INFORMING THE DEVELOPMENT OF INTERVENTIONS AIMING TO INCREASE PARTICIPATION IN MAIL-OUT BOWEL CANCER SCREENING PROGRAMMES

A Thesis submitted by

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For the award of

Doctor of Philosophy

2021

ABSTRACT

Background: Bowel cancer is the second leading cause of cancer-related death worldwide. Population mail-out faecal occult blood test (FOBT) screening, such as the Australian National Bowel Cancer Screening Program (NBCSP), is an effective way to increase the rates of early detection and thereby reduce bowel cancer mortality and the overall health burden associated with this disease. However, screening in these programmes is low and interventions aiming to increase participation rates have only had small to moderate effects. This thesis aimed to investigate ways in which interventions aiming to increase participation in mail-out FOBT screening programmes can be improved upon and better designed. Three studies using multiple research methods were conducted to achieve this aim.

Study one: The first study was a systematic review and meta-analysis. The review aimed to identify all interventions that promoted participation in mail-out bowel cancer screening programmes and explored if intervention effectiveness can be increased through targeting certain intervention types at specific subpopulations or by combining intervention types together. The review found 32 studies that met the inclusion criteria, these contained 30 trials that reported intervention effects within subpopulations and 17 trials that combined interventions. It was found that interventions rarely affect subpopulations differently, suggesting a targeting approach may not be effective, but combining interventions together generally led to larger increases in participation rates.

Study two*:* While findings suggest that a multifaceted intervention design approach should be taken, through reviewing the literature in study one it became evident that when designing multifaceted interventions, psychological and behaviour change theory was rarely considered, and it was unclear what the active components or underlying mechanisms responsible for the effectiveness of the interventions were. Therefore, study two implemented realist review methodologies to (a) use the behaviour change techniques (BCT) taxonomy v1 to identify the active components within each intervention, (b) use the accompanying theory and techniques tool to link each BCT with a theorised mechanism of action responsible for the behaviour change, and (c) apply a behaviour change model, the Health Action Process Approach (HAPA), to inform how BCTs can be combined to increase FOBT screening participation. Sixty-eight intervention trials were identified and analysed. Within these, 16 BCTs and 10 mechanisms of action were identified that successfully

increased participation rates. Further, interventions that targeted both the motivational and volitional stage of the HAPA model were the most likely to be successful at increasing FOBT participation.

***Study three**:* There has been limited research applying psychological theory to explain variation in FOBT screening participation or that explores invitee's preferences for different intervention strategies. Study three involved the development and implementation of two scales designed for these purposes. First, the process approach to mail-out screening (PAMS) scale was developed to measure the constructs and process proposed by the HAPA model to explain the variation in FOBT screening behaviour. The user-ratings of mail-out screening interventions (UR-MSI) scale consisted of a series of example interventions based on the BCT taxonomy v1 to assess which intervention strategies were preferred by NBCSP invitees. The results of study three found that the HAPA model could explain half of the variation in FOBT screening participation and therefore should be used as a theoretical framework to base intervention design. The UR-MSI showed which intervention strategies had the highest endorsement rating within each factor of the HAPA model. This information can be used to create theory-based intervention strategies that are endorsed by the end-user.

Conclusion: The collective findings from this thesis provide a framework from which a multifaceted intervention can be constructed that makes the best use of the available evidence and psychological theory. Future interventions should take a multifaceted approach whereby several behaviour change strategies are implemented that target all motivational and volitional components of behaviour change specified in the HAPA model and BCTs should be selected that have high end-user endorsement to maximise participant engagement. In terms of increasing participation in the Australian NBCSP, motivational messaging in the initial invitation needs to be enhanced. The inclusion of general practitioners (GPs) in the invitation process, through GP endorsement letters, should be implemented. Further actions need to be taken to prevent invitees with high screening intentions from procrastinating and forgetting to participate.

Keywords: Mail-out bowel cancer screening, interventions, HAPA, BCTs

CERTIFICATION OF THESIS

This Thesis is the work of Larry Stewart Myers except where otherwise acknowledged, with the majority of the authorship of the papers presented as a Thesis by Publication undertaken by the Student. The work is original and has not previously been submitted for any other award, except where acknowledged.

