Quality assessment							№ of patients		Effect		Quality	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	MI-CBT	standard care	Relative (95% CI)	Absolute (95% CI)		
Anthropometric changes												
4	randomised trials	not serious	not serious	Serious ^a	Not serious	none	487	492	-	SMD 0.12 lower (0.24 higher to 0.01 higher)	⊕⊕⊕○ MODERATE	

CI: Confidence interval; SMD: Standardised mean difference; a. wide confidence intervals

10.5 Appendix 3.5 Risk of bias for included studies

NOTE - Appendix 3.5 has been published: Barrett S, Begg S, O'Halloran P, & Kingsley M. (2018). Integrated motivational interviewing and cognitive behaviour therapy for lifestyle mediators of overweight and obesity in community-dwelling adults: a systematic review and meta-analyses. *BMC Public Health*. 18(1), 1160. <https://doi.org/10.1186/s12889-018-6062-9>.

	A	B	C	D	E	F	G	H	I
Bennett et al., 2007	+	+	-	-	+	?	?	+	+
Conn et al., 2003	?	?	-	+	+	+	+	+	+
Greaves et al., 2008	+	+	-	+	+	?	+	+	+
Groeneveld et al., 2011	+	+	-	?	+	+	+	+	+
Janssen et al., 2014	+	?	-	+	+	?	+	?	?
Knittle et al., 2015	+	+	-	+	?	?	+	+	+
Lakerveld et al., 2013	+	+	-	+	-	-	+	+	+
Marques et al., 2017	+	?	-	-	+	+	+	+	+
Martens et al., 2012	+	+	-	-	?	+	+	?	?
Murphy et al., 2013	+	?	-	+	+	+	+	+	-
<p>A: random sequence generation (selection bias). B: allocation concealment (selection bias). C: Blinding of participants (performance bias). D: Blinding of outcome assessment (detection bias). E: Incomplete outcome data (attrition bias). F: Selective reporting (reporting bias). G: Baseline similarity. H: Compliance. I: Co-interventions.</p> <p>+: low risk of bias. ?: unclear risk of bias. -: high risk of bias.</p>									

10.6 Appendix 4.1 Institutional ethical approvals for Chapter 4



HEALTHY COMMUNITIES AND
WORLD CLASS HEALTHCARE

CARING | PASSIONATE | TRUSTWORTHY

Ms Sally McCarthy
Research Manager
Bendigo Health Care Group HREC
Bendigo Health Care Group
PO Box 126
Bendigo, Victoria, 3552

A/Prof Michael Kingsley
Associate Professor in Exercise Physiology
Rural Health School
La Trobe University
PO Box 199
Bendigo, VIC 3552

16 September 2016

Dear A/Prof Kingsley

Study title: Healthy 4U Project

HREC Reference Number: LNR/16/BHCG/42

Protocol version: 1

The Bendigo Health Care Group HREC reviewed the above application at the meeting held on 16 September 2016.

Decision of the reviewing HREC

The HREC approved the above application on the basis of the information provided in the application form, protocol and supporting documentation.

Approval

The HREC approval is from the date of this letter *and expires on 02 October 2017*. Approval is given in accordance with the research conforming to the *National Health and Medical Research Council Act 1992* and the *National Statement on Ethical Conduct in Human Research (2007)*. The HREC has ethically approved this research according to the Memorandum of Understanding between the Consultative Council and the participating organisations conducting the research.

Approval is given for this research project to be conducted at the following sites and campuses: Bendigo Health.

You must comply with the following conditions:

- a. *Limit of Approval:* approval is limited strictly to the research proposal as submitted in your application. In addition, approval by the HREC *does not* guarantee that an individual BHCG unit or service will agree to provide resources or support to your research. Such assistance will need to be negotiated separately.
- b. *Start date:* You are responsible for advising the HREC of the date when the project starts at this site.
- c. *Variation to Project:* any subsequent variations or modifications you might wish to make to your project must be notified formally to the committee for further consideration and approval. If the committee considers that the proposed changes are significant, you may be required to submit a new application for approval of the revised project.

MEMORANDUM

To: Assoc Prof Michael Kingsley – La Trobe Rural Health School
Student: Stephen Barrett
From: Secretariat, SHE College Human Ethics Sub-Committee (SHE CHESC)
Reference: SHE CHESC acceptance of Bendigo Health Care Group HREC approved project – LNR/16/BHCG/42.
Title: Healthy 4U Project
Date: 3 October, 2016

Thank you for submitting the above protocol to the SHE College Human Ethics Sub-Committee (SHE CHESC). Your material was forwarded to the SHE CHESC Chair for consideration. Following evidence of a full review and subsequent final approval by **The Bendigo Health Care Group HREC**, the SHE CHESC Chair agrees that the protocol complies with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* and is in accordance with La Trobe University's *Human Research Ethics Guidelines*.

Endorsement is given for you to take part in this study in line with the conditions of final approval outlined by The Bendigo Health Care Group HREC.

Limit of Approval. La Trobe SHE CHESC endorsement is limited strictly to the research protocol as approved by The Bendigo Health Care Group HREC.

Variation to Project. As a consequence of the previous condition, any subsequent modifications approved by The Bendigo Health Care Group HREC for the project should be notified formally to the SHE CHESC

Annual Progress Reports. Copies of all progress reports submitted to The Bendigo Health Care Group HREC are to be forwarded to the SHE CHESC. Failure to submit a progress report will mean that endorsement for your involvement in this project will be rescinded. An audit related to your involvement in the study may be conducted by the SHE CHESC at any time.

Final Report. A copy of the final report is to be forwarded to the CHESC within one month of it being submitted by The Bendigo Health Care Group HREC.

If you have any queries related to the information above or require further clarifications, please contact chesc.she@latrobe.edu.au. Please quote reference number **LNR/16/BHCG/42-Kingsley**.

On behalf of the College Human Ethics Sub-Committee, best wishes with your research!

10.7 Appendix 4.2 Research invitation for Chapters 4 Version 1



Are you interested in being more physically active?

You are invited to participate in the Healthy 4U project- this project is looking at ways to help patients to be more physically active.

Why?

- This project is offering a new program which is designed to increase people's confidence and motivation to be as physically active as they would like.

What will taking part involve?

- Attending a brief information session at Bendigo Health.
- You get to wear a device that measures your physical activity at the beginning, middle and the end of the project.
- Completing a survey and have some measures taken here at Bendigo Health at the beginning, middle and the end of the project.
- You may receive telephone support from a health professional to assist you with your physical activity plans.

I would like to find out more.

- We are more than happy to explain more about the project and answer any questions you may have; please call or email the research contact person below.

Contact:

Stephen Barrett

P: 5454 9118 Email: sbarrett@bendigohealth.org.au

HREC Approval Number: LNR/16/BHCG/42

10.8 Appendix 4.3 Research invitation for Chapters 4 Version 2



Are you interested in being more physically active?

You are invited to participate in the Healthy 4U project- this project is looking at ways to help patients to be more physically active.

Why?

- This project is offering a new program which is designed to increase people's confidence and motivation to be as physically active as they would like.

What will taking part involve?

- Attending a brief information session at Bendigo Health.
- Wearing a device that measures your physical activity at the beginning, middle and the end of the project.
- Completing a survey and having some measures taken here at Bendigo Health at the beginning, middle and the end of the project.
- You may receive telephone support from a health professional to assist you with your physical activity plans.

I would like to find out more.

- We are more than happy to explain more about the project and answer any questions you may have; please contact Stephen Barrett by

Text: YES to 0447 195 166

Phone: 5454 9118

Email: sbarrett@bendigohealth.org.au



HREC Approval Number: LNR/16/BHCG/42

10.9 Appendix 5.1 Reporting checklist for economic evaluation of health interventions.

NOTE - Appendix 5.1 has been published: Barrett S, Begg S, O'Halloran P, & Kingsley M. (2019). Cost-effectiveness of telephone coaching for physically inactive ambulatory care hospital patients: economic evaluation alongside the Healthy4U randomised controlled trial. *BMJ Open*. 9(12). Doi:10.1136/bmjopen-2019-032500

		Reporting Item	Page number
Title	#1	Identify the study as an economic evaluation or use more specific terms such as “cost-effectiveness analysis”, and describe the interventions compared	1
Abstract	#2	Provide a structured summary of objectives, perspective, setting, methods (including study design and inputs), results (including base case and uncertainty analyses), and conclusions	2-3
Introduction			
Background and objectives	#3	Provide an explicit statement of the broader context for the study. Present the study question and its relevance for health policy or practice decisions	4-5
Methods			
Target population and subgroups	#4	Describe characteristics of the base case population and subgroups analysed, including why they were chosen.	5
Setting and location	#5	State relevant aspects of the system(s) in which the decision(s) need(s) to be made.	5
Study perspective	#6	Describe the perspective of the study and relate this to the costs being evaluated.	7
Comparators	#7	Describe the interventions or strategies being compared and state why they were chosen.	5-6
Time horizon	#8	State the time horizon(s) over which costs and consequences are being evaluated and say why appropriate.	5
Discount rate	#9	Report the choice of discount rate(s) used for costs and outcomes and say why appropriate	8
Choice of health outcomes	#10	Describe what outcomes were used as the measure(s) of benefit in the evaluation and their relevance for the type of analysis performed	6-7

		Reporting Item	Page number
Measurement of effectiveness	<u>#11a</u>	Single study-based estimates: Describe fully the design features of the single effectiveness study and why the single study was a sufficient source of clinical effectiveness data	n/a
Measurement of effectiveness	<u>#11b</u>	Synthesis-based estimates: Describe fully the methods used for identification of included studies and synthesis of clinical effectiveness data	n/a
Measurement and valuation of preference based outcomes	<u>#12</u>	If applicable, describe the population and methods used to elicit preferences for outcomes.	n/a
Estimating resources and costs **	<u>#13a</u>	Single study-based economic evaluation: Describe approaches used to estimate resource use associated with the alternative interventions. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs	n/a
Estimating resources and costs	<u>#13b</u>	Model-based economic evaluation: Describe approaches and data sources used to estimate resource use associated with model health states. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs.	n/a
Currency, price date, and conversion	<u>#14</u>	Report the dates of the estimated resource quantities and unit costs. Describe methods for adjusting estimated unit costs to the year of reported costs if necessary. Describe methods for converting costs into a common currency base and the exchange rate.	7-8
Choice of model	<u>#15</u>	Describe and give reasons for the specific type of decision analytical model used. Providing a figure to show model structure is strongly recommended.	n/a
Assumptions	<u>#16</u>	Describe all structural or other assumptions underpinning the decision-analytical model.	n/a
Analytical methods	<u>#17</u>	Describe all analytical methods supporting the evaluation. This could include methods for dealing with skewed, missing, or censored data; extrapolation methods; methods for pooling data; approaches to validate or make adjustments (such as half cycle corrections) to a model; and methods for handling population heterogeneity and uncertainty.	n/a

		Reporting Item	Page number
Results			
Study parameters	<u>#18</u>	Report the values, ranges, references, and, if used, probability distributions for all parameters. Report reasons or sources for distributions used to represent uncertainty where appropriate. Providing a table to show the input values is strongly recommended.	9-13
Incremental costs and outcomes	<u>#19</u>	For each intervention, report mean values for the main categories of estimated costs and outcomes of interest, as well as mean differences between the comparator groups. If applicable, report incremental cost-effectiveness ratios.	9-13
Characterising uncertainty	<u>#20a</u>	Single study-based economic evaluation: Describe the effects of sampling uncertainty for the estimated incremental cost and incremental effectiveness parameters, together with the impact of methodological assumptions (such as discount rate, study perspective).	11-13
Characterising uncertainty	<u>#20b</u>	Model-based economic evaluation: Describe the effects on the results of uncertainty for all input parameters, and uncertainty related to the structure of the model and assumptions.	n/a
Characterising heterogeneity	<u>#21</u>	If applicable, report differences in costs, outcomes, or cost effectiveness that can be explained by variations between subgroups of patients with different baseline characteristics or other observed variability in effects that are not reducible by more information.	n/a
Discussion			
Study findings, limitations, generalisability, and current knowledge	<u>#22</u>	Summarise key study findings and describe how they support the conclusions reached. Discuss limitations and the generalisability of the findings and how the findings fit with current knowledge.	14-17
Other			
Source of funding	<u>#23</u>	Describe how the study was funded and the role of the funder in the identification, design, conduct, and reporting of the analysis. Describe other non-monetary sources of support	20
Conflict of interest	<u>#24</u>	Describe any potential for conflict of interest of study contributors in accordance with journal policy. In the absence of a journal policy, we recommend authors comply with International Committee of Medical Journal Editors recommendations	20

10.10 Appendix 5.2 Characteristics of participants at baseline.

Note - Appendix 5.2 has been published: Barrett S, Begg S, O'Halloran P, & Kingsley M. (2019). Cost-effectiveness of telephone coaching for physically inactive ambulatory care hospital patients: economic evaluation alongside the Healthy4U randomised controlled trial. *BMJ Open*. 9(12). Doi:10.1136/bmjopen-2019-032500

Variable	Total 72	Intervention 36	Control 36	p-value
Age (years)	53 ± 8	53 ± 8	54 ± 7	0.70 ^a
Sex: female, n (%)	54 (75%)	28 (78%)	26 (72%)	0.58 ^a
Stature (cm)	166 ± 8	165 ± 9	168 ± 7	0.20 ^a
Weight (kg)	84.9 ± 9.4	84.5 ± 9.9	85.3 ± 8.9	0.72 ^a
BMI (kg/m ²)	30.8 ± 4.1	31.1 ± 4.0	30.5 ± 4.2	0.51 ^a
MVPA (min/day)	31.2 ± 10.1	28.1 ± 9.9	33.3 ± 10.3	0.03 ^a
PA Self-efficacy	31 ± 10	28 ± 8	33 ± 10	0.05 ^a
Smoker, n (%)	23 (32%)	12 (33%)	11 (31%)	0.80 ^b
Obesity, n (%)	38 (53%)	22 (61%)	16 (44%)	0.16 ^b
Hypertension, n (%)	14 (20%)	9 (25%)	5 (14%)	0.23 ^b
OA/RA, n (%)	27 (38%)	16 (44%)	11 (31%)	0.22 ^b
Depression/anxiety, n (%)	30 (42%)	16 (44%)	14 (40%)	0.63 ^b
Employment status, n (%)				0.43 ^b
Full time	22 (31%)	10 (28%)	12 (33%)	
Part time	30 (42%)	18 (50%)	12 (33%)	
Unemployed	7 (10%)	4 (11%)	3 (8%)	
Retired	12 (16%)	4 (11%)	8 (22%)	
Other	1 (1%)	0	1 (4%)	
Education, n (%)				0.47 ^b
Year 10/11	10 (14%)	4 (11%)	6 (17%)	
Year 12	22 (31%)	12 (33%)	10 (28%)	
Cert I-IV	18 (25%)	7 (20%)	11 (30%)	
Diploma	13 (18%)	9 (25%)	4 (11%)	
Bachelor or higher	9 (12%)	4 (11%)	5 (14%)	

10.11 Appendix 6.1 PRISMA checklist

NOTE - Appendix 6.1 has been published: Barrett S, Begg S, O'Halloran P, Howlett O, Lawrence J, & Kingsley M. (2021). The effect of behaviour change interventions on changes in physical activity and anthropometrics in ambulatory hospital settings: a systematic review and meta-analysis. *International Journal of Behavioral Nutrition and Physical Activity*. 18, 7. <https://doi.org/10.1186/s12966-020-01076-6>.

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	3-4
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	4

Section/topic	#	Checklist item	Reported on page #
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	4
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	5-6
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	4-5
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Additional file 1
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	6
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	6
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	6
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	6-7
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	7-8
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	7-8
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	7
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	8

Section/topic	#	Checklist item	Reported on page #
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	8 Figure 1
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	9 Table 1
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	10. Figure 2. Additional file 2
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	10-13 Figures 3-6
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	10-13 Figures 3-6
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	12-13. Table 2
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	12-13. Table 2

Section/topic	#	Checklist item	Reported on page #
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	13-16
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	15-16
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	16
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	19

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. *PLoS Med* 6(7): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit: www.prisma-statement.org.

10.12 Appendix 6.2 MEDLINE search

NOTE - Appendix 6.2 has been published: Barrett S, Begg S, O'Halloran P, Howlett O, Lawrence J, & Kingsley M. (2021). The effect of behaviour change interventions on changes in physical activity and anthropometrics in ambulatory hospital settings: a systematic review and meta-analysis. *International Journal of Behavioral Nutrition and Physical Activity*. 18, 7. <https://doi.org/10.1186/s12966-020-01076-6>.

#	Searches	Result	Type
1	Hospitals/	77929	Advanced
2	Outpatients/	15910	Advanced
3	Outpatient Clinics, Hospital/	15573	Advanced
4	Ambulatory Care/	42903	Advanced
5	1 or 2 or 3 or 4	147509	Advanced
6	Health Behavior/	49806	Advanced
7	health behav* change.mp.	1762	Advanced
8	Exercise/ or Walking/ or Health Promotion/ or Motivation/	266728	Advanced
9	lifestyle change.mp.	1713	Advanced
10	Preventive Health Services/	13424	Advanced
11	lifestyle intervention.mp.	4362	Advanced
12	Secondary Prevention/	20297	Advanced
13	Health Promotion/ or Obesity/ or health coach*.mp.	249606	Advanced
14	Telephone/ or Health Promotion/ or telephone coach*.mp. or Self Care/ or Mentoring/	117804	Advanced
15	6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14	536284	Advanced
16	Exercise/	108971	Advanced
17	physical activity.mp. or Exercise/	182310	Advanced
18	(weight or mass).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	2084460	Advanced
19	obesity.mp. or Obesity/ Metabolic Syndrome/ or Waist Circumference/ or waist circum*.mp. or Obesity/ or Body Mass	323560	Advanced
20	Index/	295558	Advanced
21	body mass index.mp. or Body Mass Index/	238801	Advanced
22	16 or 17 or 18 or 19 or 20 or 21	2368023	Advanced
23	5 and 15 and 22	1200	Advanced
24	limit 23 to "all adult (19 plus years)"	854	Advanced

10.13 Appendix 6.3 Risk of bias summary for all included studies

NOTE - Appendix 6.3 has been published: Barrett S, Begg S, O'Halloran P, Howlett O, Lawrence J, & Kingsley M. (2021). The effect of behaviour change interventions on changes in physical activity and anthropometrics in ambulatory hospital settings: a systematic review and meta-analysis. *International Journal of Behavioral Nutrition and Physical Activity*. 18, 7. <https://doi.org/10.1186/s12966-020-01076-6>.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Aas, 2005	?	?	?	?	?	?	?
Ahmadi, 2020	?	?	?	?	?	?	?
Alsaleh, 2016	?	?	?	?	?	?	?
Allenburg, 2014	?	?	?	?	?	?	?
Barrett, 2018	?	?	?	?	?	?	?
Cakir, 2006	?	?	?	?	?	?	?
Carrasquillo, 2017	?	?	?	?	?	?	?
Cheung, 2019	?	?	?	?	?	?	?
Dogru, 2018	?	?	?	?	?	?	?
Duskh, 2018	?	?	?	?	?	?	?
Elkoustaff, 2019	?	?	?	?	?	?	?
Fappa, 2012	?	?	?	?	?	?	?
Freedland, 2015	?	?	?	?	?	?	?
Gade, 2014	?	?	?	?	?	?	?
Goedendorp, 2010	?	?	?	?	?	?	?
Goodwin, 2014	?	?	?	?	?	?	?
Harting, 2014	?	?	?	?	?	?	?
Ijzelenberg, 2012	?	?	?	?	?	?	?
Kim, 2019	?	?	?	?	?	?	?
Kirk, 2004	?	?	?	?	?	?	?
Kosake, 2005	?	?	?	?	?	?	?
Lear, 2003	?	?	?	?	?	?	?
Miura, 2004	?	?	?	?	?	?	?
O'brian, 2018	?	?	?	?	?	?	?
Oldroyd, 2006	?	?	?	?	?	?	?
Rimmer, 2009	?	?	?	?	?	?	?
Sone 2010	?	?	?	?	?	?	?
Wattanakorn, 2013	?	?	?	?	?	?	?
Williams, 2019	?	?	?	?	?	?	?