Principal Supervisor: Professor Sonja March
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Student and supervisors' signatures of endorsement are held at the University.

STATEMENT OF CONTRIBUTION

The following detail is the agreed share of contribution for candidate and co-authors in the presented publications in this thesis. All journal H-index scores and quartile ranking were sourced from Scimago Journal and Country Rank:

Article 1

Myers, L., Goodwin, B., March, S., & Dunn, J. (2019). Ways to use interventions to increase participation in mail-out bowel cancer screening: a systematic review and meta-analysis. Transl Behav Med. doi:10.1093/tbm/ibz081 (Q2: Applied psychology, H = 33)

- The overall contribution of Larry Myers was 80% to the concept development, analysis, article screening, data extraction, risk of bias assessments, drafting and revising of the final submission; Sonja March, Belinda Goodwin, and Jeff Dunn contributed the other 20% to concept development, analysis, editing and providing important technical inputs. Belinda Goodwin also contributed to the risk of bias assessment and developed the search protocol.

Article 2

Myers, L., Goodwin, B., Ralph, N., Castro, O., & March, S. (2020). Implementation Strategies for Interventions Aiming to Increase Participation in Mail-Out Bowel Cancer Screening Programmes: A Realist Review. Frontiers in oncology, 10, 1799. doi: 10.3389/fonc.2020.543732 (Q1: Oncology, H = 71)

- The overall contribution of Larry Myers was 80% to the concept development, analysis, drafting and revising of the final submission; Sonja March, Belinda Goodwin, Oscar Castro, and Nicholas Ralph contributed the other 20% to concept development, analysis, editing and providing important technical inputs.

Article 3

Myers, L., Goodwin, B., Ralph, & March, S. A Health Action Process Approach for Developing Invitee Endorsed Interventions to Increase Mail-Out Bowel Cancer Screening. (article under review at Annals of Behavioral Medicine)

- The overall contribution of Larry Myers was 80% to the concept development, analysis, drafting and revising of the final submission; Sonja March, Belinda Goodwin, and Nicholas Ralph contributed the other 20% to concept development, analysis, editing and providing important technical inputs.

LIST OF CONFERENCE PRESENTATIONS

Myers, L., Goodwin, B., March, S., & Dunn, L. Optimising evidence-based strategies to increase participation in mail-out bowel cancer screening programs: a systematic review and meta-analysis. [conference presentation] Australasian Society of Behavioural Medicine (2019).

ACKNOWLEDGEMENTS

First and foremost, I would like to thank my wife, Emma, for her love and unwavering support over the last seven and a half years. This journey through university was far longer than originally planned and you have been nothing but supportive, so thank you for your patience as we put so much of our life on hold.

I would also like to acknowledge how fortunate I am to have had such an incredible supervisory team. Professor Sonja March, in addition to the invaluable guidance you have given me throughout this process, you are, and will continue to be, a great source of inspiration. The thousands of families you have helped and the extensive teams and networks you have built has shown me what I should be aiming for as I begin to make my own research program. Dr. Belinda Goodwin, thank you for the tireless work you have put into this thesis; thank you for the countless hours you must have spent translating my initial rambling thoughts into coherent arguments and persuasive prose, I could not have done this without you. But of course, this is merely the start of our work together and I look forward to seeing what the future will bring. Associate Professor Nicholas Ralph, thank you for all the support you have given over the years, and thank you for introducing me to the HAPA model it really did shape this thesis.

To the late great Professor Gerry Tehan, without question, you will be one of the greatest influences I will ever have as a researcher. At any time, of which there many, that I am confused and do not know what to do, one of the first thoughts that help me through it is always, what would Gerry do. You will be missed.

And finally, I am grateful to be able to say that this research was supported by an Australian Commonwealth Government Research Training Scheme scholarship.