10.14 Appendix 6.4 Summary of finding table

NOTE - Appendix 6.4 has been published: Barrett S, Begg S, O'Halloran P, Howlett O, Lawrence J, & Kingsley M. (2021). The effect of behaviour change interventions on changes in physical activity and anthropometrics in ambulatory hospital settings: a systematic review and meta-analysis. *International Journal of Behavioral Nutrition and Physical Activity*. 18, 7. <https://doi.org/10.1186/s12966-020-01076-6>.

Outcome	Anticipated absolute effects* (95% CI)	No of participants (studies)	Certainty of the evidence (GRADE)	Informative statements
Physical Activity (<=6mo follow-up)	SMD 1.30 higher [0.53 to 2.07]	728 (8 RCTs)	⊕○○○ VERY LOW ^{a,b,c,d,e}	The evidence is very uncertain about the effect of behaviour change interventions on physical activity change in ambulatory hospital patients when the follow-up is 6 months or less.
Physical Activity (>6mo follow-up)	SMD 0.43 higher [-0.07 to 0.93]	726 (5 RCTs)	⊕○○○ VERY LOW ^{a,b,c,d,e}	The evidence is very uncertain about the effect of behaviour change interventions on physical activity change in ambulatory hospital patients when the follow-up is greater than 6 months.
Physical activity (low risk of bias)	SMD 1.04 higher [0.15, 1.92]	677 (5 RCTs)	⊕○○○ VERY LOW ^{b,c,e}	The evidence is very uncertain about the effect of behaviour change interventions on physical activity change in ambulatory hospital patients when studies with a high risk of bias are excluded.

Outcome	Anticipated absolute effects* (95% CI)	No of participants (studies)	Certainty of the evidence (GRADE)	Informative statements
Mass (kg) (<=6mo follow-up)	MD -3.15 lower [-5.96 to -0.34]	411 (5 RCTs)	⊕○○○ VERY LOW ^{a,c,d,e,f}	The evidence is very uncertain about the effect of behaviour change interventions on changes in mass in ambulatory hospital patients when the follow-up is 6 months or less.
Mass (kg) (>6mo follow-up)	MD -2.37 lower [-4.40 to -0.35]	461 (4 RCTs)	⊕○○○ VERY LOW ^{a,c,d}	The evidence is very uncertain about the effect of behaviour change interventions on changes in mass in ambulatory hospital patients when the follow-up is greater than 6 months.
Mass (kg) (low risk of bias)	MD -2.59 lower [-4.49 to -0.68]	253 (3 RCTs)	⊕○○○ VERY LOW ^{c,d}	The evidence is very uncertain about the effect of behaviour change interventions on changes in mass in ambulatory hospital patients when studies with a high risk of bias are excluded.
BMI (<=6mo follow-up)	MD -1.55 lower [-2.58 to -0.53]	529 (7 studies)	⊕○○○ VERY LOW ^{a,c,d,e,f}	The evidence is very uncertain about the effect of behaviour change interventions on changes in BMI in ambulatory hospital patients when the follow-up is 6 months or less.
BMI (>6mo follow-up)	MD -0.75 lower [-1.35 to -0.16]	4199 (8 RCTs)	⊕○○○ VERY LOW ^{a,b,c,d,e}	The evidence is very uncertain about the effect of behaviour change interventions on changes in BMI in ambulatory hospital patients when the follow-up is greater than 6 months.
BMI (low risk of bias)	MD -0.57 lower [-1.20, 0.05]	589 (5 RCTs)	⊕○○○ VERY LOW ^{c,d,f}	The evidence is very uncertain about the effect of behaviour change interventions on changes in BMI in ambulatory hospital patients when studies with a high risk of bias are excluded.

Outcome	Anticipated absolute effects* (95% CI)	No of participants (studies)	Certainty of the evidence (GRADE)	Informative statements
Waist Circumference (<=6mo follow-up)	MD -3.91 lower [-5.96, -1.85]	194 (3 RCTs)	⊕⊕○○ LOW ^{c,d}	The evidence suggests that behaviour change interventions results in a slight reduction in waist circumference in ambulatory hospital patients.
Waist Circumference (>6mo follow-up)	MD -0.66 lower [-2.28, 0.95]	336 (2 RCTs)	⊕○○○ VERY LOW ^{a,c,d}	The evidence is very uncertain about the effect of behaviour change interventions on changes in waist circumference in ambulatory hospital patients.
Waist Circumference (low risk of bias)	MD 2.34 lower [-4.49, -0.18]	472 (4 RCTs)	⊕○○○ VERY LOW ^{c,d,f}	The evidence is very uncertain about the effect of behaviour change interventions on changes in waist circumference in ambulatory hospital patients.

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

Explanations

a. Large number of studies with high risk of bias; b. High heterogeneity; c. Differences in population and outcome measures; d. Wide confidence intervals; e. Asymmetry in the pattern of results; f. Moderate heterogeneity

10.15 Appendix 6.5 GRADE assessment

NOTE - Appendix 6.5 has been published: Barrett S, Begg S, O'Halloran P, Howlett O, Lawrence J, & Kingsley M. (2021). The effect of behaviour change interventions on changes in physical activity and anthropometrics in ambulatory hospital settings: a systematic review and meta-analysis. *International Journal of Behavioral Nutrition and Physical Activity*. 18, 7. <https://doi.org/10.1186/s12966-020-01076-6>.

Outcome	Studies	I	C	I ²	MD or SMD (and 95%CI)	P	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias	Overall Certainty of Evidence	Reasons for Limitations across the Domains
Physical activity	13	729	725	95%	0.96 [0.45, 1.48]	<0.001	Serious limitation	Very serious limitation	Serious limitation	Very serious limitation	strongly suspected	Very low	a, b, c, d, e
Physical Activity (<=6mo follow-up)	8	356	372	95%	1.30 [0.53, 2.07]	0.001	Serious limitation	Very serious limitation	Serious limitation	Very serious limitation	strongly suspected	Very low	a, b, c, d, e
Physical Activity (>6mo follow-up)	5	373	353	90%	0.43 [-0.07, 0.93]	0.09	Serious limitation	Very serious limitation	Serious limitation	Very serious limitation	strongly suspected	Very low	a, b, c, d, e
Physical activity (low RoB)	5	340	337	96%	1.04 [0.15, 1.92]	0.02	No serious limitation	Very serious limitation	Serious limitation	Very serious limitation	strongly suspected	Very low	b, c, e
Mass	9	419	453	45%	-2.74 [-4.42, -1.07]	0.001	Serious limitation	Serious limitation	Serious limitation	Serious limitation	strongly suspected	Very low	a, b, c, d, e
Mass (<=6mo follow-up)	5	193	218	62%	-3.15 [-5.96, -0.34]	0.03	Serious limitation	Serious limitation	Serious limitation	Serious limitation	strongly suspected	Very low	a, c, d, e; f
Mass (>6mo follow-up)	4	226	235	22%	-2.37 [-4.40, -0.35]	0.02	Serious limitation	No serious limitation	Serious limitation	Serious limitation	undetected	Very low	a, c, e

Outcome	Studies	I	C	I ²	MD or SMD (and 95%CI)	P	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias	Overall Certainty of Evidence	Reasons for Limitations across the Domains
Mass (low RoB)	3	123	130	2%	-2.59 [-4.49, -0.68]	0.008	No serious limitation	No serious limitation	Serious limitation	Serious limitation	undetected	Very low	c, e
BMI	15	2358	2343	77%	-0.99 [-1.48, -0.50]	<0.001	Serious limitation	Very serious limitation	Serious limitation	Serious limitation	strongly detected	Very low	a, b, c, d, e
BMI (<=6mo follow-up)	7	252	277	57%	-1.55 [-2.58, -0.53]	0.03	Serious limitation	Serious limitation	Serious limitation	Serious limitation	strongly detected	Very low	a, b, c, d, e
BMI (>6mo follow-up)	8	2133	2066	85%	-0.75 [-1.35, -0.16]	0.01	Serious limitation	Very serious limitation	Serious limitation	Serious limitation	strongly detected	Very low	a, b, c, d, e
BMI (low RoB)	4	265	266	37%	-0.57 [-1.20, 0.05]	0.07	No serious limitation	Serious limitation	Serious limitation	Serious limitation	undetected	Very low	c, e, f
Waist C	5	265	265	41%	-2.21 [-4.01, -0.42]	0.02	Serious limitation	Serious limitation	Serious limitation	Serious limitation	undetected	Very low	a, c, d, e; f
Waist C (<=6mo follow-up)	3	94	100	0%	-3.91 [-5.96, -1.85]	<0.001	No serious limitation	No serious limitation	Serious limitation	Serious limitation	undetected	Low	c, e, f
Waist C (>6mo follow-up)	2	171	165	0%	-0.66 [-2.28, 0.95]	0.42	Serious limitation	No serious limitation	Serious limitation	Serious limitation	undetected	Very low	a, c, d,
Waist C (low RoB)	3	206	206	45%	2.34 [-4.49, 0.18]	0.03	No serious limitation	Serious limitation	Serious limitation	Serious limitation	undetected	Very low	b, c, d,

a Large no high RoB studies; b High heterogeneity; c differences in population and outcome measures; d wide CI; e asymmetry in pattern of results; f Moderate heterogeneity

10.16 Appendix 7.1 Institutional ethical approvals for Chapter 7



HEALTHY COMMUNITIES AND
WORLD CLASS HEALTHCARE

CARING | PASSIONATE | TRUSTWORTHY

Ms Sally McCarthy
Research Manager
Bendigo Health Care Group HREC
PO Box 126
Bendigo, Victoria, 3552

A/Prof Michael Kingsley
Associate Professor in Exercise Physiology
La Trobe Rural Health School
PO Box 199
Bendigo, VIC 3552

01 June 2017

Dear A/Prof Kingsley

Study title: Surgeons and Preventative Health
HREC Reference Number: LNR/17/BHCG/21
Protocol version: 1

The Bendigo Health Care Group HREC reviewed the above application at the meeting held on 24 May 2017.

Decision of the reviewing HREC

The HREC approved the above application on the basis of the information provided in the application form, protocol and supporting documentation.

Approval

The HREC approval is from the date of this letter and expires on 01 June 2018.

Approval is given in accordance with the research conforming to the *National Health and Medical Research Council Act 1992* and the *National Statement on Ethical Conduct in Human Research (2007)*. The HREC has ethically approved this research according to the Memorandum of Understanding between the Consultative Council and the participating organisations conducting the research.

Approval is given for this research project to be conducted at the following sites and campuses: Bendigo Health.

You must comply with the following conditions:

- Limit of Approval:** approval is limited strictly to the research proposal as submitted in your application. In addition, approval by the HREC *does not* guarantee that an individual BHCG unit or service will agree to provide resources or support to your research. Such assistance will need to be negotiated separately.
- Start date:** You are responsible for advising the HREC of the date when the project starts at this site.
- Variation to Project:** any subsequent variations or modifications you might wish to make to your project must be notified formally to the committee for further consideration and approval. If the committee considers that the proposed changes are significant, you may be required to submit a new application for approval of the revised project.
- Incidents of Adverse Effects:** researchers must report immediately to the committee anything which might affect the ethical acceptance of the protocol including adverse

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MEMORANDUM

To: A/Prof Michael Kingsley – Department of Community and Allied Health

Student: Stephen Barrett

From: Secretariat, SHE College Human Ethics Sub-Committee (SHE CHESC)

Reference: SHE CHESC acceptance of the Bendigo Health HREC approved project – LNR/17/BHCG/21.

Title: Surgeons and Preventative Health

Date: 19 June, 2017

Thank you for submitting the above protocol to the SHE College Human Ethics Sub-Committee (SHE CHESC). Your material was forwarded to the SHE CHESC Chair for consideration. Following evidence of a full review and subsequent final approval by the **Bendigo Health HREC**, the SHE CHESC Chair agrees that the protocol complies with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* and is in accordance with La Trobe University's *Human Research Ethics Guidelines*.

Endorsement is given for you to take part in this study in line with the conditions of final approval outlined by the Bendigo Health HREC.

Limit of Approval. La Trobe SHE CHESC endorsement is limited strictly to the research protocol as approved by the Bendigo Health HREC.

Variation to Project. As a consequence of the previous condition, any subsequent modifications approved by the Bendigo Health HREC for the project should be notified formally to the SHE CHESC

Annual Progress Reports. Copies of all progress reports submitted to the Bendigo Health HREC are to be forwarded to the SHE CHESC. Failure to submit a progress report will mean that endorsement for your involvement in this project will be rescinded. An audit related of your involvement in the study may be conducted by the SHE CHESC at any time.

Final Report. A copy of the final report is to be forwarded to the CHESC within one month of it being submitted by the Bendigo Health HREC.

If you have any queries related to the information above or require further clarifications, please contact chesc.she@latrobe.edu.au. Please quote reference number **LNR/17/BHCG/21 - Kingsley/Barrett**.

On behalf of the College Human Ethics Sub-Committee, best wishes with your research!

10.17 Appendix 7.2 Research invitation for Chapter 7

Email script

Dear Doctor,

A group of researchers from La Trobe University are undertaking research around chronic disease, and health-related behaviour change. The involved parties are A/Prof Michael Kingsley, Dr. Stephen Begg and Mr. Stephen Barrett.

What continues to be missing from this research field is the voice of hospital surgeons; highly professionalised clinical specialists, whose expertise has been demonstrated to have positive influences in patient health behaviours.

As health services continue to look at their role in preventative healthcare, this research aims to understand which health promotion activities are carried out by surgeons. This research will attempt to fill an important gap in the understanding of how and why surgeons make their decisions around health promotion activities.

All General and Orthopaedic surgeons, and their registrars consulting in Bendigo Health are invited to participate in this study.

The research comprises of two components, designed to deliver a thorough and unique perspective on this topic:

1. A clinician survey, based upon a validated tool from previous research. This survey takes approximately 10-15 minutes to complete, and is completely anonymous. The survey link is here:

<https://www.surveymonkey.com/r/D9KZL3>

Should an individual wish to complete a hard copy of the survey instead, this can be distributed by a research assistant, Stephen Barrett, contactable on 5454 9118.

2. A short, semi-structured interview, requiring 15-20 minutes, to offer understanding of the unique perspective of individuals.

Interviews will be carried out at participant's discretion, and facilitated through contact with Stephen Barrett.

Participants can complete the clinician survey, the interview, or both.

Participation in this research is voluntary. Analysis of the results will be at the group level.

Any publication will not attribute specific comments to identifiable participants.

This research has been approved by the Executive Director of Acute Health and the Bendigo Health HREC.

If you have any questions feel free to contact.

Stephen Barrett, Associate Researcher on 5454 9118, or email sbarrett@bendigohealth.org.au , or

Sally McCarthy, Research Manager on 5454 6412, or email SAMcCarthy@bendigohealth.org.au

Dr John Edington

Director Anaesthesia

Bendigo Health

PO Box 126 Bendigo Victoria 3552

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10.18 Appendix 7.3 Surgeons and preventative health survey

NOTE - Appendix 7.3 has been published: Barrett S, Begg S, & Kingsley M. (2018). Barrett S, Begg S, Sloane A, & Kingsley M. (2019). Surgeons and preventive health: a mixed methods study of current practice, beliefs and attitudes influencing health promotion activities amongst public hospital surgeons. *BMC Health Services Research*. 19, 358. <https://doi.org/10.1186/s12913-019-4186-y>

Surgeons and Preventative Health Survey

This survey takes approximately 15-20 minutes to complete.
This survey has been adapted with permission from a survey used by Laws et al, 2008 doi:10.1186/1472-6963-8-44. We would like to thank the authors for their permission to use the survey.

It will be analysed by researchers and reported as group findings- no individual responses will be reported.

Clinician details

Gender: ☐ Female ☐ Male

Age:

Working status: ☐ Full-time ☐ Part-time

If part-time, how many hours do you work per week? _____

Clinician type: ☐ General Surgeon (GS) ☐ Orthopedic Surgeon (OS)
☐ (GS) Registrar ☐ (OS) Registrar

How many years of clinical practice have you undertaken? _____

Please circle the appropriate answer

Management of risk factors

1. Thinking of the new clients that you have seen over the **past 2 weeks**, what percentage of these clients did you **ask** about the following risk factors:

Smoking	None	1-25%	26-50%	51-75%	>75%
Nutrition	None	1-25%	26-50%	51-75%	>75%
Alcohol	None	1-25%	26-50%	51-75%	>75%
Physical Activity	None	1-25%	26-50%	51-75%	>75%

2. Thinking of the clients that you have seen for **review appointments** over the **past 2 weeks**, what percentage of these clients did you **ask** about the following risk factors:

Smoking	None	1-25%	26-50%	51-75%	>75%
Nutrition	None	1-25%	26-50%	51-75%	>75%
Alcohol	None	1-25%	26-50%	51-75%	>75%
Physical Activity	None	1-25%	26-50%	51-75%	>75%

3. Of the clients that you identified as having a lifestyle risk factor in the **past 2 weeks**, what percentage of these clients did you **assess their readiness to change their behaviour** (stage of change):

Smokers	None	1-25%	26-50%	51-75%	>75%	did not identify any smokers
Clients with poor nutrition	None	1-25%	26-50%	51-75%	>75%	did not identify any clients with poor nutrition
Clients with at risk drinking	None	1-25%	26-50%	51-75%	>75%	did not identify any clients with at risk drinking
Physically inactive clients	None	1-25%	26-50%	51-75%	>75%	did not identify any clients who were physically inactive

4. Of the clients that you identified as having a lifestyle risk factor in the **past 2 weeks**, what percentage of these clients did you provide **verbal advice** to:

Smokers	None	1-25%	26-50%	51-75%	>75%	did not identify any smokers
Clients with poor nutrition	None	1-25%	26-50%	51-75%	>75%	did not identify any clients with poor nutrition
Clients with at risk drinking	None	1-25%	26-50%	51-75%	>75%	did not identify any clients with at risk drinking
Physically inactive clients	None	1-25%	26-50%	51-75%	>75%	did not identify any clients who were physically inactive

5. Of the clients that you identified as having a lifestyle risk factor in the **past 2 weeks**, what percentage of these clients did you provide **written advice (e.g. pamphlet, summary sheet etc)** to:

Smokers	None	1-25%	26-50%	51-75%	>75%	did not identify any smokers
Clients with poor nutrition	None	1-25%	26-50%	51-75%	>75%	did not identify any clients with poor nutrition
Clients with at risk drinking	None	1-25%	26-50%	51-75%	>75%	did not identify any clients with at risk drinking
Physically inactive clients	None	1-25%	26-50%	51-75%	>75%	did not identify any clients who were physically inactive

6. Of the clients that you identified as having a lifestyle risk factor in the **past 2 weeks**, what percentage of these clients did you **refer to other service providers/agencies or support groups (quitline)** for help in managing their risk factor:

Smokers	None	1-25%	26-50%	51-75%	>75%	did not identify any smokers
Clients with poor nutrition	None	1-25%	26-50%	51-75%	>75%	did not identify any clients with poor nutrition
Clients with at risk drinking	None	1-25%	26-50%	51-75%	>75%	did not identify any clients with at risk drinking
Physically inactive clients	None	1-25%	26-50%	51-75%	>75%	did not identify any clients who were physically inactive

7. When you provide advice about lifestyle risk factors, **how much time do you estimate that you spend on average addressing each of the following:**

Smoking advice	1-2 mins	3-5 mins	6-10 mins	11-15 mins	More that 15 mins	Do not provide advice
Nutrition advice	1-2 mins	3-5 mins	6-10 mins	11-15 mins	More that 15 mins	Do not provide advice
Alcohol advice	1-2 mins	3-5 mins	6-10 mins	11-15 mins	More that 15 mins	Do not provide advice
Physical activity advice	1-2 mins	3-5 mins	6-10 mins	11-15 mins	More that 15 mins	Do not provide advice

8. For clients that you have given advice to about their lifestyle, what percentage of these clients do you **check their progress** in subsequent visits (on average):

Smokers	None	1-25%	26-50%	51-75%	>75%	did not identify any smokers
Clients with poor nutrition	None	1-25%	26-50%	51-75%	>75%	did not identify any clients with poor nutrition
Clients with at risk drinking	None	1-25%	26-50%	51-75%	>75%	did not identify any clients with at risk drinking
Physically inactive clients	None	1-25%	26-50%	51-75%	>75%	did not identify any clients who were physically inactive

9. How easy is it to find **accessible services/agencies/support programs to refer your clients to for the following?**
(1=Very difficult, 5= very easy)

	Very difficult			Very easy		
Smoking cessation	1	2	3	4	5	Don't know
Nutrition counselling	1	2	3	4	5	Don't know
Alcohol counselling	1	2	3	4	5	Don't know
Physical activity	1	2	3	4	5	Don't know

10. Please rate your **knowledge** in relation to each of the following (1=very poor, 5= excellent)

	Very poor				Excellent
Assessing nicotine dependency	1	2	3	4	5
Smoking cessation recommendations	1	2	3	4	5
Assessing nutrition	1	2	3	4	5
Nutrition recommendations	1	2	3	4	5
Assessing for risk alcohol consumption	1	2	3	4	5
Recommendations for safe alcohol consumption	1	2	3	4	5
Assessing physical activity levels	1	2	3	4	5
Physical activity recommendations	1	2	3	4	5
Motivational Interviewing	1	2	3	4	5
Assessing a client's readiness to change	1	2	3	4	5

11. Please rate how **confident** you are in undertaking the following activities with clients
(1=not at all confident, 5= very confident)

	Not at all confident			Very confident	
Assessing nicotine dependency	1	2	3	4	5
Smoking cessation recommendations	1	2	3	4	5
Assessing nutrition	1	2	3	4	5
Nutrition recommendations	1	2	3	4	5
Assessing for risk alcohol consumption	1	2	3	4	5
Recommendations for safe alcohol consumption	1	2	3	4	5
Assessing physical activity levels	1	2	3	4	5
Physical activity recommendations	1	2	3	4	5
Motivational Interviewing	1	2	3	4	5
Assessing a client's readiness to change	1	2	3	4	5

12. Please rate how **effective** you think your advice is in helping clients to:
(1=not at all effective, 5= very effective)

	Not at all effective			Very effective		
Give up smoking	1	2	3	4	5	Do not provide advice
Improve nutrition/ eating habits	1	2	3	4	5	Do not provide advice
Reduce alcohol consumption	1	2	3	4	5	Do not provide advice
Become more physically active	1	2	3	4	5	Do not provide advice

13. Clients I see find it agreeable for me to raise the following lifestyle issues routinely as part of consultation:
(1=strongly agree, 5= strongly disagree)

	Not at all effective			Very effective		
Smoking	1	2	3	4	5	Do not discuss smoking
Nutrition	1	2	3	4	5	Do not discuss nutrition
Alcohol consumption	1	2	3	4	5	Do not discuss alcohol
Physically activity	1	2	3	4	5	Do not discuss physical activity

14. Please rate **how important** you think the following lifestyle changes are for **improving health**:
(1=not at all important, 5= very important)

	Not at all important			Very important	
Giving up smoking	1	2	3	4	5
Improving nutrition/ eating habits	1	2	3	4	5
Reducing alcohol consumption	1	2	3	4	5
Becoming more physically activity	1	2	3	4	5

15. Please rate **how important** you think it is to address these lifestyle risk factors with the clients you see:
(1=not at all important, 5= very important)

	Not at all important			Very important	
Smoking	1	2	3	4	5
Nutrition	1	2	3	4	5
Alcohol consumption	1	2	3	4	5
Physically activity	1	2	3	4	5

16. How much of a **work priority** is it for you/your tem to address lifestyle risk factors with clients as **part of your normal clinical work**:
(1=not at all important, 5= very important)

	Very low priority			Very high priority	
Smoking cessation	1	2	3	4	5
Poor nutrition	1	2	3	4	5
At risk alcohol consumption	1	2	3	4	5
Inadequate physical activity	1	2	3	4	5

17. In the past 12 months have you had any education or training in the management of these risk factors or strategies towards helping clients change their behaviour?

Smoking	Yes	No
Nutrition	Yes	No
Alcohol	Yes	No
Physical Activity	Yes	No
Motivational Interviewing	Yes	No
Assessing clients readiness to change	Yes	No
Client education	Yes	No

18. Any other comments: _____

Thank you for completing the questionnaire.

OFFICE USE ONLY	Date received	Date entered	Entered by (ID)

10.19 Appendix 7.4 Codes, categories and themes relating to surgeons' attitudes and beliefs towards the management of lifestyle risk factors.

NOTE - Appendix 7.4 has been published: Barrett S, Begg S, & Kingsley M. (2018). Barrett S, Begg S, Sloane A, & Kingsley M. (2019). Surgeons and preventive health: a mixed methods study of current practice, beliefs and attitudes influencing health promotion activities amongst public hospital surgeons. *BMC Health Services Research*. 19, 358. <https://doi.org/10.1186/s12913-019-4186-y>

Codes	Categories	Themes
<ul style="list-style-type: none"> • Time required to do preventive health. • Time available for surgical consultations. • Not trained in this speciality. • The best use of surgeon time. • Opportunity cost. • It is important, but is it my job? • Not why people become surgeons. • Address risk when it has direct influence on surgery/outcomes. • Need to deliver in black and white. • Self-fulfilment. • Role of primary care to manage behaviour. • No follow-up visit to question/reinforce change. • All clinicians have responsibility. 	<ul style="list-style-type: none"> ○ Is it my role? ○ Does it fit within my role? ○ Clinical barriers to preventive health. ○ Should I do this? ○ Capacity- how can I do this? 	<p>The role of the surgeon in preventive health</p>

Codes	Categories	Themes
<ul style="list-style-type: none"> • Difficult to change behaviours. • Entrained behaviours. • Lots of public health messages out there. • Mass media. • People already know. • Personal choice. • Patient ownership of their issues. • What motivates patients? • Patients want specialist advice- not general advice. • Some things (e.g. smoking) are their only enjoyment. • Maintain behaviours despite advice. • They all claim to do the right things. • Frustrating. • Those who want to change will ask for help. • Time required to do preventive health. • Time pressure per patient in clinic. • Clinic pressures- management. • Answer to management for clinic throughput. • Is it effective- and is it worth my time? • Disconnect between preventive health and surgical outcomes. • Limited/no hospital referral pathways. • Pressure for hospital resources. • Don't know what's available in community. 	<ul style="list-style-type: none"> ○ Patient behaviours. ○ Patient understanding (of risk and reward). ○ Patient beliefs. ○ Patient preferences. ○ Will they change? ○ Institutional practice/ way of working. ○ Institutional pressures. ○ Cost effectiveness of adding preventive health. ○ Trade-off between clinic throughput and optimal practice. ○ Hospital resource and capacity. ○ External resources. 	<p>The motivation of the patients</p> <p>The hospital structure</p>

Codes	Categories	Themes
<ul style="list-style-type: none"> • Patients like something tangible. • Give information to patients. • Easy to read handouts. • Information needs to be specific to problem. • Surgeon can sell importance of change. • Links to a specialist clinic/program. • Referrals into specialist change programs. 	<ul style="list-style-type: none"> ○ Educational material. ○ Internal referral pathways/capacity. ○ External referral pathways/capacity. ○ Time efficient pathways. 	Facilitators experienced by surgeons

10.20 Appendix 7.5 Themes and corresponding quotes relating to surgeons' attitudes and beliefs towards the management of lifestyle risk factors.

NOTE - Appendix 7.5 has been published: Barrett S, Begg S, & Kingsley M. (2018). Barrett S, Begg S, Sloane A, & Kingsley M. (2019). Surgeons and preventive health: a mixed methods study of current practice, beliefs and attitudes influencing health promotion activities amongst public hospital surgeons. *BMC Health Services Research*. 19, 358. <https://doi.org/10.1186/s12913-019-4186-y>

Theme	Quote
The role of the surgeon in preventive health	<i>"These patients are being referred to the clinic, despite these problems, so these problems aren't the reason they are being referred to clinic. If these [SNAP] were the problems they were being referred to clinic for we would be addressing those problems" (Surgeon 3).</i>
	<i>"So it probably isn't the best use of our time, but I think it's still important" (Surgeon 9).</i>
	<i>"So in a Specialist Clinic where you are seeing them for a specialist problem you try and deal with that [problem] first and foremost, and you hope that the person referring them into the specialist has taken the time to initiate management for these preventative measures, because that's what we [surgeons] anticipate our GP to be doing for us" (Surgeon 4).</i>
	<i>"It's hard to know, I mean, do we have a responsibility to promote that more for their long term management? Yes, probably, but, also we are seeing them from a specialty point of view as well, so it's hard" (Surgeon 2).</i>
	<i>"And unless you have a really strong motivator its unlikely to happen. So I think, and if that's what your bent is [behaviour change], then you won't have chosen surgery. People who choose surgery choose surgery because they have got a problem, we fix it, and they get better. And that's not how behaviour change works" (Surgeon 10).</i>

Theme	Quote
The role of the surgeon in preventive health	<i>"It's always more difficult to do non-operative management than operative management. Operative is: you have a worn out knee we need to do a knee replacement- these are the risks. Non-operative is you have to change your life" (Surgeon 11).</i>
	<i>"There's probably more to gain for us as surgeons as well, if we can get someone to stop smoking or lose weight, you know, who has like complex hernia, it will have a big impact on immediate complications and things for us" (Surgeon 12).</i>
	<i>"So I have probably 20 patients to see in clinic and I want to get them in and out as quickly as I can because the more I see the better that is; I'm under pressure to see as many patients as I can, and get the turnover and we earn more money for the hospital" (Surgeon 12).</i>
	<i>"I just think people should not ignore the fact that you know... society is to blame, all this sort of concept that people have, "I should never have been this sick, oh I don't know why I have cancer". There is a lot that can be done by them [patients] to improve their own circumstances. And if they don't have someone throw it up to them particularly someone they don't know very well... if you have had a long term effort with someone you have known for twenty years, there's very little impact there" (Surgeon 4).</i>
	<i>"I think it's hard, it's hard for any doctor to know what to advise people on because there isn't a one size fits all. And we don't get, we don't get the education ourselves, because there is so much confusion in the literature, so you can't, you know, you are going to be constantly chopping and changing, and you know there is so many things you need to know about, you can't keep up with everything you need to know about [surgery], as well as what vogue lifestyle changing diet are we doing this week" (Surgeon 5).</i>
	<i>"I mean, I think if we can have an impact, and we know they may listen to us more I think we probably should make more of an effort and address that [preventive health] with every patient we get if they are concerned" (Surgeon 6).</i>
	<i>"Well I don't get paid for dealing with all of their other health problems" (Surgeon 12).</i>

Theme	Quote
The motivation of the patients	<p><i>"What I have found is a lot of the motivated ones just stop, they just do it on their own. They don't need us [surgeons], they don't need anybody else telling them" (Surgeon 3).</i></p> <p><i>"So if I see somebody with chronic diarrhoea, and I said to them 'if you stop smoking then your diarrhoea will get better' then I think they would listen to that. But if I've got somebody with chronic diarrhoea and I give them advice about their chronic diarrhoea and I say to them 'oh yeah, by the way for the benefit of your health in general you should stop smoking' then I think they will probably go 'oh yeah, heard it all before'" (Surgeon 13).</i></p> <p><i>"Well if I tell people they need to stop smoking for their health, but, for example I will still take out their gall bladder whether they smoke or don't smoke, they are going to keep smoking. Because there is a reason why they are still smoking, and it's because they have decided that they like smoking, or they 'can't' stop" (Surgeon 5).</i></p> <p><i>"Absolutely. Absolutely. I think they already know, but I think a lot of the time they, sort of, they just continue on anyway. And it's sort of... it does get emotionally exhausting telling these people over and over again not to do this and not to do that. And it's almost like it's ah, the work that you are trying to do to help them is actively coming against that" (Surgeon 7).</i></p>

Theme	Quote
The motivation of the patients	<p><i>"I think sometimes, I feel like these days you have to be in modern times, you need to be more careful in the way you word thing to patients; certainly as a junior doctor you know, there is this assumption that you can't just tell patients... If you have someone come in that is obese and they have got problems with their galls stones and they have high blood pressure and diabetes, the facts are they are obese, they've got diabetes- it's poorly controlled, and they are a smoker. It's all self-inflicted. But if you read a patient the riot act and said 'you are overweight, you are eating too much, you are eating the wrong things, you are smoking, you are not looking after yourself and this is why it is happening [to you]. It's all from things that are self-inflicted'. You would probably get a complaint. And then it would go to an administrator. And then it would come to my boss. And then I would get in strife for it. And I think in modern day times with all the... you can classify it, in the general media everyone is a little more politically correct these days, which is great in a lot of way, but when you are in a busy situation, that's what patients really need to be told. But if you tell someone, in those hard terms, it will reflect back. And hospitals have a lot of pressure now to be, you know, really patient centred. We have patient centred surveys with how they are happy with their care" (Surgeon 8).</i></p> <p><i>"I think, patients, I don't think at this point in time, patients are, and this is my personal opinion, I don't think they [patients] are as likely to listen to doctors as they are to listen to the media. I think it's changed in the last 20 or 30 years" (Surgeon 6).</i></p>

Theme	Quote
The hospital structure	<p><i>"If I am not sort of too busy out there [clinic waiting room] I might be open to discussing it further. Where if you know you have all these sort of things going on in the background, I just don't think about that [preventative health] part to discuss, because in my mind I'm in this mode of trying to be efficient, so it's probably that I don't think about it because of that sort of feeling of wanting to keep things moving" (Surgeon 2).</i></p> <p><i>"Apart from physio referrals, and that is mainly for strength based exercises, I don't really make any referrals to anyone else, to any other external ancillary service. No. if it was an easy process, or there was some sort of pathway but in this service, I wouldn't even [know how]. Say if I needed to make a referral for hydrotherapy, I wouldn't know how to do that" (Surgeon 1).</i></p> <p><i>"Part of it is knowing what you have at your disposal. And equally knowing, say from a public health system, it's hard to get them [patients] involved in exercise programs" (Surgeon 11).</i></p> <p><i>"Unless there is somebody who has ischemic heart disease, and there are specific programs for rehab; for the average person who just needs more physical activity I don't know that there is a whole number of funded programs except for like local council initiatives, and then that's not really my sphere of influence" (Surgeon 12).</i></p>

Theme	Quote
Facilitators experienced by surgeons	<p><i>"A flyer would be good. Because I often like... when I see patients in the 6 months or 12 months I always sort of give them their x-ray slip, and I say put that on your fridge, something like that, where you see it every day, and you think 'of the specialist gave it to me' (Surgeon 6).</i></p> <p><i>"If it [information] comes from us, and you then emphasise it, you emphasise but it comes from us, the sales is there" (Surgeon 6).</i></p> <p><i>"... if we had more clinics to send people to [for behaviour change]" (Surgeon 5).</i></p> <p><i>"So maybe there is a role for another clinic, or program such as yourself, or you have a specific program... We [surgeons] probably are time constrained to come extent. To do this properly you need probably 15-20 minutes to do it, and that's probably longer than we spend with most of our patients. So it probably isn't the best use of our time, but I think it's still important. Particularly, as you say, for those ones who would be waiting 6 months or so, then there is time to actually improve on all these things, and they would maybe benefit" (Surgeon 9).</i></p> <p><i>"You want to make the most of the expertise that you have, that's special to you as opposed to [spending time on preventive health]. So if you are trying to address it better in clinic, then I think you need to have people there, for whom that's their role [preventive health/behaviour change]. Who can sit and go, while you are here, you should go and talk to this person and then they can establish a relationship. If you had a counsellor or something" (Surgeon 10).</i></p> <p><i>"If there was a defined pathway with information for the patients that says 'this is your condition and this is the management'. And then tracking. Because part of the management is tracking. And ensuring that patients are engaged" (Surgeon 11).</i></p>

Theme	Quote
Facilitators experienced by surgeons	<p><i>"I wish we had handouts and things that we could give to patients. I don't have patient information brochures for operations that I refer them for. I don't have Quit pamphlets. So I don't know that it's always the information that's on it that's that helpful, but it's the fact that the physically have something that they have taken away, they have something, they can show it to someone. Prompt more discussions" (Surgeon 12).</i></p> <p><i>"No. No I think what would be best is if I did fill out the paperwork for them to go to whatever is available, or that I would know what is available. But I don't know what is available. I don't know how to refer them. If I did, and could refer them" (Surgeon 13).</i></p>

10.21 Appendix 8.1 Institutional ethical approvals for Chapter 8



Bendigo Health Care Group Human Research Ethics Committee ETHICS APPROVAL

Mr. Stephen Barrett
Healthy Communities
Bendigo Health
PO Box 126
Bendigo, Vic 3552.
1 November 2018
Dear Steve,

Project Title	H4U-2
Project ID	44121
Review Reference	LNR/44121/BHCG-2018-155762(v5)
Local Reference Number	LNR/18/BHCG/44121

I am pleased to advise that the above project has received ethical approval from Bendigo Health Care Group Human Research Ethics Committee (HREC).

The HREC confirms that your proposal meets the requirements of the *National Statement on Ethical Conduct in Human Research* (2007). This HREC is organised and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research* (2007), and all subsequent updates, and in accordance with the *Note for Guidance on Good Clinical Practice* (CPMP/ICH/135/95), the Health Privacy Principles described in the *Health Records Act 2001* (Vic) and Section 95A of the *Privacy Act 1988* (and subsequent Guidelines).

Participating Sites

Ethical approval for this project applies at the following site(s): Bendigo Health.

PreHREA.Site.Name	PreHREA.Site.State
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13 November 2018

Research Office

To	Michael Kingsley
From	University Human Ethics Committee
Reference Number	LNR/18/BHCG/44121
Project title	Healthy 4U 2
Subject	Externally Approved Project
Date	13 November 2018

The externally approved project submitted above was reviewed and **noted** by the University Human Ethics Committee Chair.

Please note that all requirements and conditions of the original ethical approval for this project still apply.

Should you require any further information, please contact the Human Research Ethics Team on:
T: +61 3 9479 1443 | E: humanethics@latrobe.edu.au.