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ABBREVIATIONS

AIHW	Australian Institute of Health and Welfare
BCT	Behaviour Change Technique
CFA	Confirmatory Factor Analysis
CFI	Comparative Fit Index
CI	Confidence Interval
CRC	Colorectal Cancer
CVI	Content Validity Index
FIT	Faecal Immunochemical Test
FOBT	Faecal Occult Blood Test
gFOBT	Guaiac Faecal Occult Blood Test
GP	General Practitioner
HAPA	Health Action Process Approach
iFOBT	Immunochemical Faecal Occult Blood Test
NBCSP	National Bowel Cancer Screening Program
NHS	National Health Service
PAMS	Process Approach to Mail-Out Screening
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PROSPERO	Prospective Register of Systematic Reviews
RAMESES	Realist and Meta-Narrative Evidence Synthesis: Evolving Standards
RCT	Randomised Controlled Trial
RMSEA	Root Mean Squared Error of Approximation
ROB 2	Risk of Bias 2
ROBINS-I	Risk Of Bias in Non-Randomized Studies - of Interventions
RR	Risk Ratio
SE	Standard Error
SEM	Structural Equation Modelling
SES	Socioeconomic Status
SLR	Systematic Literature Review
TLI	Tucker Lewis Index
TTM	Transtheoretical Model
UK	United Kingdom
UR-MSI	User Ratings of Mail-Out Screening Interventions

USA	United States of America
USQ	University of Southern Queensland

CHAPTER 1: INTRODUCTION

1.1. Impact of Bowel Cancer

Colorectal cancer (CRC), commonly (and herein) referred to as bowel cancer, is the second leading cause of cancer-related death and accounts for one in ten cancer cases worldwide (Bray et al., 2018). There are an estimated 1.8 million new bowel cancer cases and 881,000 bowel cancer-related deaths per year (Rawla et al., 2019). In addition to the mortality risk, those diagnosed with bowel cancer suffer from lower health-related quality of life linked to increased levels of pain and discomfort, reduced control of bowel movements, and greater difficulties with their body image and sex drive (Downing et al., 2015; Wood et al., 2015). These reductions in quality of life often lead to emotional difficulties (e.g., depression) for both those with bowel cancer and their caregivers (Kim et al., 2015). There is also considerable financial strain associated with a bowel cancer diagnosis for the individual. Often patients with bowel cancer lose income from an inability to work and report difficulties meeting household financial needs as a result of their bowel cancer diagnosis (McGrath et al., 2017; Sharp et al., 2018).

In terms of the broader community, bowel cancer is among the most costly of all cancers to treat, with a single advanced case costing over $100,000 in Australia (John & Grogan, 2016). The high incidence rate of bowel cancer along with the high cost of treatment places considerable strain on health care systems. For example, over the 2015 to 2016 period, the Australian government reported $876 million in bowel cancer-related expenditure; this being up from $427 million over the 2008 and 2009 period (Australian Institute of Health and Welfare; AIHW, 2013, 2021). Given these high mortality rates, adverse effects on quality of life, and the financial costs to both the individual and society, it is imperative that actions are taken to reduce the overall burden of bowel cancer.

1.2. Development and Trajectory of Bowel Cancer

The slow and unique disease trajectory of bowel cancer is a key factor in the current efforts to prevent the progression of the disease and associated deaths. Bowel cancer typically develops through multiple stages beginning in the inner lining of the large intestine. Epithelial cells, which form part of the inner lining, replicate as part of the intestine's normal functioning. However, this replication process can, at times, lead to a mutation resulting in a benign polyp, which are abnormal tissue growths. These polyps can then mutate into adenomas, which can then develop into malignant

bowel cancer (AIHW, 2020). Importantly, this trajectory from pre-clinical adenomas to malignancy can take up to 10 years (Singh et al., 2006). The progression of bowel cancer is classified into four stages based on the Tumour, Nodes, and Metastasis Classification of Malignant Tumours system (Sobin et al., 2011). When the cancerous cells remain in the same location where they developed, this is classified as a stage one disease. If the cancer significantly increases in size in this location, it is then classified as a stage two disease. If the cancer spreads to the local lymph nodes it is classified as a stage three disease. Finally, if the cancer spreads to other parts of the body it is classified as a stage four disease (AIHW, 2020). Metastatic disease, attributable to stage three and four bowel cancer, is the leading cause of death for those diagnosed with bowel cancer (Luo et al., 2017).