Warm regards,

David Finlay
Chair, University Human Ethics Committee



Want to be more physically active?



You are invited to participate in a research project- we want to know if telephone coaching can help people to be more physically active

What is involved?

- Attending a brief information session at Bendigo Health
- Complete a survey and have some measures taken at the beginning, middle and the end of the project.
- You may receive telephone coaching from a health professional to assist you with your physical activity plans.
- Wear a device that measures your physical activity at the beginning, middle and the end of the project.



I would like to find out more

We are more than happy to explain more about the project and answer any questions you may have; please contact Stephen Barrett:

P: 5454 9118 E: sbarrett@bendigohealth.org.au

Text: YES to 0439 379 132

10.23 Appendix 8.3 CONSORT checklist

NOTE - Appendix 8.3 has been published: Barrett S, Begg S, O'Halloran P, & Kingsley M. (2020). A physical activity coaching intervention can improve and maintain physical activity and health-related outcomes in adult ambulatory hospital patients: the Healthy4U-2 randomised controlled trial. *International Journal of Behavioral Nutrition and Physical Activity*. 17, 156. <https://doi.org/10.1186/s12966-020-01063-x>



CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist Item	Reported on page no
Title and abstract	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	3
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	5-6
	2b	Specific objectives or hypotheses	6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	7
	4b	Settings and locations where the data were collected	7-8
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8-9
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	6-7
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	10
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A

Section/Topic	Item No	Checklist Item	Reported on page no
Randomisation			
Sequence generation	8a	Method used to generate the random allocation sequence	8
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	8
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	8
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	5
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	N/A
	11b	If relevant, description of the similarity of interventions	10-11
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	10-11
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	7
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	11 (flow diagram)
	13b	For each group, losses and exclusions after randomisation, together with reasons	11 (flow diagram)
Recruitment	14a	Dates defining the periods of recruitment and follow-up	7-8
	14b	Why the trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	12
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	11
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	12 (table 2)
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A

Section/Topic	Item No	Checklist Item	Reported on page no
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	N/A
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N/A
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	13-16
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	13-16
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	13-16
Other information			
Registration	23	Registration number and name of trial registry	4
Protocol	24	Where the full trial protocol can be accessed, if available	N/A
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	N/A

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

10.24 Appendix 8.4 TIDieR Checklist

NOTE - Appendix 8.4 has been published: Barrett S, Begg S, O'Halloran P, & Kingsley M. (2020). A physical activity coaching intervention can improve and maintain physical activity and health-related outcomes in adult ambulatory hospital patients: the Healthy4U-2 randomised controlled trial. *International Journal of Behavioral Nutrition and Physical Activity*. 17, 156. <https://doi.org/10.1186/s12966-020-01063-x>



The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other [†] details
	BRIEF NAME		
1	Provide the name or a phrase that describes the intervention.	8-9	
	WHY		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	8 - 9	
	WHAT		
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	N/A	
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	9	
	WHO PROVIDED		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	9	
	HOW		
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	9	

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † details
	WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	9	
	WHEN and HOW MUCH		
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	9	
	TAILORING		
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	N/A	
	MODIFICATIONS		
10.‡	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	N/A	
	HOW WELL		
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	9	
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	12	

**** Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use ‘?’ if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

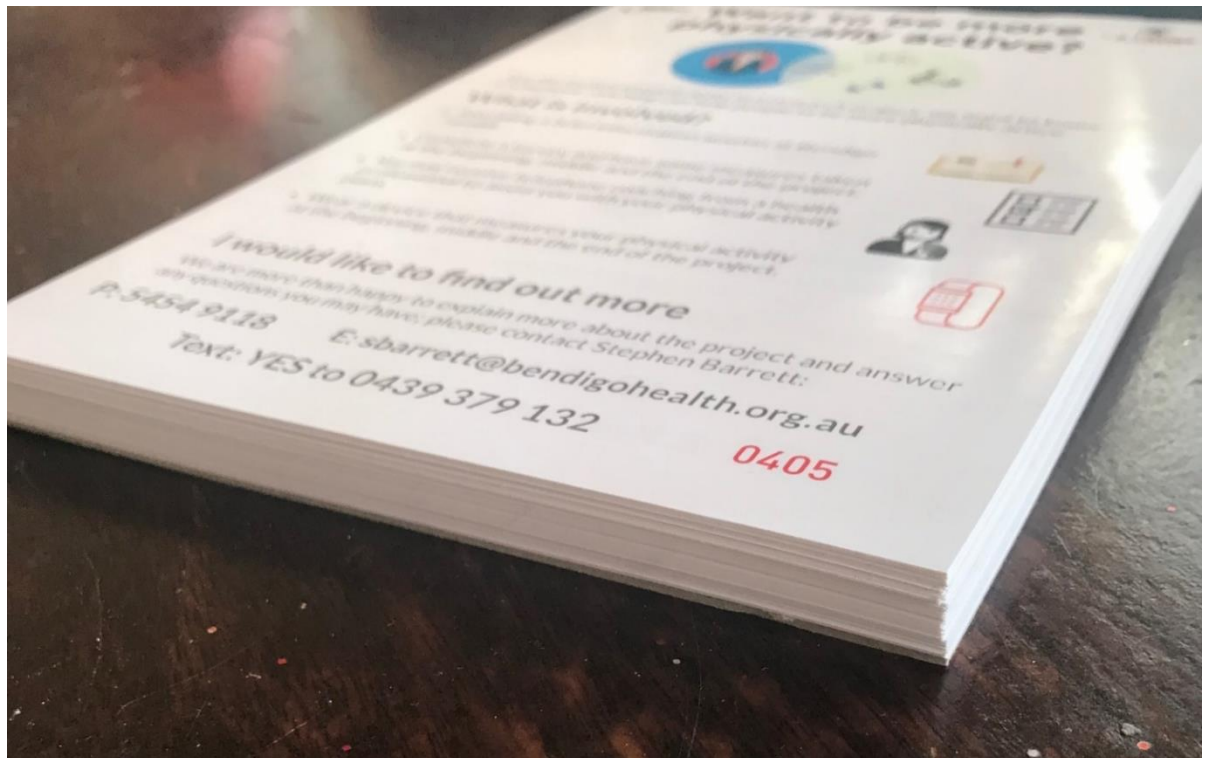
‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement**. When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).

10.25 Appendix 8.5 Research invitation image

NOTE - Appendix 8.5 has been published: Barrett S, Begg S, O'Halloran P, & Kingsley M. (2020). A physical activity coaching intervention can improve and maintain physical activity and health-related outcomes in adult ambulatory hospital patients: the Healthy4U-2 randomised controlled trial. *International Journal of Behavioral Nutrition and Physical Activity*. 17, 156. <https://doi.org/10.1186/s12966-020-01063-x>



10.26 Surgeons and preventative health: protocol for a mixed methods study of current practice, beliefs and attitudes influencing health promotion activities amongst public hospital surgeons

NOTE - This protocol underwent external peer review and is available at:

Barrett, S., Begg, S. & Kingsley, M. (2018) Surgeons and preventative health: protocol for a mixed methods study of current practice, beliefs and attitudes influencing health promotion activities amongst public hospital surgeons. *BMC Health Services Research*. 18, 780. <https://doi.org/10.1186/s12913-018-3606-8>

Abstract

Background: The high prevalence of non-communicable diseases places significant demands on the healthcare system. As a result, hospitals are seeking to broaden their role to include more integrated health promotion. Strong leadership at different levels of the organisation is required for the successful integration of health promotion in hospital settings. The status of surgeons within healthcare affords them significant influence over clinical practice, and by extension, institutional policy and practice. The voice of this professional group is, however, absent from preventative health literature. The aim of this research is to identify which health promotion activities surgeons undertake, and to explore the attitudes of the profession towards health promotion activities.

Methods: A mixed methods study will be conducted, guided by the principles of sequential explanatory design. Quantitative results from a clinician survey will be followed by in-depth, semi structured interviews to explore findings in more depth through qualitative analysis. We will recruit from general and orthopaedic surgeons and registrars in a major tertiary hospital in a regional city in Australia (n ≈ 31). Data will be collected, independently coded and analysed using a qualitative descriptive approach. Quantitative and qualitative results will be merged during interpretation to provide complementary perspectives of interrelated contextual factors that influence health promotion activities amongst hospital surgeons.

Discussion: The depth of insight gained from these highly professionalised clinicians will offer a distinctive perspective on current practice, as well as the challenges of implementing effective health promotion into surgical practice. The findings from this research will assist in guiding strategy and policy at both clinical and institutional levels on health promotion planning and practice. Gaining insights from surgeons will strengthen the evidence base to assist the integration of health promotion into hospital practice.

Keywords: Surgeons, Health promotion, Professional practice, Hospitals, Attitude

Background

Chronic non-communicable diseases are the leading cause of illness, disability and death worldwide (Alwan, 2011). These diseases include cardiovascular diseases, chronic respiratory diseases, diabetes, and some cancers (Alwan, 2011), and are largely preventable (Bloom et al., 2012). There are a number of key reasons behind the rise in chronic diseases, including increasing life expectancy, the ageing of the population and behavioural health risk factors (Alwan, 2011). Chronic diseases have an intricate association with modifiable lifestyle risk factors, such as physical inactivity, poor nutrition, and smoking (Beaglehole et al., 2011). The increased prevalence of non-communicable diseases over the past number of decades has influenced the demands that are placed on the health system (Sanders, Fuhrer, Johnson, & Riddle, 2008). Hospitals, as a result, have been required to broaden their role from their primary focus of disease treatment towards a position of more integrated health promotion and holistic care (Johnson & Baum, 2001).

Hospitals are in a suitable position within the health care system to be advocates for health promotion (Ziglio et al., 2011). Hospitals represent the primary concentration of health resources, professional skills and medical technology in the community (Johnson & Baum, 2001). The extensive resources that hospitals command mean that even a small shift of focus has the potential to bring about an increase in resources dedicated to health promotion (Johnson & Baum, 2001; Ziglio et al., 2011). This shift, over time, could bring potential health benefits to a community (Aiello et al., 1990; Johnson & Baum, 2001). The hospital healthcare system also provides important opportunities to reach the most disadvantaged in the community, who are often hard to reach by wider population-based approaches (Mchugh et al., 2010). Moreover, hospital-based clinicians are seen as credible sources of advice and expertise on health issues that extend beyond their responsibilities for services related to sick care and can be strong advocates for health promotion (Aiello et al., 1990).

Surgeons have an important role within the hospital system in the promotion of healthy lifestyles and behaviour change for patients with, or at risk of, chronic disease (Surgeons, 2012). Due to their extensive training, specialisation and medical expertise, surgeons are perceived as dependable sources of advice and expertise on health issues that extend beyond their responsibilities for services related surgical care (Ziglio et al., 2011). Surgeons as such, are influential in the promotion of lifestyle behaviour change (Aiello et al., 1990). The surgical

profession is one of responsibility and leadership, playing key roles in strategic planning, especially pertaining to clinical care (Lipman, 2000). Strong leadership at different levels of the organisation has been indicated as the key element for integrating health promotion in a hospital setting (Aiello et al., 1990; Mchugh et al., 2010). Hospital surgeons therefore have significant influence over clinical settings, and by extension, institutional policy and practice, necessary for the implementation of research into clinical practice (Lipman, 2000).

The persuasive role of hospital doctors in promoting health-related behaviour change has been acknowledged (Jones et al., 2004). There is however, a significant gap between potential and practice, with low rates of preventive health interventions reported by hospital doctors (Daley et al., 2008). Only a small proportion of emergency physicians reported routine screening and counselling of patients about preventive health; furthermore, the majority were not confident in their ability to assist patients change their health-related behaviours (Williams et al., 2000). When surveyed, hospital speciality clinicians also felt that they were not the most appropriate person to offer patients advice about behaviour change (Daley et al., 2008). The authors suggested that this result provides an explanation for the low implementation rates of behaviour change interventions in the hospital setting (Daley et al., 2008); however, no interviews were carried out to further probe the survey findings to gain a deeper understanding of the topic. Decisions on implementing evidence into surgical practice have been found to be multifactorial (Grol & Grimshaw, 2003). These decisions are influenced by local, contextual and social circumstances (Gagliardi & Alhabib, 2015; Grimshaw et al., 2004), as well as organisational processes and available resources (Gagliardi & Alhabib, 2015; Grimshaw et al., 2004). Given the prevalence of chronic diseases and the recommendation for hospitals to broaden their role towards a position of more integrated health promotion (Aiello et al., 1990; Groene, Jorgensen, Fugleholm et al., 2005; Johnson & Baum, 2001; Mchugh et al., 2010), it is important to gain insights from hospital surgeons due to the influence that they exert on patient behaviour and clinical policy and practice. Existing literature has reported qualitative and quantitative findings separately rather than linking quantitative data of actual clinical practice to qualitative data on beliefs and attitudes that influence such practices (Laws et al., 2008). Therefore, a better understanding of how attitudes towards risk factor management influence clinical practice is required to guide future preventive health policy and practice.

The aim of this mixed-methods study is to identify which health promotion activities surgeons carry out in public hospitals, and to explore the attitudes of the profession towards health

promotion practice. Combining quantitative data on levels of risk factor intervention with qualitative data about beliefs and attitudes will highlight ways in which interventions and practice can be implemented in clinical care to increase the overall rate of risk factor management. The depth of insight gained from the study of these highly professionalised clinical groups will offer a distinctive perspective on current practice, and the challenges of implementing effective health promotion into hospital settings. The results of this study have potential to guide health promotion policy and practice into the future.

Methods/design

This study will use a mixed methods approach to explore which health promotion activities surgeons carry out in public hospitals, and to understand attitudes of surgeons towards health promotion activities. Quantitative data will be derived from a clinician survey. Semi-structured interviews will be used to obtain qualitative data. The mixed methods study will use a sequential explanatory design (Ivankova et al., 2006). This is a two phase design where quantitative data are collected prior to the collection of qualitative data. The sequential explanatory design uses the qualitative results to further explain and interpret the findings from the quantitative component. The study framework is grounded in pragmatic epistemology (Creswell & Zhang, 2009; Kaur, 2016), to explore clinician views, behaviours and actions relating to preventive health practice. To promote transparency of our planned research, Table 1 presents qualitative research design aspects within the COnsolidated criteria for REporting Qualitative (COREQ) studies framework (Tong et al., 2007).

Clinician Survey

Surgeons will be invited to complete a short 17-item self-administered clinician survey to assess health behaviour risk factor management, perceived knowledge, confidence and attitudes towards preventative health (Appendix 7.3). The clinician survey asks respondents to report on proportions of clients seen over a recent period who they: (1) asked about smoking, nutrition, alcohol and physical activity; (2) assessed for readiness to change; (3) provided verbal and written advice on these risk factors and; (4) referred to other services for support in changing risk factors. These clinician practices are the dependent variables. The clinician survey also questions the participants about their knowledge and confidence in screening and managing each risk factor. In addition, attitudinal measures will be included for: (1) the clinicians' opinion

on the perceived effectiveness of the interventions; (2) the perceived importance of the intervention for the clients they see; (3) perceived work priority; and (4) perceived acceptability on the part of the client of raising the topic of lifestyle risk factors. The answers to these questions constitute the independent variables. All clinician survey items are measured on a 5-point Likert scale. The clinician survey has been adapted with permission from a previously developed instrument used to assess health behaviour risk factor management practices and capacity in community dwelling participants (Amoroso, Hobbs, & Harris, 2005; Laws et al., 2008).

Semi- structured interviews

Qualitative data permits the recording of first-hand accounts of the individuals studied, offering rich, straight descriptions of experience or events (Rice, 1996; Rice & Ezzy, 1999). Following analysis of the clinician survey, semi-structured interviews will be conducted with a purposeful sample of surgeons and surgical registrars. Interviews will be structured in an attempt to gain participant's opinions on factors that influence their decisions to undertake health promotion activities. Interviews offer value in understanding the perspective of individuals as well as the rationale for their actions (Patton, 1990). The interviews will take place face-to-face where possible, with telephone interviews used where required for practical reasons

This research will use qualitative description as the theoretical framework for the qualitative component (Sandelowski, 2000). Qualitative description provides straightforward, rich descriptions of experiences or events. Unlike other qualitative approaches which seek to develop new concepts or theories, the final outcome of qualitative description is a description of a participant's experiences in a language similar to the participant's own (Sandelowski, 2000). In qualitative description interviews are typically designed to focus on areas in health care that are either poorly understood and/or potentially amenable to intervention [27].

To facilitate uniformity, open-ended questions as well as question-related probes will be drafted. These questions will be designed to fit with the objectives of the research; however, they will not be finalised a priori, rather, they will be built from the analysis of clinician survey answers (Creswell & Zhang, 2009). Interview questions might be altered and adapted to differ between different groups of surgeons given the heterogeneity of the patients they see. Pilot interviews will be undertaken and audiotaped. The resulting interviews will be transcribed

verbatim and used to refine the interview script. In keeping with the qualitative description framework, the interview script will be developed and amended formatively, based upon findings and emerging concepts (Rice, 1996; Strauss & Corbin, 1990)

Descriptive information, such as years of practice and specialisation level, will be captured at the outset through the clinician survey. All participants will be encouraged to express opinions understanding that every answer is valuable and of use in the analysis (Rice, 1996; Rubin & Rubin, 2011). Full interviews will be audiotaped and transcribed verbatim. Field notes will be used to supplement audio and transcripts. After each interview the questions and answers will be assessed and reviewed to establish how well the interview script facilitated exploration of the topic. Where required, the script will be revised prior to the next interview (Rubin & Rubin, 2011).

Ethics

The study has been approved by the Research Ethics Committees of the governing Hospital and University. Participants will choose to complete the clinician survey online or in hard copy. Participants who choose to complete the online version of the survey will be informed electronically, prior to commencing the survey that if they continue and complete the survey they agree to provide informed consent. Participants who choose to complete a hard copy version of the clinician survey will be given a Participant Information and Consent Form to complete prior to undertaking the clinician survey, as well as a stamped addressed envelope to return the consent form and clinician survey. Participants who choose to complete a hard copy version of the clinician survey will be reminded not to place their name on the clinician survey. Participants will be notified that their involvement is voluntary and can be withdrawn at any time, and that confidentiality is protected through the anonymization of all collected data. Any publication will not attribute specific comments to identifiable participants.