Crucially, the survival rate of patients diagnosed with bowel cancer greatly depends on which stage the cancer is diagnosed, and how early the onset of treatment can begin. For those who are diagnosed with stage one bowel cancer, the five-year relative survival rate is as high as 99%. However, if diagnosed with stage four bowel cancer, the relative survival rate is only 13% (AIHW, 2020). Thus, diagnosing bowel cancer at the earliest stage is vital for improving prognosis and reducing bowel cancer mortality rates.

Currently, most people who are diagnosed with bowel cancer have advanced disease upon diagnosis and subsequently have a late onset of treatment (Moreno et al., 2016). A key factor delaying the diagnosis of bowel cancer for most patients is that noticeable symptoms of the disease (e.g., bowel obstruction, bleeding, or anaemia) tend to only emerge once the cancer has developed into its later stages (AIHW, 2020). While the cancer is still in its early stages, patients remain largely asymptomatic (Bond, 2000; Moreno et al., 2016). Meaning, people with bowel cancer who seek medical attention upon the onset of symptoms tend to already have late-stage bowel cancer (i.e., stage three or four) and their treatment options become restricted and less effective. For these reasons it is vital that the adult population undergo regular, pre-symptomatic screening for bowel cancer to increase early detection and decrease bowel cancer mortalities rates (Moreno et al., 2016).

1.3. The Australian National Bowel Cancer Screening Program

Regular screening for bowel cancer is considered important from the age of 50 and needed until the age of 75 due to the increased chance of developing bowel cancer during this period (National Health and Medical Research Council, 2017). Colonoscopies are considered to be the gold standard in terms of detecting and diagnosing bowel cancer (Issa & Noureddine, 2017). Using an endoscopic camera to inspect the inner lining of the large intestine, colonoscopies visually detect signs of cancerous cells or precancerous adenomas (Van Gossum et al., 2009). While highly effective, health care systems do not have the capacity to offer colonoscopies to all members of the community in need of bowel cancer screening (NBCSP, 2017; Wolf et al., 2018). Further, colonoscopies are an invasive procedure that, while generally safe, do carry some risks such as bleeding, perforation of the bowel, and infection (Ginsberg, 2008; Schreuders et al., 2016). A less invasive bowel cancer screening alternative is to distribute faecal occult blood tests (FOBT) to those at higher risk of developing bowel cancer. FOBTs are used to collect small stool samples in order to detect microscopic traces of blood that may be an indicator of precancerous adenomas or bowel cancer (Allison, Fraser, Halloran, & Young, 2014). A systematic review and meta-analysis of the diagnostic performance of FOBTs estimated that FOBTs detect 79% of bowel cancer cases (Lee et al., 2014). Meaning FOBTs are less sensitive at detecting bowel cancer than colonoscopies, which tend to detect 92 – 99% of bowel cancer cases (Zauber et al., 2008). Despite their lower sensitivity, FOBTs are less expensive, are non-invasive, and more accessible to community members than colonoscopies (AIHW, 2020; Hol et al., 2010; Quintero et al., 2012). For these reasons, over 40 countries utilise FOBTs as part of their national bowel cancer screening programmes including, Austria, England, Finland, Germany, and Japan (Schreuders et al., 2015).

The Australian National Bowel Cancer Screening Program (NBCSP) distributes FOBTs to all members of the population aged between 50 – 74 years for bowel cancer screening (AIHW, 2020; Siegel et al., 2017). There are two stages of screening in the NBCSP. In the first stage, FOBT kits are mailed directly to members of the target population once every two years. This is done automatically without the need for the individual to request an FOBT kit. In the second stage, any person with a positive FOBT result is offered a colonoscopy for a comprehensive diagnosis (NBCSP, 2017).

The FOBT distributed in the NBCSP requires that participants collect small stool samples from two separate bowel motions. The sample is collected with a small plastic spatula and placed into a sealed test tube, stored in the fridge to prevent overheating, and mailed to the processing lab by the recipient once both samples have been collected. These tests can be completed at the participant's home, unsupervised, at a time that is convenient for the recipient, and at no out-of-pocket costs to the individual. If the test is positive for occult (i.e., hidden) traces of blood, the person is notified and advised to see their general practitioner (GP) who can refer them to have a colonoscopy (AIHW, 2020).

This two-stage process is highly effective as people who are diagnosed through the Australian NBCSP have a 171% higher chance of being diagnosed at an earlier stage and a 59% lower chance of dying from bowel cancer (AIHW, 2018a, 2018b). It has also been projected that the NBCSP will prevent 92,200 cases of bowel cancer, 59,000 bowel cancer-related mortalities, and reduce the bowel cancer control expenditure by $1.7 billion by the year 2040 (Lew et al., 2017). However, there is a large potential for these outcomes of the NBCSP to be greatly enhanced by increasing the low participation rate. In total, the NBCSP delivers over 3.2 million testing kits every year to eligible adults (AIHW, 2020). Currently, participation in the program is 42% (AIHW, 2020). For comparison, the two other Australian national cancer screening programs, BreastScreen Australia and the National Cervical Screening Program, have much higher participation rates than the NBCSP, with participation rates of 55% each (AIHW, 2019a). This problem of low participation in bowel cancer screening is not isolated to Australia. Other countries that have similar mail-out FOBT screening programmes also have low participation rates. Countries such as France, Czech Republic, Germany, Latvia, and Croatia all have participation rates lower than 50% in their national bowel cancer screening programs (Navarro et al., 2017; Swan et al., 2012).

1.4. Benefits of Increasing Participation Rates

Increasing NBCSP participation rates can greatly reduce the burden associated with the bowel cancer. If the NBCSP participation rate were to be increased by 20%, in absolute terms, it has been estimated an additional 37,300 cases and 24,800 deaths would be prevented over the 2015-40 timeframe (Lew et al., 2017). Financial projections also show that an increase in participation of that magnitude will result in lowering the cost of national bowel cancer expenditure by a

further $2.1 billion over the same period (Lew et al., 2017). From these projections, it is clear that there are potential benefits to be gained from implementing strategies to increase participation in the Australian NBCSP. In order to do so, the barriers associated with NBCSP non-participation need to be understood and appropriate interventions to address these barriers need to be implemented (Worthington et al., 2020b).

1.5. Barriers Associated with Non-Participation

1.5.1. Sociodemographic Barriers

Within the Australian NBCSP, and in other similar national screening programmes, certain sociodemographic groups show lower participation rates than others. Studies consistently show lower participation among males (Duncan et al., 2014; Frederiksen et al., 2010; Mansouri et al., 2013), younger invitees (AIHW, 2020; Steele et al., 2010), people of indigenous status (Christou et al., 2010; Sandiford et al., 2018), people of lower socioeconomic status (Javanparast et al., 2010; Miles et al., 2011), and people with lower levels of education (Frederiksen et al., 2010). Remoteness is also an influencing factor, with the highest rates of participation found in inner regional areas with a steady decrease in participation with increasing remoteness (AIHW, 2020; Sun et al., 2018). These differences suggest some subpopulations may have specific systemic (e.g., specific cultural barriers) that prevent them from participating in FOBT screening. Meaning, in addition to increasing the general participation rate of mail-out FOBT screening programmes, additional and specific interventions may be needed to increase participation within these subpopulations that show lower levels of participation.

1.5.2. Individual Level Barriers

In addition to these sociodemographic factors, several individual-level barriers to bowel cancer screening and the use of FOBT kits specifically have been identified. These barriers relate to a broad range of factors associated with FOBT screening, including low motivation to participate, negative emotional and physical reactions to the FOBT screening process, and broader health attitudes held by the recipient of the FOBT kit (Goodwin et al., 2019b; Hall et al., 2015; Javanparast et al., 2012).

Commonly reported barriers to participation relate to an insufficient motivation to engage with the FOBT screening process. Many invitees believe that FOBT screening is unnecessary and cite their lack of symptoms as a reason for not

needing to participate (Goodwin et al., 2019b; Hall et al., 2015; Todorov et al., 2018; Woudstra et al., 2016). This reasoning is particularly concerning as bowel cancer screening needs to occur before the onset of symptoms for the full benefit to be achieved. Invitees also often erroneously doubt that the test can provide valid results and, for some, the fact that the test is sent through the mail enhances these doubts (Goodwin et al., 2019b; Hall et al., 2015; Javanparast et al., 2012). These validity concerns regarding the FOBT screening process may lead to a lower motivation to participate in the NBCSP and are more prevalent in low-income areas that generally show lower participation rates (James et al., 2008). This indicates that behaviour change strategies may be needed to correct these misconceptions regarding bowel cancer screening and motivate people to participate.