Table 1 Qualitative study design

Domain 1: Research team and reflexivity	
Personal characteristics	
1. Interviewer/facilitator	All interviews will be conducted by the same member of the study team.
2. Credentials	The interviewer will be a masters-level trained research assistant.
3. Occupation	The interviewer will be employed full-time as a project officer.
4. Gender	The interviewer will be male.
5. Experience and training	The interviewer will be a masters-level trained research assistant.
Relationship with participants	
6. Relationship established	Potential interviewees will be contacted with a standardised recruitment email to introduce the study and the interviewer and to request their participation.
7. Participant knowledge of the interviewer	The recruitment email will explain the study goals and why the interviewer is interested in conducting this research. This information will be reviewed at the start of each interview.
8. Interviewer characteristics	The recruitment email will provide information about the research team, including the interviewer. This information will be reviewed at the start of each interview.
Domain 2: Study design	
Theoretical framework	
9. Methodological orientation and theory	The qualitative portion of the study will use a qualitative description approach.
Participant selection	
10. Sampling	Potential interviewees will be selected based on their practicing status in the target hospital.
11. Method of approach	Potential interviewees will be approached with a standardised recruitment email.
12. Sample size	We anticipate conducting 5 to 10 interviews.
13. Non-participation	We will document any reasons provided by those who decline to participate as well as any individuals who do not respond to our recruitment email.
Setting	
14. Setting of data collection	14. Setting of data collection
15. Presence of non-participants	15. Presence of non-participants
16. Description of sample	16. Description of sample

Data collection	
17. Interview guide	The interview guide will be developed by the study team. It will be pilot-tested and refined before data collection begins.
18. Repeat interviews	We do not anticipate conducting repeat interviews.
19. Audio/visual recording	Once permission is granted, interviews will be audio recorded.
20. Field notes	The interviewer will draft summary notes immediately after concluding each interview.
21. Duration	We anticipate that interviews will last no more than 30 minutes.
22. Data saturation	Data saturation was discussed
23. Transcripts returned	Transcripts will not be returned to participants for comment and/or correction
<i>Domain 3: Analysis and findings</i>	
Data analysis	
24. Number of data coders	We plan to have two coders pilot a sub-sample of transcripts. Once discrepancies are resolved and the codebook is finalised, the full set of transcripts will be coded by one individual.
25. Description of the coding tree	We plan to develop a coding tree (i.e., codebook) based on a review of the literature, a priori knowledge within the study team, and summary notes from interviews.
26. Derivation of themes	Themes will be derived once data have been coded. Preliminary themes may be identified based on discussions with the interviewer and review of field notes.
27. Software	We plan to use NVivo qualitative research software.
28. Participant checking	A bulleted list of key findings will be shared with participants once data have been coded and analysed.
Reporting	
29. Quotations presented	Quotations from interviews will be used to present findings, and they will be accompanied by an interviewee identification number.
30. Data and findings consistent	Our planned use of quotations will allow for assessment of consistency between our data and findings. We will also create supplemental tables with additional quotations to share as much information as possible when presenting our findings.
31. Clarity of major themes	We plan to use sub-headings listing our major themes to promote clarity when writing up our findings.
32. Clarify of minor themes	We plan to provide quotations from interviewees who raised minor themes or shared information contrary to findings of our major themes.

Participants

The target participants for this study are general and orthopaedic surgeons, and their registrars who consult out of the elective outpatient clinic in a major tertiary hospital in a regional city in Australia. The clients presenting to this clinic are ambulatory, non-admitted clients. While this group may be seen as a representation of the general community-dwelling population, research indicates that patients presenting to hospital clinics are more likely to have higher rates of

chronic disease than the general population (Aiello et al., 1990; Beaglehole et al., 2011).

As there are only a limited number of surgeons (general and orthopaedic) (n=20) and registrars (n=11) operating out of the study hospital, we will offer participation to all of these practitioners. Recruiting all surgeons and registrars consulting out of the hospital will increase the potential sample size, and provides a participant sample with differences in career stage and level of training. In qualitative description, the methodology seeks to gather enough data to saturate the explanation (Sandelowski, 2000; Strauss & Corbin, 1990). Interviews will be continued until no interviewees are providing new information, and data saturation is determined (Richards & Morse, 2012). If it is deemed that theoretical saturation is reached prior to full recruitment, then recruitment will discontinue (Rice & Ezzy, 1999; Richards & Morse, 2012; Sandelowski, 2000).

We will recruit participants from one study site only. We have chosen to recruit participants from one study site only due to the heterogeneity that exists between hospitals in terms of infrastructure, clinical practice and resources, as well as broader contextual factors that may differ between areas serviced by hospitals such as the availability of, and access to, local preventative health providers and programs (Mosadeghrad, 2014). This study is part of a broader body of work, investigating health promotion in non-admitted secondary care patients. We have already undertaken a clinical trial investigating behaviour change interventions for non-admitted secondary patients in a single-hospital setting (ANZCTR trial id: ACTRN12616001331426). This proposed mixed-methods study aims to fill the gap in knowledge pertaining to surgeons' actual involvement in the practice of health promotion in an ambulatory care setting; these results can be used in the design of subsequent clinical trials involving surgeons screening and recruiting secondary care patients for behaviour change interventions.

Recruitment

An email will be sent to all potential participants by their head of department, explaining the rationale for the study and the inherent requirements. The email will explain that participants can take part in the clinician survey, the interview, or both. The email will contain a link to the electronic version of the clinician survey. The email will also inform participants that a hard copy version of the clinician survey is available if this is preferred. The email will contain contact details for the research team for those individuals who would like more information. To assist

with completion rates (Asch et al , 1997), two subsequent reminder emails with attached clinician survey link will be sent out through the same electronic channel, at four-weeks and eight-weeks post initial email.

Individual participants will be approached to discuss involvement in the interviews, and where interested, a time will be arranged with each clinician to undertake the interview. Every effort will be made to allocate sufficient time in the interview to discuss informed consent and undertake the interview. Participants will be given a Participant Information and Consent Form to complete prior to undertaking the interview. Where appropriate, and to coordinate scheduling, the coordination of the interview times may be facilitated through the personal assistants of the surgeons. To facilitate the development of interview topics and question design, we aim to have at least 5 clinician surveys completed and analysed before undertaking any interview.

Analyses

Clinician Survey

Consistent with published literature utilising this survey (Amoroso et al., 2005; Laws et al., 2008), the relationship between the dependent variables (clinician practices) and independent variables (confidence, knowledge and attitudes) will be analysed. Due to the small sample of clinicians available for recruitment, dependant variables will be recorded as low, moderate or high. Low implementers will be defined as clinicians with screening and intervention scores, across all risk factors, in the first quartile. High implementers will be defined as clinicians with screening and intervention stores, across all risk factors in the fourth quartile. Given the relatively small sample size, a Generalized Estimating Equation will be used to estimate the parameters of a generalized linear model with a possible unknown correlation between outcomes (Ballinger, 2004). The generalized estimating equation procedure extends the generalized linear model to allow for analysis of repeated measurements or other correlated observations (Ballinger, 2004). Generalized estimating equations allows for the highlighting of moderators that do not directly correlate with the outcome of interest, but influence other related factors (Ballinger, 2004; Mickey & Greenland, 1989; Sheu, 2000). Analysis of the surveys will be used to offer exploratory themes, questions and question-related probes for the semi-structured interviews.

Interviews

Data from individual interviews will be collected and analysed promptly, to allow emerging themes to be added to and explored in following interviews. Qualitative description analysis requires the reading and re-reading of transcripts, allowing the development of a coding scheme that accurately reflects concepts in the text (Patton, 1990; Rice & Ezzy, 1999). Coding is a critical part of the data analysis stage and aims to merge concepts and themes that emanate from reviews of the interviews and corresponding text, taking the text from the descriptive to the interpretive (Charmaz & Belgrave, 2012). The qualitative description process utilises open and axial coding of transcripts, which, in keeping with the concurrent methodological approach, will occur simultaneously (Rice, 1996). Open coding describes the reading of interview transcription linearly with the aim of identifying concepts and then grouping concepts into categories and subcategories (Charmaz & Belgrave, 2012). The analytic process may be used to identify the more general categories that these concepts are instances of, such as institutions, work activities, social relations and so forth (Patton, 1990). Axial coding is the process of developing connections between code categories and sub-categories via a combination of inductive and deductive thinking (Patton, 1990). Consistent themes are integrated, reducing the overall number of categories (Patton, 1990). The emerging categories will be reviewed by the research team with the aim of using the categories to explain the factors that influence surgeons' decisions to use health promotion activities.

Following open and axial coding, a process of selective coding is undertaken (Saldaña, 2015). This process defines the central or core category, and its clear relationship to other categories (Saldaña, 2015; Strauss & Corbin, 1990). The core category has the analytic power to combine all categories to form an explanatory whole (Saldaña, 2015; Strauss & Corbin, 1990). Data will be coded and analysed independently by two investigators. The investigators will identify and code themes using NVivo 10.0 software (QSR International). An electronic codebook will be developed to assist with the coding scheme and data characterisation. The codebook will contain code definitions as well as rules related to each unique code. To improve reliability, a third investigator will review the codebook and samples of transcripts. Disagreement between investigators will be resolved through discussion, and where required, the thorough re-examining of transcripts. Categories will be represented visually using diagrams to illustrate the conceptual relationship between the emerging categories. See Table 1 for additional qualitative analysis details.

Risk of Bias

This study seeks to avoid the weakness or intrinsic biases inherent in single method, single observer, and single theory studies by adopting a mixed methods approach (Kaur, 2016). It will involve a series of steps consistent with rigorous qualitative research (Creswell & Zhang, 2009; Kaur, 2016), including: note-taking during clinician interviews; systematic data coding and analysis; detailed documentation of analytic decisions to explicitly demonstrate the means of arriving at the codes, and to avoid overgeneralisation and speculative conclusions; including direct quotations from participants to offer readers some perspective on the evidence from which the study findings and conclusions are based; and reviewing data coding processes, analytic decisions, and resultant themes by the two investigators (Leung, 2015). These steps allow for the triangulation of findings by the research team, with high degrees of team involvement required through the stages of data analysis and interpretation (Leung, 2015; Strauss & Corbin, 1990). This process is designed to increase rigor by decreasing the likelihood that substantial thematic ideas get overlooked, and ensure transparency in both data coordination and interpretation (Strauss & Corbin, 1990).

Trial status

Further to the approval for the research from the ethics boards of the hospital and university, the study has also been approved by the Group Executive at the study hospital, including Executive Director of Acute Health and the Chief Medical Officer.

Discussion

Hospitals play an important role in sick care, the provision of rehabilitation services, the promotion of health, and the prevention of disease (Sanders et al., 2008). These activities have been core components of hospital work; however, the increasing prevalence of lifestyle-related chronic diseases necessitates a more expanded scope, and standardised provision of initiatives to enable clients to take an active role in preventative health and chronic disease management (Aiello et al., 1990; Johnson & Baum, 2001; Mchugh et al., 2010). This requires the reorientation of health care facilities to integrate health promotion, disease prevention and rehabilitation services in curative care (Groene et al., 2005). Hospitals can have a strong influence on health behaviour, with patients demonstrating more responsiveness to health advice in situations

when they are experiencing ill-health (World Health Organization, 2003). A fundamental necessity towards integrating health promotion in hospital settings is strong leadership at different levels of hospital governance (Aiello et al., 1990; Mchugh et al., 2010). This leadership is epitomised by hospital surgeons, influential figures within both clinical settings, and by extension, hospital organisational culture and practice (Grimshaw et al., 2004; Grove, Clarke, & Currie, 2015). Surgeons are seen as the predominant authoritative source of advice and expertise on health issues, having influential roles in both clinical and administrative structure (Aiello et al., 1990; Lipman, 2000; W, 2003). In spite of this, information regarding the professional practice, and the opinions of these exemplars of clinical practice pertaining to preventative health are absent from the literature.

The primary outcomes of this study will be to: (1) identify what health promotion activities surgeons carry out in public hospitals, and (2) explore the attitudes of surgeons towards preventative health practice. The depth of insight gained from the study of these highly professionalised clinical groups will offer a distinctive perspective on current practice, as well as the challenges of implementing effective health promotion into surgical practice. The findings from this study will offer insight into individual, institutional and contextual factors that influence surgeons' decisions to participate in health promotion activities.

There are a number of limitations to the proposed study design. A limited number of participants will be recruited for this mixed-methods study. The demographic characteristics of the surgeons who participate in this study will be captured to enable comparison to broader communities of surgeons. Additionally, participants will be recruited from one study site to minimise the range of external influences. Although this might limit the transferability of the findings to other hospital settings, to our knowledge this will be the first study to capture the opinions of hospital surgeons on this issue.

The findings from this research might be used to guide strategy and policy in both clinical and institutional levels around health promotion planning and practice. Gaining the insights from surgeons will be an important step towards the proposed reorientation of hospital practice towards more integrated health promotion settings, culminating in environments that permit patients to take active roles in preventative health and management.

10.27 Exercise and COVID-19: reasons individuals sought coaching support to assist them to increase physical activity during COVID-19

NOTE - This study underwent external peer review and is available at:

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Abstract

Objective: This paper explores the experiences of individuals who reported substantially decreasing physical activity (PA) as a result of COVID-19 and sought coaching support to increase PA.

Methods: A qualitative study using phenomenological analysis. Eight individuals participated in semi-structured interviews that focused on their experiences of decreasing PA as a result of physical distancing measures, and why they sought PA coaching to overcome these issues. Responses were analysed thematically.

Results: The participants reported markedly decreasing their PA following the enactment of physical distancing measures. The inability to subsequently engage in regular PA was a source of frustration for participants. Interview analysis revealed two themes that contributed to the understanding of why these individuals felt they needed PA coaching to increase PA; namely, a desire for both listening support and PA self-regulation support.

Conclusion: The individuals who decreased PA due to COVID-19 desired an autonomy-supportive counselling style, centred on listening support and self-regulatory support. Online PA interventions were not highlighted as strategies to overcome PA barriers.

Implications for public health: The effect of physical distancing measures on the determinants of overall PA is important, particularly if prolonged physical distancing is required.

Keywords: Exercise barriers, motivation, self-determination

Background

COVID-19 appears to be having a major impact on physical activity (PA) behaviours (Hammami et al., 2020). Physical distancing, while a safe measure, might have unintended negative consequence of reducing PA (Giustino et al., 2020; Hall et al., 2020). Prolonged periods of home stay can lead to increased sedentary behaviours, resulting in an increased risk of physical inactivity and related chronic health morbidity (Pratt et al., 2019). The measures required to limit the spread of COVID-19 may exacerbate the longstanding issues of physical inactivity and sedentary behaviour (Ozemek et al., 2019). The syndemic nature of the COVID-19 threat requires a nuanced approach to minimise the spread of the virus alongside the strong health rationale for maintaining PA in the current environment (Hall et al., 2020; Horton, 2020; Maugeri et al., 2020; Ozemek et al., 2019; Pratt et al., 2019).

Opportunities to be physically active have been restricted in the state of Victoria, Australia. In March 2020, the Victorian Government introduced a variety of physical distancing policies under 'Stage 3' restrictions, including the closure of gyms, pools, community-based exercise centres and outdoor exercise groups. The suspension of traditional PA opportunities coupled with prolonged periods of self-isolation can increase the risk that adults do not undertake sufficient PA (Elovainio et al., 2017). In general, adults who report being socially isolated spend less time engaging in PA, and spend more time in sedentary behaviours when compared to adults who do not report being socially-isolated (Schrempft et al., 2019).

Efforts have been made to address these barriers to PA. For example, scholars in a variety of fields have published on the importance of maintaining PA during physical distancing periods (Jiménez-Pavón et al., 2020; Ravalli & Musumeci, 2020; Rodríguez et al., 2020) and official bodies have disseminated information on how to remain active during COVID-19 by exercising at home (Fallon, 2020). However, individuals who did not engage in regular PA prior to COVID-19 are unlikely to increase their daily PA during COVID-19, and may potentially do even less (Hall et al., 2020). Indeed in Canada, individuals who were physically inactive prior to COVID-19 decreased their PA even further (Lesser & Nienhuis, 2020). Broad based messaging around maintaining PA is important, but it is unlikely to have much impact on this group (Dishman et al., 2005; Grady & Gough, 2014). The social impacts of the COVID-19 restrictions and the influence of this on psychophysical wellbeing may require more targeted behaviour change

approaches to address barriers to PA engagement (Maugeri et al., 2020; Saladino et al., 2020).

The Healthy 4U-2 (H4U-2) study used telephone coaching to increase PA in adults attending secondary care clinics in a tertiary hospital in regional Australia (Barrett et al, 2020).

Insufficiently physically active patients were referred to the study by their consulting clinician and a number of these individuals (n= 32) declined to participate as they did not believe they would benefit from PA coaching. Following the introduction of physical distancing measures as a result of COVID-19, the H4U-2 research team received unsolicited calls from 8 of these individuals who had reported substantially decreasing their PA. A period of more than 9 months had passed since the initial contact with the study team. These individuals had initially declined PA coaching but were now expressing the desire for coaching support to be more physically active during the physical distancing period.

This contact provided the opportunity to explore with these individuals why they felt in need of coaching support to increase their PA during COVID-19 restrictions and what elements of PA coaching they were seeking. The aim of the research was to explore the experiences of individuals who had decreased PA as a result of the COVID-19 pandemic, and what components of PA coaching people think are important in assisting them to increase PA.

Methods

Study design and participants

A qualitative study design using semi-structured interviews was undertaken. An empirical phenomenological approach was used to obtain detailed descriptions of the experiences of individuals who decreased PA as a result of the COVID-19 pandemic (Alase, 2017).

Phenomenological research is used to describe commonalities of lived experiences across a population and provides a deeper understanding of the phenomenon studied (Alase, 2017; Karlsson, 1993)

The eight individuals who contacted the research team seeking coaching support to be physically active were invited to participate in this study. All eight individuals consented to participate, and made up the convenience sample of study participants. The interviews were completed between June 10 and June 24, 2020. The participants were reflecting on the time

period from March 2020 up to the time of interview. The Stage 3 restrictions introduced by the Victorian State Government only permitted four reasons to leave home: food and supplies, medical care, exercise, and work or education. Organised exercise programs were ceased, and outdoor gyms were closed. The State Government restrictions were eased somewhat on May 13, 2020 with outdoor exercise activities permitted in groups of up to 10 people, though the requirements on physical distancing remained. Up to the time of interviews no changes were made to the restrictions on indoor exercise.

Ethics approval for this research was gained from the human research and ethics committee of the participating hospital and the associated university. The study objectives and voluntary nature of the study were explained to participants. Verbal informed consent was obtained before each telephone interview. Confidentiality was assured by using numbers instead of names (participant 1, participant 2 etc.), and by removing identifying information from transcripts. All audio recordings and transcripts were saved on a password-protected computer. Throughout this study, we followed the Standards for Reporting Qualitative Research guidelines (O'Brien et al., 2014)

Procedures

Semi-structured, in-depth telephone interviews were done at a time convenient for participants. With participant permission, all interviews were audio-recorded. Participants' age, marital status, employment and living arrangement was obtained at the start of the interview. Open-ended questions and question-related probes were used in the interviews to obtain detailed descriptions from the participants (Additional file 1). Data collection occurred concurrently with data analysis. The interviews were carried out over the telephone by the first author. The audio recordings were transcribed verbatim.

Analysis

In keeping with the phenomenological approach, the analysis included reading the transcript multiple times to gain an understanding of meanings conveyed, identifying significant phrases and summarising them in general terms, or codes (Alase, 2017) The codes were grouped to formulate meanings, with the validation of meanings through research team discussions to reach consensus. Finally, the codes were organised into categories, before developing a full description of themes. Several strategies were used to ensure trustworthiness and credibility.

Two co-authors analysed all the transcripts independently. Findings were then compared and discussed by the two co-authors until consensus on codes, categories and themes was achieved. Emergent categories and themes were discussed amongst the research team. Transferability was established by considering variations of participant characteristics and sufficient quotations collected through in-depth interviews. The audit trail was maintained to ensure all analysis steps could be traced back to original interviews.

Results

The sample consisted of five females and three males, aged between 40 and 61 years. Seven of the participants were employed, and one participant was retired at the time of interview. Interviews lasted approximately 20 to 25 minutes. Participant characteristics and the normal PA they undertook pre COVID-19 are summarised in Tables 1 and 2. Two broad themes emerged from the analysis with respect to what these individuals were seeking to assist with increasing PA during the COVID-19 restrictions: (1) listening support; and (2) PA self-regulation support.