Negative emotions towards the screening process itself are related to lower participation. For instance, people often report uncomfortable feelings regarding their age when receiving the kit—as they believe bowel cancer screening is only for "older" people—and this, in turn, reduces the willingness to engage with the program (Goodwin et al., 2019b; Hall et al., 2015). The fear of receiving a positive result and the disruption to their life that a bowel cancer diagnosis will bring can also act as a deterrent; with some evidence suggesting that this effect is larger in culturally and linguistically diverse groups (Dharni et al., 2017; Javanparast et al., 2012; Palmer et al., 2014). Disgust in the process of collecting the stool sample often deters people from participating in FOBT screening with the anxiety of being in contact with germs and faecal manipulation being the predominant drivers of this disgust (Hall et al., 2015; Palmer et al., 2014). Those with lower levels of education show greater concerns regarding germs from the sampling procedure and lack the confidence to keep track of the multiple samples that need to be taken (James et al., 2008). While reports of disgust in the testing procedure are common, many of the people that do not participate in mail-out FOBT programmes state that the disgust is only a minor concern for them (Hall et al., 2015; Woudstra et al., 2016). Rather, some non-participants suggest that collecting multiple samples and storing them hygienically is more problematic than the actual contact with faeces while sampling (Hall et al., 2015). This evidence highlights the need for interventions that help people overcome, these complex and varying negative responses to mail-out FOBT screening.

General attitudes towards health can also inhibit people from participating in FOBT screening. For example, attitudes that tend to minimise one's proactive health

behaviours such as stoicism, fatalism, and lack of consideration of future consequences have also been associated with lower screening rates (Goodwin et al., 2018b; Javanparast et al., 2012; Ward et al., 2015b). These factors were more likely to be influential for certain demographic groups. For instance, stoicism and consideration of future consequences were shown to have an effect in rural and peri-urban areas (Goodwin et al., 2018b) and fatalistic attitudes towards cancer having a negative effect in culturally and linguistically diverse groups (Javanparast et al., 2012). Some invitees also have a general mistrust towards large health care systems and as a consequence do not participate in the NBCSP (Ward et al., 2015a). Differences in attitudes towards health that negatively impact FOBT screening participation may account for some of the variation reported in participation rates across sociodemographic groups. They also suggest different behaviour change interventions may be needed to address these varying attitudes towards health and cancer prevention.

Finally, many screening program invitees report having high intentions to participate in bowel cancer screening but still fail to complete and return their FOBT kits. These invitees often report procrastination, an overload of other responsibilities, or forgetfulness as their reason for not returning their FOBT kit (Dharni et al., 2017; Goodwin et al., 2019b; Hall et al., 2015; Palmer et al., 2014). This suggests that in addition to interventions aiming to reduce negative emotions and change health attitudes, some invitees may benefit from assistance in planning completion of the kit or reminders to help translate their intentions into actual participation.

1.6. Intervention Targets Based on Barriers

While research on barriers to FOBT screening participation is still ongoing, it is apparent that the factors associated with lower participation are complex and multifaceted. However, the barriers identified thus far can, and should, be the basis of designing interventions intended to enhance participation with screening programmes. For example, for an intervention to be successful at increasing participation rates, it will need to sufficiently motivate people to participate, enable invitees to overcome their negative emotions regarding FOBT screening, and change health attitudes towards the behaviour. Further, additional strategies will need to be implemented to prevent invitees from procrastinating and forgetting to complete and return their FOBT kit.

1.7. Interventions

Many intervention strategies have been trialled to overcome barriers to FOBT screening in an attempt to increase participation. These interventions have been trialled within national screening programmes and localised screening programmes within health networks. These have mainly comprised of high quality randomised controlled trials (RCTs) which are of a low risk of bias (Goodwin et al., 2019a). While the many interventions that have been trialled to date vary in content and delivery, they can be categorised into several intervention types based on common features (e.g., behaviour priming and digital reminders). Research suggests that there are five different intervention types that can consistently increase participation rates in mail-out FOBT screening programmes. These include issuing a different type of FOBT kit, sending advance notification letters, having personal GPs endorse the kit use, and contacting invitees via the telephone (Goodwin et al., 2019a). Recently in Australia, mass media campaigns have also demonstrated effectiveness in increasing participation (Durkin et al., 2019). However, the overall effects observed from these interventions tend to be small to moderate and show large amounts of variation in how similar interventions are implemented.

1.7.1. *FOBT Kit Type*

There are two major types of FOBT kits; guaiac-based tests known as gFOBT and immunochemical-based tests known as faecal immunochemical tests (FIT or less commonly iFOBT). Both detect occult traces of blood in stool samples but use different methodologies to do so (Zhu et al., 2010). From the FOBT invitee's standpoint, the use of FIT kits have two main advantages over gFOBT kits. First, FITs do not require any dietary or medication restrictions (such as refraining from red meat and vitamin C) in the days prior to taking the stool sample which the gFOBT kits do require (Zhu et al., 2010). Second, FITs require fewer samples to be collected (generally three samples for gFOBT and two samples for FIT) while remaining superior in their ability to detect bowel cancer or precursors of bowel cancer (Zhu et al., 2010). In studies that have compared the use of these two kits in mail-out screening programmes, participation rates are consistently higher for invitees offered a FIT kit when compared to those offered gFOBT kits; both in studies tracking participation rates in national programmes that have switched from gFOBT to FIT and in RCTs that directly compare the participation rates of using gFOBT kits and FIT kits (Clark et al., 2020; Moss et al., 2016; Zhu et al., 2010).

1.7.2. *Advance Notification Letters*

One simple and cost-effective method used to increase participation rates in mail-out FOBT screening programmes is to issue advance notification letters to invitees. This involves providing invitees with a notification that an FOBT kit will arrive in the mail in approximately 2-weeks' time. The use of advance notification letters has repeatedly shown to significantly increase participation rates in mail-out FOBT screening programmes (Cole et al., 2007; Libby et al., 2011; Senore et al., 2015; Van Roon et al., 2011). As most of the infrastructure is already in place to deliver advance notification letters in mail-out FOBT screening programmes, the cost-effectiveness of such an intervention is estimated to be as low as $3,976 per life-year-gained (Cronin et al., 2013).

1.7.3. *GP Endorsement*

GPs play a critical role in patient care for those diagnosed with bowel cancer or those who receive a positive FOBT result (Ferrat et al., 2013). However, typically GPs are not involved in the distribution of kits or the invitation to take part in bowel cancer screening programs. Instead, kits are sent directly to the invitee's home without solicitation from the invitee or invitee's GP. Research has shown that even small involvement of the invitee's personal GP in the invitation process can lead to greater FOBT uptake. In the past effective GP endorsement interventions involved statements from the invitee's personal GP, or GP practice, endorsing the use of the FOBT kit with the bowel cancer screening invitation materials (Benton et al., 2017; Cole et al., 2002; Hewitson et al., 2011; Wardle et al., 2016). For example, Hewitson et al. (2011) showed that sending an FOBT invitation letter endorsed by the invitee's personal GP—outlining the importance of bowel cancer screening and recommending the invitee participate in the screening program—resulted in a 6% increase in participation. Findings such as these support the notion that patient GP relationships can be leveraged to support population bowel cancer screening (Goodwin et al., 2019c).

1.7.4. *Mass Media Campaigns*

Mass media campaigns have been shown to change a variety of health behaviours such as reducing tobacco use, improving road safety, and increasing the number of blood donations (Wakefield et al., 2010). The research evaluating the impact of media campaigns on FOBT screening participation is relatively sparse but has shown some initial success. So far, media campaigns have increased participation

in FOBT screening by using television, print, and online advertising. Often the messaging used in such campaigns provide information regarding the high rates of bowel cancer-related deaths and emphasise the importance of FOBT screening as a preventative action (Durkin et al., 2019; White et al., 2015). Durkin et al. (2019) found that their media campaign, which combined 30-second television commercials, a 4-minute televised advertorial, and magazine advertising, increased the number of people completing FOBT kits by 15-20%. This form of intervention is also highly cost-effective with cost-effectiveness ratios estimated to be under $4800 per life-year-gained (Worthington et al., 2020a), but do require ongoing investment to sustain.