Table 1 Participant characteristics

Age (years)	
Mean	51
SD	7
Range	40 – 61
Marital Status	
Married/living together	7
Widowed	1
Highest completed education	
Secondary/high school	2
Post-school vocational	4
University	2
Employment	
Full-time	6
Part-time	1
Retired	1

Table 2 Overview of participants' pre COVID-19 physical activity

Participant	Age	Gender	Pre COVID-19 physical activity
1	54	Female	Gym: 3-4 sessions/week - mixture of spin classes, body pump, body combat and yoga.
2	44	Female	Boot-camp group training: 3 sessions a week.
3	61	Male	Strength training: 2 days a week. Walking group: 1 day a week
4	40	Male	Swimming: 2 sessions a week. Basketball: 1 session a week.
5	48	Female	Parkrun: 1 session a week. Gym: 2 sessions a week – mixture of weights and cardio.
6	57	Female	Walking: 4 x 5km walks a week.
7	51	Female	Gym: 3 sessions a week – mixture of weights and cardio.
8	50	Male	Mixed Martial Arts: 3 sessions a week.

Listening support

This theme reflected participants' desire for a person-centred style of interaction, providing support that was centred on listening. For the most part, participants felt that they knew what to do to increase their PA; the problem manifested in doing so in an environment that they felt discouraged it. Although the majority of participants received a degree of social support and encouragement from significant others in relation to their PA, the support offered was generally directive in nature. The participants were not always receptive to the style of these interactions.

I knew that I couldn't make the transition to home exercise alone. My husband was great; is great. But he isn't the deep listener... he sees things in black and white. If he said, "tomorrow I'm going for a run" then he would do it. So, I don't think he has ever understood my battles with exercise. So, I wanted a voice to talk this through. To problem solve together. Participant 2 (P2).

So, I imagine it [physical activity coaching] would be more about why – why don't I do it... why not and this and that. Which is different to the 'do this, do that' advice. I don't need that. P6

The desire for listening support was particularly present among those who not only changed their PA as a result of COVID-19, but were required to change their daily schedules, necessitating a change to work from home and assisting with home schooling. The participants expressed a desire for coaching support that provided validation of the issues they were facing, and permitted the individual to explore potential avenues to address the problems.

I want someone to hear my problems, my unique problems. Someone who isn't my husband. Someone who might have heard similar things and can give their perspective to my situation. P7

I'd like to be listened to, to be heard. But I'd also like to be questioned I think, by a neutral party, because I think some worthwhile questions might force me to soul search a bit and work out the solutions. P3

Alongside being listened to, the importance of having autonomy was also apparent. It was important to individuals that they could lead the conversations and consultations. Individuals felt that the drive for change needed to come from themselves, and listening support could help verbalise, explore and solve problems. Within this, support and encouragement were deemed necessary components, but the provision of advice was not necessarily wanted.

I don't need to be told what I to, I already know. But I do need some help in doing it. P6

Physical activity self-regulation support

The second theme reflected participants' desire for PA self-regulatory support. The participants expressed a feeling that they had lost a degree of control over their capacity to be physically active. They voiced a desire to not only increase PA, but to gain personal control back over their PA routines that had been impacted by COVID-19 restrictions.

Well now, my sense of control has been taken from me. I don't have the option to go to the gym, so that's gone. P1

...I was trying to wrestle back some control. P2

The participants reported a shift from undertaking regular PA prior to the lockdown, to undertaking little to no PA in a short period of time. To have lost the capacity to self-regulate their PA during the restrictions was a source of frustration and accounted for the desire for help.

And that's what's disappointed me, my failure to do something I know I can do. P3

The changes to daily routine and the loss of structured exercise options greatly impacted the PA levels of the participants. The participants did not account for the impact of the COVID-19 physical distancing policies on their PA patterns and did not have contingency plans or coping strategies to remain physically active. In the face of competing demands, participants were unable to regulate their PA, and sought out support to assist with the physical and psychological ramifications. The effect of the restrictions and the desire for support is exemplified by the following quote:

I think I needed to keep face with my family, that we were okay, and home school and me working on the business was all fine. So, I didn't want to appear weak or helpless in anyway, even though I guess I was helpless now thinking about it. So, I put this front on to keep them happy and motivated. While I was crumbling a bit underneath. And again, I think that the role of the external person, to listen to these issues and be outside of them. So perhaps that was what I

was seeking the most. P2

Female participants appeared to find it particularly difficult to self-regulate PA while navigating changes to their employment and social roles. The females reported investing significant time in home schooling and work from home tasks, dedicating time to family and co-workers at the expense of allocating time towards their own PA. The males, in contrast, did not highlight the impact that home-schooling had on their PA self-regulation, though only one male participant had dependent school-aged children.

Home-schooling has been an issue. It's taken up some of my time to be present with my kids when they have needed the time. So, I have to prioritise them. And, of course, my own work, and navigating the work from home situation. Some days at the beginning I was sitting at my desk at 9pm doing some work things, and not because I was busier than pre-corona, but I hadn't gotten my timing and schedules right. P1

...but also a lack of, or failure in prioritisation I think. I've failed to put my wellbeing up front, or as a priority. I invested lots of energy making sure my son was comfortable with his home schooling... And then I threw myself into work as well, to show that I could run my team from home, so demonstrating my capacity to my boss, and also to my staff as a leader. Again, did I do too much? I'm not sure. But I have accountability in my role, so I felt I needed to step up. And I wanted my staff to feel like I was there for them, to get them through it. To look after their needs. P7

Discussion

This study explored the experiences of individuals who significantly decreased their PA as a result of Covid-19 and sought coaching support as a means to increase activity. Pervasive throughout the participants' descriptions was the conflict between their desire to be more physically active and their actual participation in PA. The qualitative approach permitted the capture of the range of influences that impacted PA behaviour during the physical distancing restrictions imposed due to Covid-19. The findings are important in relation to PA behaviour change and also in relation to the design of interventions that seek to maintain PA changes in

general.

Lack of support

A dominant theme that emerged from the analyses was the desire for a support specific to their PA issues. At the time of interview all participants were staying at home due to physical distancing rules. The only PA support they received was from partners; support which was typically directive in nature. Participants perceived these interactions as negative experiences. They felt like they were being told what to do, and not being listened to. This was one of the factors that led to them seeking external support. Interactions perceived as unsupportive to psychological needs are likely to undermine autonomous motivation and self-efficacy (Deci & Ryan, 2010). This highlights the importance of person-centred interventions to support PA change, and points to the significance of an autonomy-supportive influence, as outlined by self-determination theory, which posits that the quality of support will impact both the motivation and well-being of individuals (Deci & Ryan, 2010; Teixeira et al., 2012). Supportive interactions utilising empathy and non-judgemental understanding have been shown to build the autonomy and motivation required to maintain PA (Chatzisarantis et al., 2003; Hagger et al., 2008).

The individuals felt constrained by a lack of listening support within their social environment. This highlights some of the issues faced by individuals when the social environment does not support both physical and psychological needs. Individuals ambivalent about behaviour change can benefit from sufficient feedback or information to foster self-efficacy (Miller & Rollnick, 2012), which these individuals did not receive. A lack of appropriate support means that individuals are less likely to receive necessary feedback to support the success of their PA changes. This in turn undermines individual competence and can result in reduced self-efficacy (McAuley & Blissmer, 2000). Further to this, a lack of social support from significant others in the home is known to impede efforts to maintain autonomous motivation, and can hinder psychological needs (Hardcastle et al., 2011). This can subvert autonomous motivation, which leads to failed attempts at behavioural change and maintenance.

Lack of self-regulation

The second main theme that emerged from individuals who significantly decreased PA during Covid-19 physical distancing was a lack of PA self-regulation. This is consistent with existing evidence suggesting that self-regulation mediates exercise behaviour (Hallam et al., 2004). The

participants in this study reported decreasing almost all PA once the physical distancing rules were enacted, and were unable to subsequently increase PA up to the time of interview. The participants had remained physically active where structural supports were present but could only persist with their behaviour as long as the external support was available. It is likely that they had externalised their PA support system, and could no longer self-regulate PA in the absence of this support (Orsega-Smith et al., 2007). Hardcastle et al. (2011) detailed that individuals who internalised PA support and perceived the structural PA as supportive of their autonomy tended to view PA as part of their self. In that study, the individuals were able to continue with behaviour change even when the structural support was removed (Hardcastle et al., 2011). The degree to which a PA intervention is perceived as autonomy-supportive is likely to influence motivation, internalisation of behaviour and overall self-regulatory behaviour change (Williams et al., 2004).

The findings highlight the importance of self-regulation, which reflects one's self-belief and self-efficacy to be physically active. Such strategies usually involve behaviour planning which has been shown to be very effective in promoting motivation alongside self-efficacy (French et al., 2014). The participants maintained self-regulation over their employment and household duties, but not over PA scheduling and actions. The inability to maintain self-regulation over PA was particularly prevalent amongst the females in this study who, consistent with the literature, tended to prioritise their family responsibilities over their own PA (Sciomer et al., 2019). The desire to gain personal control over PA is consistent with the importance of self-regulation. Self-regulation is an important component of psychosocial theories of PA behaviour, and lack of self-regulatory skills are associated with low adherence to PA (Hagger et al., 2010). Increases in PA self-regulation were observed following behavioural interventions that focused on individuals developing their own strategies to regulate their PA (Murray et al., 2009). The participants in this study expressed a desire for a coaching style that supported their autonomy and assisted them regain control of self-belief. PA coaching interventions can show patients how to recognize signs of self-regulatory depletion or failures, and individuals can learn to monitor their self-regulatory capacity, which could help them to engage in regular PA (French et al., 2014).

Limitations

The limitations of this study include the use of opportunistic convenience sampling which resulted in a relatively homogenous study population. More research is needed to assess

whether the barriers presented in this study are the same in a more heterogeneous population. The opportunistic convenience sample also resulted in a small sample of individuals seeking support to be physically active. These individuals may have been more motivated to engage in PA, which may have introduced bias into the results. Although the opportunistic convenience sample may reduce the generalisability of these results to other populations, the results do provide understanding and insight into experiences and perceptions of participants who decreased PA due to COVID-19 restrictions (Jager et al., 2017). Finally, the convenience sampling meant that theoretical saturation was not known to have been reached due to the small sample of participants.

Implications for public health

The participants in this study did not express a desire to perform PA at home. A recent study indicated that online exercises could be easily integrated into everyday routines and were positively regarded by inactive adults (Wichmann et al., 2020). Some of the participants in our study had tried online exercise videos, but none persisted with it. This suggests that despite their appeal, online tools are not the panacea for overcoming PA barriers related to physical distancing. To maintain PA during periods of restricted opportunities, and to encourage PA in general, there are motivational factors that need to be considered when developing PA messages. Information needs to be targeted to audience's existing views and practices to produce more powerful persuasive effects (Goethals et al., 2020). Messages to promote PA could also be targeted towards significant others in an individual's environment and portray the importance of a non-judgemental form of listening support.

Long-term PA adherence is difficult (Springer et al., 2013); however, numerous forms of structural and social support can result in adherence to PA (Seefeldt et al., 2002). For the participants in this study, support from structural agents such as gyms and exercise groups were important in their regular attainment of PA. The removal of support manifested in recidivism to physical inactivity. Despite facilitating regular PA, the exercise programs undertaken by the participants had not fostered an internalisation of PA control. Formal exercise-based programs may benefit from incorporating behaviour change theories into the design of exercise interventions to build self-efficacy and PA self-regulation (Rajati et al., 2014). Addressing determinants of PA relapse such as those highlighted in this study may be beneficial for PA adherence within formal PA programs such as cardiac rehabilitation, where we know PA

maintenance remains suboptimal post-completion (Everett et al., 2009).

While the findings of this small sample cannot be applied to the general community, it is relevant to consider how the physical distancing rules have impacted PA behaviours within the community at large. It is also relevant to consider the self-regulatory capacity within the broad community, its implication on PA levels, and how this can be addressed to assist in the promotion and maintenance of PA during ongoing COVID-19 restrictions.

Conclusion

Individuals who decreased PA due to physical distancing measures desired a PA coaching intervention to build autonomy support. The individuals were not seeking PA advice, rather, listening support and self-regulatory support were deemed necessary for these individuals to increase PA. Due to the high proportions of the population who are insufficiently physically active, and the ongoing physical distancing restrictions imposed in Australia, this study highlights the importance of understanding the perspectives of insufficiently active individuals when attempting to increase PA levels in this group.

It is likely that the world will recover from COVID-19 and a period of 'new normal' will emerge. It is just as likely that the world will be challenged by future pandemics and that levels of insufficient PA will continue or even worsen by that time. An understanding of the needs of insufficient physically active individuals can go towards the development of behavioural and educational strategies to increase PA levels, now and into the future.

10.28 Meta data for Chapter 4

Allocation	Participant	WC Base	WC T2	WC T3	H	BM Base	BM T2	BM T3
0	1	117.0	117.1	117.0	157.1	99.9	99.9	100.0
0	2	124.8	124.8	124.9	160.0	113.7	113.7	113.8
1	3	110.0	108.4	108.6	172.5	97.2	96.3	96.1
1	4	115.6	113.3	113.6	163.1	113.3	110.5	110.0
0	5	122.3	122.0	122.0	167.4	105.0	104.4	104.8
1	6	106.0	106.1	105.2	155.0	79.8	80.0	79.1
0	7	103.0	102.9	102.9	172.0	82.5	82.5	82.8
1	8	88.0	86.2	86.0	161.0	75.7	75.1	75.1
0	9	102.0	102.1	102.1	162.6	89.8	90.0	90.1
0	10	88.0	87.3	87.8	160.0	80.2	80.0	80.3
0	11	90.0	90.0	90.2	154.9	80.7	81.0	81.0
1	12	93.0	92.2	91.5	149.8	79.4	77.2	77.0
0	13	86.0	86.0	86.5	165.1	80.7	80.6	80.5
0	14	94.0	94.0	93.9	175.2	80.2	80.3	80.6
0	15	86.0	85.5	86.1	167.6	89.8	89.0	89.5
0	16	88.1	87.1	87.1	167.6	80.2	79.4	79.4
1	17	76.3	75.2	75.2	165.1	68.9	67.1	67.0
0	18	93.6	93.2	93.2	160.0	80.5	80.1	80.2
1	19	89.3	85.8	84.5	161.0	75.7	71.7	71.8
1	20	91.1	90.1	89.6	190.5	90.2	87.1	87.0
0	21	84.1	84.2	84.5	180.3	85.2	85.2	85.1
1	22	80.0	77.6	77.4	167.6	73.9	70.2	70.0
1	23	87.1	85.2	85.2	160.0	73.4	71.1	71.0
0	24	86.0	85.1	85.5	166.6	80.7	78.9	79.5
1	25	71.0	70.5	70.6	165.1	67.1	67.0	66.6
1	26	91.4	90.6	90.6	167.0	85.3	83.3	83.3
1	27	108.4	104.2	104.1	157.4	78.2	76.0	75.8
1	28	84.0	81.1	81.1	175.3	78.0	74.4	74.5
0	29	92.0	93.1	93.2	177.8	84.4	86.0	86.0
0	30	108.0	108.2	108.0	175.3	93.4	93.9	93.8
1	31	111.2	108.2	108.0	162.6	80.7	79.9	79.4
1	32	107.7	104.4	104.6	162.6	80.8	80.1	79.8
1	33	112.1	111.5	110.4	149.8	79.4	77.9	77.4
0	34	92.6	94.2	94.2	165.1	78.1	79.2	79.5
1	35	103.2	103.3	103.3	175.6	97.5	97.3	97.1
0	36	82.2	84.0	84.2	165.8	68.5	71.1	71.6
1	37	86.6	86.7	85.9	177.8	87.1	86.4	86.1
0	38	84.4	84.4	84.9	166.1	73.1	73.1	73.3
1	39	115.4	111.8	110.8	154.9	81.6	78.8	78.7
0	40	106.6	106.4	106.4	162.5	77.5	77.5	77.9
0	41	94.6	94.6	94.5	170.1	82.5	82.4	82.4
0	42	90.5	90.5	91.2	187.9	94.8	95.1	95.1
1	43	97.2	97.2	96.8	162.5	77.5	77.5	74.4
1	44	103.3	101.5	101.3	162.6	87.5	85.5	82.8
0	45	98.9	98.4	98.6	167.6	85.3	84.9	85.0
0	46	111.7	114.2	114.2	154.9	83.4	85.0	85.0

1	47	112.8	112.5	111.1	162.5	95.7	95.1	92.4
0	48	83.6	85.2	85.0	162.5	75.7	77.7	77.7
1	49	96.6	92.5	92.5	175.2	83.9	80.1	80.1
0	50	91.1	91.4	91.3	172.7	83.9	83.9	84.1
1	51	99.6	96.1	96.1	178.0	85.3	81.4	81.0
1	52	89.6	89.2	88.5	157.4	68.5	68.5	67.8
0	53	81.6	83.4	83.4	167.6	72.6	74.1	74.4
0	54	101.1	101.2	101.0	177.3	88.1	91.1	91.1
1	55	112.1	109.5	109.0	177.8	100.2	94.5	94.1
1	56	112.2	108.0	107.8	154.9	87.6	84.9	83.6
1	57	96.5	91.2	91.3	162.5	80.2	78.1	78.0
0	58	89.6	92.4	92.3	167.6	82.6	82.6	82.8
0	59	92.2	93.6	93.5	165.1	77.1	80.2	80.2
1	60	92.6	90.1	90.0	157.4	85.3	83.3	82.8
0	61	104.8	104.9	105.2	167.6	94.8	96.0	96.0
1	62	103.3	100.2	99.8	167.4	93.4	91.4	89.5
1	63	102.2	100.0	99.4	177.5	90.2	87.6	87.2
0	64	98.6	95.2	94.2	162.6	87.5	84.2	84.2
1	65	107.7	103.3	103.4	167.6	94.3	90.1	89.1
0	66	102.6	104.2	104.2	172.7	89.8	91.2	91.2
1	67	106.7	105.7	105.4	170.4	87.1	86.9	84.8
1	68	111.6	106.2	105.8	160.1	96.2	92.1	91.4
0	69	106.1	106.1	106.1	168.1	89.7	89.7	89.7
1	70	102.6	102.5	101.0	157.0	84.8	84.8	81.0
0	71	115.0	115.0	115.0	161.1	88.9	88.9	89.4
0	72	98.3	98.4	98.4	180.3	88.4	88.4	88.4

WC: Waist Circumference; H: Height; BM: Body Mass.

Allocation	Participant	PASE Base	PASE T2	PASE T3	AUSD Base	AUSD T2	AUSD T3
0	1	34	30	30	18	18	19
0	2	49	45	38	15	17	17
1	3	51	44	32	19	17	17
1	4	43	46	40	20	18	18
0	5	45	38	34	19	21	22
1	6	25	35	35	18	18	18
0	7	32	30	38	12	12	11
1	8	32	38	33	11	10	10
0	9	21	22	34	10	10	10
0	10	28	28	35	15	14	16
0	11	32	38	28	11	9	10
1	12	29	41	44	13	10	10
0	13	28	26	29	7	4	4
0	14	32	36	30	12	10	12
0	15	29	37	26	13	13	14
0	16	25	22	38	12	13	12
1	17	22	42	46	8	6	6
0	18	34	38	32	12	12	12

1	19	20	36	45	7	7	7
1	20	19	36	38	10	10	11
0	21	46	40	25	21	20	20
1	22	22	42	41	5	7	7
1	23	26	38	30	7	6	6
0	24	22	25	34	17	17	17
1	25	26	28	40	7	7	7
1	26	25	39	39	15	14	14
1	27	40	44	48	20	18	18
1	28	19	28	28	9	9	9
0	29	47	38	28	12	10	10
0	30	50	44	26	16	15	15
1	31	19	38	38	16	14	14
1	32	18	26	30	15	13	12
1	33	23	26	48	16	15	15
0	34	46	39	33	21	21	22
1	35	31	32	37	16	16	16
0	36	21	23	30	12	13	14
1	37	28	26	42	11	12	12
0	38	50	42	30	6	8	9
1	39	22	33	42	14	14	14
0	40	36	36	32	19	18	18
0	41	48	48	40	14	13	13
0	42	48	46	42	12	12	12
1	43	25	27	50	9	8	8
1	44	22	27	38	16	15	15
0	45	47	47	38	8	9	9
0	46	31	25	26	25	25	25
1	47	24	34	28	12	11	11
0	48	38	30	24	6	8	8
1	49	32	48	48	12	13	13
0	50	24	25	34	14	14	14
1	51	29	41	34	12	11	11
1	52	27	33	38	15	15	15
0	53	52	48	40	5	6	7
0	54	35	36	26	16	17	19
1	55	31	44	33	12	11	10
1	56	37	42	28	19	18	18
1	57	41	50	45	20	17	17
0	58	39	30	36	8	8	8
0	59	20	20	44	17	16	16
1	60	22	29	23	24	22	22
0	61	23	24	38	15	15	15
1	62	22	37	27	18	17	15
1	63	25	31	40	21	21	21
0	64	16	22	24	11	10	10
1	65	33	45	47	16	15	15
0	66	14	15	28	18	18	18

1	67	23	24	41	18	18	17
1	68	29	39	33	14	13	13
0	69	49	47	47	18	18	18
1	70	41	41	32	13	14	11
0	71	28	26	32	14	14	13
0	72	19	16	16	12	12	12

PASE: Physical Activity self-efficacy; AUSD: AUSDRISK tool

Allocation	Participant	HrQoL			MVPA		
		Base	HrQoL T2	HrQoL T3	Base	MVPA T2	MVPA T3
0	1	0.8	0.66	0.66	50.57	26.57	12.14
0	2	0.58	0.52	0.58	40.14	22.86	9.17
1	3	0.535	0.695	0.583	26.00	34.86	26.71
1	4	0.758	0.796	0.88	7.29	38.14	45.14
0	5	0.618	0.618	0.573	1.00	24.14	5.29
1	6	0.615	0.755	0.755	25.71	27.71	48.29
0	7	0.58	0.58	0.58	31.86	27.57	43.00
1	8	0.735	0.657	0.657	14.57	27.86	35.57
0	9	0.57	0.57	0.57	17.00	22.43	40.43
0	10	0.657	0.657	0.657	19.00	41.71	18.57
0	11	0.612	0.657	0.612	32.00	44.14	30.00
1	12	0.573	0.573	0.758	40.71	54.86	44.29
0	13	0.675	0.797	0.612	47.00	45.29	28.00
0	14	0.58	0.615	0.58	39.29	41.00	19.29
0	15	0.734	0.583	0.612	35.29	53.14	16.43
0	16	0.615	0.618	0.615	14.00	44.29	44.00
1	17	0.628	0.628	0.797	22.86	48.57	43.29
0	18	0.657	0.657	0.657	30.71	46.57	29.14
1	19	0.735	0.657	0.657	22.57	61.86	31.86
1	20	0.559	0.481	0.573	34.00	46.43	29.29
0	21	0.8	0.8	0.615	29.14	39.29	35.00
1	22	0.618	0.618	0.8	24.43	52.71	36.71
1	23	0.735	0.657	0.657	13.57	47.43	26.29
0	24	0.565	0.565	0.565	25.71	40.71	22.86
1	25	0.657	0.657	0.719	34.00	39.43	18.71
1	26	0.535	0.535	0.535	39.00	49.57	49.57
1	27	0.615	0.615	0.615	25.43	44.86	28.71
1	28	0.613	0.535	0.615	31.57	43.57	18.57
0	29	0.601	0.601	0.601	38.71	19.57	27.86
0	30	0.535	0.57	0.535	39.43	20.14	27.00
1	31	0.544	0.511	0.636	35.14	57.43	26.43
1	32	0.598	0.52	0.646	4.17	32.86	32.29
1	33	0.57	0.57	0.615	32.17	36.86	31.43
0	34	0.737	0.606	0.615	32.00	18.29	18.14
1	35	0.658	0.658	0.58	30.67	26.29	26.86
0	36	0.701	0.701	0.701	34.67	25.43	16.86
1	37	0.583	0.583	0.646	40.17	32.00	41.57
0	38	0.723	0.723	0.678	42.67	24.86	18.14

1	39	0.658	0.58	0.58	33.17	41.43	37.14
0	40	0.737	0.859	0.674	43.00	47.67	19.86
0	41	0.72	0.72	0.72	29.57	44.17	28.14
0	42	0.601	0.601	0.538	49.71	46.33	31.00
1	43	0.538	0.538	0.615	42.71	35.57	63.86
1	44	0.57	0.57	0.615	28.71	32.14	51.57
0	45	0.646	0.646	0.601	39.14	44.67	29.14
0	46	0.643	0.583	0.643	48.57	11.57	24.29
1	47	0.598	0.565	0.658	47.43	47.57	58.43
0	48	0.643	0.643	0.643	44.43	10.86	27.43
1	49	0.797	0.797	0.797	27.43	58.14	58.14
0	50	0.615	0.615	0.57	33.43	38.86	22.86
1	51	0.583	0.583	0.646	29.43	47.57	34.00
1	52	0.538	0.538	0.583	40.57	40.29	43.43
0	53	0.583	0.58	0.583	36.00	10.43	8.00
0	54	0.657	0.657	0.657	36.57	14.14	9.57
1	55	0.6	0.6	0.66	37.00	52.57	33.00
1	56	0.758	0.758	0.8	24.43	64.14	40.00
1	57	0.661	0.583	0.72	31.29	67.57	41.71
0	58	0.616	0.616	0.616	30.71	12.29	24.71
0	59	0.657	0.66	0.657	30.14	31.86	29.00
1	60	0.58	0.58	0.58	16.50	31.43	48.71
0	61	0.643	0.755	0.598	26.50	23.71	24.29
1	62	0.678	0.695	0.734	12.50	45.71	66.14
1	63	0.675	0.597	0.615	19.50	34.43	45.57
0	64	0.737	0.737	0.737	21.75	38.43	17.57
1	65	0.8	0.8	0.8	25.57	47.57	62.14
0	66	0.604	0.604	0.559	32.71	21.14	27.29
1	67	0.657	0.657	0.797	30.57	32.43	47.43
1	68	0.565	0.583	0.646	25.43	48.17	54.14
0	69	0.738	0.735	0.735	30.29	11.43	11.43
1	70	0.628	0.628	0.628	36.86	37.29	53.43
0	71	0.738	0.657	0.693	33.43	25.14	35.43
0	72	0.642	0.6	0.6	33.29	11.00	11.00

MVPA: Moderate-to-vigorous physical activity; HrQoL: Health-related quality of life

Allocation	Participant	BMI Base	BMI T2	BMI T3
0	1	40.46	40.49	40.51
0	2	44.41	44.41	44.45
1	3	32.67	32.36	32.30
1	4	42.59	41.54	41.35
0	5	37.47	37.26	37.40
1	6	33.22	33.30	32.92
0	7	27.89	27.89	27.99
1	8	29.20	28.97	28.97
0	9	33.97	34.04	34.08
0	10	31.33	31.25	31.37

0	11	33.63	33.76	33.76
1	12	35.38	34.40	34.31
0	13	29.61	29.57	29.53
0	14	26.13	26.16	26.26
0	15	31.97	31.68	31.86
0	16	28.55	28.27	28.27
1	17	25.28	24.62	24.58
0	18	31.45	31.29	31.33
1	19	29.20	27.66	27.70
1	20	24.86	24.00	23.97
0	21	26.21	26.21	26.18
1	22	26.31	24.99	24.92
1	23	28.67	27.77	27.73
0	24	29.08	28.43	28.64
1	25	24.62	24.58	24.43
1	26	30.57	29.87	29.87
1	27	31.56	30.68	30.60
1	28	25.38	24.21	24.24
0	29	26.70	27.20	27.20
0	30	30.39	30.56	30.52
1	31	30.52	30.22	30.03
1	32	30.56	30.30	30.18
1	33	35.38	34.71	34.49
0	34	28.65	29.06	29.17
1	35	31.62	31.55	31.49
0	36	24.92	25.86	26.05
1	37	27.55	27.33	27.24
0	38	26.50	26.50	26.57
1	39	34.01	32.84	32.80
0	40	29.35	29.35	29.50
0	41	28.51	28.48	28.48
0	42	26.85	26.94	26.94
1	43	29.35	29.35	28.18
1	44	33.10	32.34	31.32
0	45	30.37	30.22	30.26
0	46	34.76	35.43	35.43
1	47	36.24	36.01	34.99
0	48	28.67	29.42	29.42
1	49	27.33	26.10	26.10
0	50	28.13	28.13	28.20
1	51	26.92	25.69	25.56
1	52	27.65	27.65	27.37
0	53	25.85	26.38	26.49
0	54	28.03	28.98	28.98
1	55	31.70	29.89	29.77
1	56	36.51	35.38	34.84
1	57	30.37	29.58	29.54
0	58	29.41	29.41	29.48

0	59	28.29	29.42	29.42
1	60	34.42	33.62	33.42
0	61	33.75	34.18	34.18
1	62	33.34	32.62	31.94
1	63	28.63	27.80	27.68
0	64	33.10	31.85	31.85
1	65	33.57	32.08	31.72
0	66	30.11	30.58	30.58
1	67	30.00	29.93	29.20
1	68	37.53	35.93	35.66
0	69	31.74	31.74	31.74
1	70	34.40	34.40	32.86
0	71	34.25	34.25	34.45
0	72	27.19	27.19	27.19

BMI: Body mass index

10.29 Meta data for Chapter 5

Cost-effectiveness for Physical Activity change

Control Group			Intervention Group		
Participant	Effect	Cost	Participant	Effect	Cost
1	12.14	\$22.14	37	26.71	\$272.70
2	9.17	\$22.50	38	45.14	\$270.55
3	5.29	\$19.80	39	48.29	\$292.66
4	43.00	\$18.00	40	35.57	\$292.66
5	40.43	\$26.54	41	44.29	\$274.73
6	18.57	\$18.00	42	43.29	\$284.55
7	30.00	\$19.80	43	31.86	\$269.33
8	28.00	\$23.40	44	29.29	\$293.32
9	19.29	\$19.80	45	36.71	\$267.30
10	16.43	\$22.50	46	26.29	\$276.66
11	44.00	\$20.70	47	18.71	\$284.55
12	29.14	\$23.40	48	49.57	\$272.97
13	35.00	\$18.90	49	28.71	\$276.75
14	22.86	\$18.72	50	18.57	\$263.80
15	27.86	\$18.20	51	26.43	\$275.99
16	27.00	\$25.38	52	32.29	\$285.66
17	18.14	\$23.76	53	31.43	\$271.49
18	16.86	\$23.00	54	26.86	\$278.79
19	18.14	\$23.66	55	41.57	\$270.47
20	19.86	\$16.25	56	37.14	\$284.55
21	28.14	\$23.40	57	63.86	\$279.20
22	31.00	\$20.16	58	51.57	\$285.66
23	29.14	\$25.30	59	58.43	\$260.22
24	24.29	\$18.90	60	58.14	\$292.66
25	27.43	\$21.21	61	34.00	\$284.55
26	22.86	\$19.44	62	43.43	\$285.66
27	8.00	\$16.30	63	33.00	\$278.87
28	9.57	\$19.62	64	40.00	\$284.55
29	24.71	\$23.04	65	41.71	\$260.08
30	29.00	\$21.65	66	48.71	\$271.15
31	24.29	\$20.70	67	66.14	\$285.66
32	17.57	\$22.77	68	45.57	\$284.65
33	27.29	\$24.50	69	62.14	\$292.66
34	11.43	\$27.72	70	47.43	\$278.38
35	35.43	\$23.55	71	54.14	\$288.36
36	11.00	\$20.21	72	53.43	\$254.32

Summary Statistics

	Control Group		Intervention Group	
	Effect	Cost	Effect	Cost
Mean	23.40	\$21.47	41.12	\$279.3
Standard deviation	9.72	\$2.77	12.51	\$10.07
Standard error	0.97	\$0.28	1.25	1.01
Difference				
	Effect	Cost		
Mean	17.72	\$257.83		
Standard error	1.58	\$1.04		
Lower 95% limit	14.62	\$254.99		
Upper 95% limit	20.83	\$259.08		
ICER				
Point estimate	\$14.55			

ICER: Incremental cost-effectiveness ratio

Cost-effectiveness for QALY change

Control Group			Intervention Group		
Participant	Effect	Cost	Participant	Effect	Cost
1	-0.0175	\$22.14	37	0.006	\$272.70
2	0	\$22.50	38	0.01525	\$270.55
3	-0.00563	\$19.80	39	0.0175	\$292.66
4	0	\$18.00	40	-0.00975	\$292.66
5	0	\$26.54	41	0.023125	\$274.73
6	0	\$18.00	42	0.021125	\$284.55
7	0.0001	\$19.80	43	-0.00975	\$269.33
8	-0.00788	\$23.40	44	0.00175	\$293.32
9	0.0001	\$19.80	45	0.02275	\$267.30
10	-0.01525	\$22.50	46	-0.00975	\$276.66
11	0.0001	\$20.70	47	0.00775	\$284.55
12	0	\$23.40	48	0	\$272.97
13	-0.02313	\$18.90	49	0	\$276.75
14	0	\$18.72	50	0.00025	\$263.80
15	0	\$18.20	51	0.0115	\$275.99
16	0	\$25.38	52	0.006	\$285.66
17	-0.01525	\$23.76	53	0.005625	\$271.49
18	0	\$23.00	54	-0.00975	\$278.79
19	-0.00563	\$23.66	55	0.007875	\$270.47
20	-0.00787	\$16.25	56	-0.00975	\$284.55
21	0	\$23.40	57	0.009625	\$279.20
22	-0.00787	\$20.16	58	0.005625	\$285.66
23	-0.00562	\$25.30	59	0.0075	\$260.22
24	0	\$18.90	60	0	\$292.66
25	0	\$21.21	61	0.007875	\$284.55
26	-0.00562	\$19.44	62	0.005625	\$285.66
27	-0.0001	\$16.30	63	0.0075	\$278.87
28	0	\$19.62	64	0.00525	\$284.55
29	0	\$23.04	65	0.007375	\$260.08
30	0	\$21.65	66	0	\$271.15
31	-0.00562	\$20.70	67	0.007	\$285.66
32	0	\$22.77	68	-0.0075	\$284.65
33	-0.00563	\$24.50	69	0	\$292.66
34	-0.00038	\$27.72	70	0.0175	\$278.38
35	-0.00562	\$23.55	71	0.010125	\$288.36
36	-0.005	\$20.21	72	0	\$254.32

Summary Statistics

	Control Group		Intervention Group	
	Effect	Cost	Effect	Cost
Mean	-0.0051	\$21.47	0.0050	\$278.50
Standard deviation	0.0038	\$2.77	0.0091	\$10.07
Standard error	0.0006	\$0.28	0.0009	\$1.01
Difference				
	Effect	Cost		
Mean	0.007	\$257.76		
Standard error	0.0011	\$1.04		
Lower 95% limit	0.0049	\$254.99		
Upper 95% limit	0.0091	\$259.08		
ICER				
Point estimate	\$36,857			

ICER: Incremental cost-effectiveness ratio

10.30 Meta data for Chapter 8

Allocation	Participant	WC Base	WC T2	WC T3	H	BM Base	BM T2	BM T3
1	1	111.6	111.6	110.9	160.1	96.2	94.2	93.8
0	2	111.7	111.8	111.8	154.9	83.4	84.4	85
1	3	89.3	89.3	89.3	161	75.7	74.5	74.8
1	4	82.2	82.2	80.2	165.1	68.5	66.2	66
1	5	112.8	112.8	112.8	162.5	95.7	95	94.2
1	6	86	86	83.1	165.8	80.7	78.2	76.2
1	7	92.6	92.6	92.6	157.4	85.27	84.6	82.5
0	8	84.1	84.1	84.9	180.3	85.2	86	87.3
0	9	86	85.9	86.2	167.6	89.8	90	90
0	10	89.6	90	90	167.6	82.6	84.1	84.5
1	11	93	93	90.1	175.6	79.4	76.2	72.3
0	12	103	102.5	102.5	175.3	82.5	83.5	83.5
1	13	91.4	91.4	90	170.5	85.27	84	84.1
1	14	92	92	91.1	157.4	84.4	84	83.2
0	15	94	94.2	94.2	175.2	80.2	80.5	80.8
0	16	88	88.4	89.5	160	80.2	82	82.1
1	17	111.2	111.2	111.2	177.3	80.7	80.1	80.1
0	18	122.3	122	122.2	167.4	105	104.9	104.9
1	19	102.6	102.6	100.8	180.3	84.8	82.1	81.5
1	20	92.6	92.6	90.2	162.5	78.1	77.3	75.3
1	21	103.3	103.3	101.2	167.4	93.44	93	90.2
1	22	96.6	96.6	96	166.2	83.9	83.2	83
1	23	88	88	87.5	162.6	75.7	75	75
1	24	115.6	115.6	114	163.1	113.3	112.2	111.5
1	25	89.6	89.6	89.1	157.4	68.5	67.2	66.6
0	26	90	90	90	154.9	80.7	80.7	80.7
1	27	111.2	111.2	111.2	162.6	80.7	81	81
1	28	91.4	91.4	90.1	170.2	85.27	83.1	80
1	29	93.6	93.6	90.4	170.1	80.5	78.2	75.2
0	30	92.2	91.9	91.9	165.1	77.1	78.2	80
0	31	92.3	94.5	96	149.8	80.2	81.5	83.5
1	32	84	84	83.4	175.3	78	78.2	78
0	33	106.6	106.5	106.5	177.5	77.5	77.6	77.6
1	34	76.3	76.3	76	165.1	68.9	68	68
0	35	112.1	112.1	113.5	154.9	79.4	80	82.6
1	36	106	106	104.2	155	79.8	79.5	79
1	37	102.2	102.2	99.8	177.5	90.2	88	88
1	38	106	106	106	177.8	79.8	79.8	79.8
0	39	108	107.9	107.6	175.3	93.4	94.5	94.5
0	40	89.3	89.2	90.5	166.6	80.7	82	82.1
0	41	122.3	123	123	175.3	105	104.8	104.8
1	42	112.2	112.2	112	154.9	87.6	85.2	85
1	43	71	71	70.5	162.8	67.1	66.6	66.5
0	44	117	117.1	117.1	157	99.85	100.6	100.8
0	45	103	103.1	105	172	82.5	84	83.9
0	46	89.3	89.3	89.9	187.9	75.7	76	78
0	47	108	108	109.2	167.6	93.4	93.4	95.6
0	48	90.5	93.2	93.2	187.9	94.8	96.2	96.7

0	49	106.1	107	107	190.5	89.7	89.7	91.2
0	50	76.3	78.6	79	162.5	68.9	70.1	70
1	51	112.1	112.1	111.5	149.8	79.4	78.5	79
0	52	84.6	84.7	84.7	165.8	68.5	69.5	70.2
0	53	80	82	82.9	167.6	73.9	80	80.5
1	54	88.1	88.1	84	154.9	80.2	79.2	77.2
1	55	86.6	86.6	86.2	177.8	87.1	86.2	86
0	56	93.6	94.9	94.8	160	80.5	81.5	81.6
0	57	88.1	88.6	88.6	167.6	80.2	82.2	83.6
1	58	115.6	115.6	111.1	157.4	113.3	111.2	108.2
0	59	102	102	104.2	162.6	89.8	90.1	92.5
1	60	107.7	107.7	106.1	177.8	80.8	78.2	76.2
1	61	103.3	103.3	100.9	162.6	87.5	86.3	84.2
1	62	107.7	107.7	103.5	167.6	94.3	91.3	90
1	63	117	117	114.5	166.6	99.85	96.3	96
0	64	124.8	124.6	125	160	113.7	113.7	113.8
1	65	87.1	87.1	87.1	160	73.4	73.1	72
1	66	96.5	96.5	96.5	162.5	80.2	80.3	80.3
1	67	106.7	106.7	103.5	170.4	87.1	84.2	84.2
0	68	94	93.9	94.2	177.8	80.2	83	83.6
0	69	104.8	104.8	104.8	167.6	94.8	95	95.2
0	70	84.4	86	86	166.1	73.1	74.2	74.3
1	71	112.1	112.1	112.1	177.8	100.2	100	100
1	72	93	93	91.5	149.8	79.4	79	78.5
1	73	71	71	70.5	165.1	67.1	66.2	66
0	74	87.1	89.3	90	154.9	73.4	75	76.4
1	75	97.2	97.2	96.2	162.5	77.5	77	76
1	76	105.3	105.3	101.5	159.9	95.7	93.4	92.8
0	77	102.6	102.7	102.7	172.7	89.8	90.1	90.8
1	78	103.3	103.3	103	170.4	87.5	85.2	85
0	79	102	102.1	102	162.6	89.8	90	90.5
0	80	88.2	89	89	167.6	73.1	73.1	73.1
0	81	110	110	110.1	172.5	97.2	99	99.1
0	82	94.5	95	95.5	165.1	80.7	81.6	82.2
0	83	98.3	99	99	160	88.4	89.2	89.8
1	84	103.2	103.2	100	175.6	97.5	96.3	94
0	85	92	92.4	92.4	177.8	84.4	84.6	85
0	86	101.1	101.1	101.1	177.3	88.1	89	89.2
1	87	91.1	91.1	91	162.5	90.2	88.1	88.1
0	88	86	88.2	88.2	165.1	80.7	91.3	91.3
1	89	115.4	115.4	114.9	154.9	81.6	80.1	80
1	90	86.6	86.6	84.4	157.4	87.1	85.1	83.2
1	91	99.6	99.6	98.1	178	85.3	84	84.2
0	92	94.6	96	97.5	162.6	82.5	82.6	84.1
1	93	107.7	107.7	105.8	162.6	80.8	80	77.5
0	94	92.6	96.2	96.2	165.1	78.1	80.1	80.1
0	95	98.6	99	99	162.6	87.5	87.6	87.6
0	96	83.6	85.6	88	170.5	75.7	75.7	77.2
1	97	98.9	98.9	98.9	160.1	85.3	85.3	85.3
1	98	86	86	86	162.5	80.7	79.6	78.5
1	99	100.2	100.2	99.5	167.4	81.6	81	80.2

0	100	81.6	82.2	82.2	167.6	72.6	74.2	74.2
0	101	111.7	112.1	112	166.3	83.4	85.1	87.2
1	102	108.4	108.4	104.5	157.4	78.2	78.1	76.2
0	103	85.5	86	85.5	178	78	78.2	78.2
0	104	108.4	108	107.8	172.7	78.2	78.2	78
0	105	97.2	98.2	99	172.7	77.5	78	78.4
0	106	86	86.4	87.3	166.1	89.8	90	90.5
0	107	106.6	106.5	106.5	162.5	77.5	77.9	79
0	108	115	115.6	115.6	167.6	88.9	89	88.9
1	109	90.5	90.5	90	167.6	94.8	93.5	93.5
0	110	94.6	96	96	170.1	82.5	84.4	84
1	111	111	111	110.5	165.1	103.5	99.2	97.2
1	112	84.1	84.1	83.5	162.6	85.2	85	84.2
1	113	80	80	81.1	167.6	73.9	73.8	74.2
1	114	91.1	91.1	91	190.5	90.2	89	89.2
0	115	110	110.1	110.1	171.2	97.2	98	96
0	116	85.6	85.7	85.7	162.5	75.7	77	76.8
0	117	103.2	103.4	103.9	167.6	97.5	97.4	97.8
0	118	98.9	89.7	89.7	167.6	85.3	85.3	85.3
1	119	88	88	86.2	161	75.7	75.7	74.2
0	120	91.1	92	92	172.7	83.9	84	84.5

WC: Waist Circumference; Height; Weight.

Allocation	Participant	BMI Base	BMI T2	BMI T3	PASE Base	PASE T2	PASE T3
1	1	37.53	36.75	36.59	21	29	31
0	2	34.76	35.18	35.43	22	22	16
1	3	29.20	28.74	28.86	29	29	24
1	4	25.13	24.29	24.21	37	37	37
1	5	36.24	35.98	35.67	22	22	29
1	6	29.36	28.45	27.72	22	40	31
1	7	34.42	34.15	33.30	19	21	37
0	8	26.21	26.45	26.85	28	28	27
0	9	31.97	32.04	32.04	28	29	29
0	10	29.41	29.94	30.08	24	25	18
1	11	25.75	24.71	23.45	25	34	31
0	12	26.85	27.17	27.17	22	22	20
1	13	29.33	28.90	28.93	28	28	34
1	14	34.07	33.91	33.58	22	29	29
0	15	26.13	26.23	26.32	21	20	20
0	16	31.33	32.03	32.07	25	24	24
1	17	25.67	25.48	25.48	21	29	29
0	18	37.47	37.43	37.43	22	22	22
1	19	26.09	25.26	25.07	26	34	31
1	20	29.58	29.27	28.52	22	31	31
1	21	33.34	33.19	32.19	18	18	41
1	22	30.37	30.12	30.05	26	30	34

1	23	28.63	28.37	28.37	26	32	28
1	24	42.59	42.18	41.91	25	25	30
1	25	27.65	27.12	26.88	25	31	40
0	26	33.63	33.63	33.63	32	32	32
1	27	30.52	30.64	30.64	25	25	25
1	28	29.44	28.69	27.62	23	29	29
1	29	27.82	27.03	25.99	24	31	41
0	30	28.29	28.69	29.35	22	22	16
0	31	35.74	36.32	37.21	28	28	19
1	32	25.38	25.45	25.38	29	29	30
0	33	24.60	24.63	24.63	22	21	21
1	34	25.28	24.95	24.95	23	21	18
0	35	33.09	33.34	34.43	27	27	16
1	36	33.22	33.09	32.88	16	20	32
1	37	28.63	27.93	27.93	23	28	30
1	38	25.24	25.24	25.24	24	24	24
0	39	30.39	30.75	30.75	25	25	26
0	40	29.08	29.54	29.58	22	22	22
0	41	34.17	34.10	34.10	26	24	24
1	42	36.51	35.51	35.43	22	32	31
1	43	25.32	25.13	25.09	24	28	28
0	44	40.51	40.81	40.89	26	26	24
0	45	27.89	28.39	28.36	29	26	25
0	46	21.44	21.53	22.09	26	24	16
0	47	33.25	33.25	34.03	29	29	18
0	48	26.85	27.25	27.39	22	22	20
0	49	24.72	24.72	25.13	33	28	20
0	50	26.09	26.55	26.51	24	25	24
1	51	35.38	34.98	35.20	34	34	24
0	52	24.92	25.28	25.54	22	34	30
0	53	26.31	28.48	28.66	24	24	17
1	54	33.43	33.01	32.17	26	30	37
1	55	27.55	27.27	27.20	19	19	18
0	56	31.45	31.84	31.88	29	30	30
0	57	28.55	29.26	29.76	24	24	23
1	58	45.73	44.88	43.67	24	33	30
0	59	33.97	34.08	34.99	26	26	25
1	60	25.56	24.74	24.10	24	31	31
1	61	33.10	32.64	31.85	26	26	35
1	62	33.57	32.50	32.04	24	34	20
1	63	35.97	34.70	34.59	28	30	37
0	64	44.41	44.41	44.45	28	30	28
1	65	28.67	28.55	28.13	28	28	29
1	66	30.37	30.41	30.41	24	24	31
1	67	30.00	29.00	29.00	31	35	31
0	68	25.37	26.26	26.44	25	24	18
0	69	33.75	33.82	33.89	19	19	19
0	70	26.50	26.89	26.93	20	24	20

1	71	31.70	31.63	31.63	19	19	19
1	72	35.38	35.20	34.98	14	18	25
1	73	24.62	24.29	24.21	19	19	24
0	74	30.59	31.26	31.84	26	26	18
1	75	29.35	29.16	28.78	22	28	34
1	76	37.43	36.53	36.30	20	30	36
0	77	30.11	30.21	30.44	23	23	19
1	78	30.13	29.34	29.27	24	31	37
0	79	33.97	34.04	34.23	28	27	23
0	80	26.02	26.02	26.02	28	28	28
0	81	32.67	33.27	33.30	22	23	23
0	82	29.61	29.94	30.16	24	24	20
0	83	34.53	34.84	35.08	21	21	19
1	84	31.62	31.23	30.48	20	20	21
0	85	26.70	26.76	26.89	29	29	25
0	86	28.03	28.31	28.38	19	19	18
1	87	34.16	33.36	33.36	24	30	30
0	88	29.61	33.49	33.49	25	25	25
1	89	34.01	33.38	33.34	32	33	28
1	90	35.16	34.35	33.58	28	41	41
1	91	26.92	26.51	26.57	25	34	30
0	92	31.20	31.24	31.81	22	23	18
1	93	30.56	30.26	29.31	22	22	32
0	94	28.65	29.39	29.39	22	22	22
0	95	33.10	33.13	33.13	18	20	19
0	96	26.04	26.04	26.56	20	20	20
1	97	33.28	33.28	33.28	27	27	27
1	98	30.56	30.14	29.73	32	32	31
1	99	29.12	28.91	28.62	30	30	30
0	100	25.85	26.42	26.42	34	34	34
0	101	30.16	30.77	31.53	24	23	16
1	102	31.56	31.52	30.76	32	32	40
0	103	24.62	24.68	24.68	24	24	24
0	104	26.22	26.22	26.15	32	32	24
0	105	25.98	26.15	26.29	23	20	20
0	106	32.55	32.62	32.80	22	22	16
0	107	29.35	29.50	29.92	19	19	18
0	108	31.65	31.68	31.65	28	27	26
1	109	33.75	33.29	33.29	20	20	31
0	110	28.51	29.17	29.03	25	24	20
1	111	37.97	36.39	35.66	22	40	41
1	112	32.23	32.15	31.85	22	29	20
1	113	26.31	26.27	26.42	21	22	26
1	114	24.86	24.52	24.58	22	23	26
0	115	33.16	33.44	32.75	28	28	28
0	116	28.67	29.16	29.08	23	22	20
0	117	34.71	34.67	34.82	24	25	19
0	118	30.37	30.37	30.37	26	26	26

1	119	29.20	29.20	28.63	27	28	34
0	120	28.13	28.16	28.33	25	25	21

BMI: Body mass index. PASE: Physical Activity self-efficacy

Allocation	Participant	HrQoL			MVPA		
		Base	HrQoL T2	HrQoL T3	Base	MVPA T2	MVPA T3
1	1	0.657	0.667	0.599	17.1	37.6	17.7
0	2	0.565	0.571	0.6	9.6	20	5.3
1	3	0.565	0.564	0.564	12.7	9.4	4.3
1	4	0.6	0.602	0.664	18.7	22.6	26.1
1	5	0.598	0.599	0.599	14.4	14.1	20.6
1	6	0.538	0.601	0.609	27.4	53.3	51.4
1	7	0.564	0.569	0.609	10.3	18	13
0	8	0.675	0.67	0.58	15.6	12	2.4
0	9	0.657	0.644	0.612	28.4	6.9	16.2
0	10	0.601	0.598	0.584	13	8.7	2.7
1	11	0.601	0.615	0.722	9.9	38.9	43
0	12	0.658	0.65	0.601	12.4	15.6	13.7
1	13	0.701	0.712	0.712	10.4	19.3	23.3
1	14	0.583	0.599	0.632	9.7	20.9	20.7
0	15	0.57	0.568	0.657	13.4	8	1.7
0	16	0.615	0.615	0.588	15.7	7.1	13
1	17	0.538	0.545	0.545	9	21.3	21.3
0	18	0.535	0.53	0.53	10.7	7.6	4.4
1	19	0.644	0.654	0.664	11	33.4	26
1	20	0.657	0.674	0.649	12.6	33	31.3
1	21	0.6	0.602	0.544	10.6	13.7	26.3
1	22	0.643	0.664	0.664	9.6	19.2	15.4
1	23	0.72	0.728	0.734	14	22.7	14.6
1	24	0.675	0.68	0.68	18.6	20.1	25.9
1	25	0.615	0.632	0.632	16.6	24.9	24
0	26	0.58	0.58	0.58	11	11	11
1	27	0.658	0.664	0.664	11.3	15.1	15.1
1	28	0.615	0.63	0.799	10.7	31.9	27.5
1	29	0.646	0.649	0.579	32.9	26.4	36.1
0	30	0.535	0.534	0.526	10.3	10.3	4
0	31	0.72	0.721	0.544	8.4	14.6	5.9
1	32	0.723	0.726	0.726	10.3	10.3	11
0	33	0.6	0.584	0.584	15	7.1	7.1
1	34	0.657	0.664	0.664	19	8.4	7
0	35	0.538	0.541	0.541	14	22.7	2.7
1	36	0.536	0.555	0.555	11.1	20.6	28.7
1	37	0.599	0.613	0.579	26.4	32.7	35.5
1	38	0.737	0.737	0.737	9.7	9.7	9.7
0	39	0.615	0.622	0.628	12.3	15.1	20
0	40	0.58	0.571	0.734	20.5	4.7	20
0	41	0.723	0.714	0.714	10.7	9.3	9.3
1	42	0.538	0.551	0.734	11.9	31.3	16.7
1	43	0.625	0.645	0.664	17.6	28.4	16.7
0	44	0.8	0.789	0.7	11.3	5.9	3.9

0	45	0.758	0.732	0.725	14.3	5.7	25
0	46	0.643	0.643	0.588	10.6	17.7	1.7
0	47	0.583	0.585	0.555	12.9	20	1.7
0	48	0.618	0.601	0.613	9.9	6.1	14.6
0	49	0.737	0.73	0.598	13.3	8	3.9
0	50	0.646	0.652	0.658	11.9	23.9	26.9
1	51	0.72	0.722	0.722	11.9	11.1	11.7
0	52	0.657	0.644	0.565	19.9	14.4	17.7
0	53	0.598	0.598	0.583	9.1	25	6
1	54	0.57	0.574	0.544	11.9	21.3	28.3
1	55	0.538	0.544	0.544	13.4	13.4	11.1
0	56	0.573	0.561	0.675	13.6	10.3	15.7
0	57	0.612	0.61	0.573	10.3	6.9	3.6
1	58	0.658	0.66	0.722	15.6	37.4	33.1
0	59	0.618	0.602	0.582	23.9	7	2.6
1	60	0.583	0.594	0.574	18.7	28.6	37.9
1	61	0.643	0.668	0.668	18.3	24	35.1
1	62	0.661	0.671	0.655	12.3	36.4	38.4
1	63	0.583	0.583	0.799	11.1	30.7	17.6
0	64	0.58	0.58	0.58	17.4	6.4	12.7
1	65	0.738	0.739	0.739	13	11	18.3
1	66	0.583	0.584	0.722	14.7	11.9	18.1
1	67	0.616	0.625	0.668	14	26	18.4
0	68	0.538	0.526	0.57	13.3	10.3	8.7
0	69	0.544	0.534	0.561	15.1	11.4	17.7
0	70	0.735	0.741	0.657	12.6	16.7	8
1	71	0.583	0.586	0.586	17.6	17	17
1	72	0.604	0.618	0.618	11.1	18.6	21.7
1	73	0.642	0.666	0.666	20	10.7	13.3
0	74	0.643	0.646	0.723	8.4	12.7	14.3
1	75	0.646	0.655	0.655	11.3	20.6	28
1	76	0.616	0.641	0.645	14.2	39.6	41.3
0	77	0.57	0.566	0.643	22	10.7	3.1
1	78	0.611	0.632	0.645	13.9	33	13.1
0	79	0.688	0.689	0.535	12.7	18.4	14.6
0	80	0.657	0.657	0.657	10.1	10.1	10.1
0	81	0.588	0.564	0.546	11.7	14.1	3.6
0	82	0.601	0.584	0.598	28.7	19.9	10.9
0	83	0.646	0.64	0.526	20.4	15.4	12.1
1	84	0.601	0.609	0.609	12.3	13.1	19.6
0	85	0.734	0.73	0.615	13	9.7	4.9
0	86	0.613	0.61	0.721	12.1	21.6	10.6
1	87	0.643	0.664	0.655	12.9	33.3	12.3
0	88	0.735	0.701	0.701	21.9	7.7	7.7
1	89	0.57	0.579	0.579	10.7	18.4	14.9
1	90	0.644	0.664	0.598	13.4	31.9	37.6
1	91	0.797	0.799	0.799	10.9	27.2	14.3
0	92	0.655	0.655	0.598	15	7.3	3.7
1	93	0.737	0.734	0.734	26.1	16.6	33.6
0	94	0.628	0.63	0.63	20.3	17.4	17.4
0	95	0.598	0.59	0.652	14	5.9	18.4

0	96	0.657	0.658	0.576	10.1	13.1	3.3
1	97	0.661	0.661	0.661	19.7	19.7	19.7
1	98	0.643	0.649	0.599	17.3	20.7	10.1
1	99	0.661	0.669	0.649	28.6	24.7	22.3
0	100	0.615	0.61	0.61	19.1	19.9	19.9
0	101	0.616	0.611	0.546	9.4	7.1	2.4
1	102	0.583	0.589	0.589	8.4	10.7	26.4
0	103	0.615	0.611	0.688	11.7	19.1	20.1
0	104	0.797	0.785	0.658	21.9	24.9	12.7
0	105	0.661	0.66	0.643	15.6	7.4	12.1
0	106	0.57	0.561	0.737	23.7	16.7	3.4
0	107	0.559	0.55	0.535	12	6.4	4.3
0	108	0.658	0.64	0.584	13.6	10	16.5
1	109	0.616	0.615	0.645	17.6	17	22.9
0	110	0.8	0.784	0.615	16.4	11.6	8.6
1	111	0.723	0.723	0.632	9.1	54.4	23.7
1	112	0.598	0.598	0.668	10.6	20	16
1	113	0.628	0.628	0.628	15.4	9.6	9.6
1	114	0.738	0.736	0.736	17.9	9.7	9.1
0	115	0.583	0.586	0.588	11.9	14.6	18
0	116	0.657	0.658	0.64	9.6	18.6	20.1
0	117	0.583	0.588	0.588	14.1	18.9	9.6
0	118	0.735	0.735	0.735	11.1	11.1	11.1
1	119	0.8	0.806	0.806	17.7	20.9	42.3
0	120	0.535	0.541	0.544	11.4	23.3	15.1

HrQoL: Health-related quality of life; MVPA: Moderate to vigorous physical activity

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