1.7.5. *Telephone Contact*

Some of the interventions that have resulted in the largest increases in participation rates involved contacting invitees via the telephone. The function of these phone calls being to remind the invitee to complete and return their FOBT kit or give further instructions on how to complete the FOBT kit (Coronado et al., 2018; Myers et al., 1991). Coronado et al. (2018) found that when compared to text message reminders or reminder letters, a live telephone reminder was the most effective at increasing FOBT return rates. However, the use of telephone calls has only been trialled within small health networks and have not been trialled in national screening programmes which invite millions of people to participate each year. As such it has yet to be demonstrated if telephoning all FOBT recipients would be feasible on the national scale and if the costs associated would be a prohibitive factor in the uptake of this intervention strategy.

1.7.6. *Less Successful Interventions*

Not all interventions trialled thus far have successfully increased participation rates. For instance, offering small financial incentives (Gupta et al., 2016; Mehta et al., 2019), including stories from peers regarding their FOBT screening experiences (Wardle et al., 2016), and including booklets containing extra information regarding bowel cancer and FOBT screening (King et al., 1994; Libby et al., 2011; White et al., 2015) did not significantly increase participation. Further, at times interventions can lead to significantly reduced participation rates through excess information burden on invitees (Watson et al., 2013). Although these intervention trials were ultimately unsuccessful, they still provide valuable information that can be used to direct future

intervention design as they provide evidence for which intervention strategies might be avoided or need to be adapted in future trials.

1.7.7. *Conclusions from Intervention Literature*

The National Colorectal Cancer Roundtable advocates that national screening programmes should aim to achieve at least an 80% participation rate (Meester et al., 2015). However, the effects from the successful interventions reported in the literature tend to be only small to moderate, with the meta-analysis conducted by Goodwin et al. (2019a) estimating absolute increases in participation of approximately 5% – 7%. Further, two of the most effective strategies, (i.e., the use of FIT kits and sending advance notification letters), are already in use in the Australian NBCSP yet participation rates remain low (AIHW, 2020; NBCSP, 2017). Implementing known successful intervention strategies may be insufficient to achieve participation targets. There is a clear need to advance intervention research in a way that incorporates these modestly successful tested interventions with novel strategies and deliver them in the most effective way.

1.8. Limitations of Intervention Development

To advance our understanding of effective interventions for increasing participation in population bowel cancer screening programs, the limitations within this literature need to be addressed. Specifically, further consideration of intervention delivery and greater detail regarding intervention design could provide the information required to create a new highly effective behaviour change strategy. Thus far a one-size-fits-all (i.e., one intervention distributed to everyone) approach has been taken when assessing intervention's effectiveness across studies via a meta-analysis (Goodwin et al., 2019a). While this meta-analytic approach provides the highest form of evidence for healthcare interventions (Evans, 2003), the methods also assess each intervention type separately and assumes that the effectiveness of each intervention type is the same for all groups of the target population. Given the multitude of barriers reported by FOBT invitees and the stark demographic differences in participation rates, it is highly plausible that demographic and individual differences play a role in the way people respond to different interventions. This indicates that a more nuanced approach to intervention delivery may be required. For example, multiple interventions may need to be delivered to increase participation rates or specific interventions may need to be delivered to certain subpopulations to better match their FOBT screening barriers and

circumstances; methods that have not been adequately explored or evaluated in this context.

Knowing the best way to deliver proven interventions into national screening programmes is often made difficult by the wide variability in their previous implementation. Goodwin et al. (2019a) found that among FOBT intervention trials that used similar intervention strategies, there were large differences in their levels of effectiveness. This could be an indication that the specifics of implementation result in real changes in how effective the intervention will be. For example, Goodwin et al. (2019a) concluded that across multiple studies GP endorsement interventions were an effective strategy. However, within these studies, one trial used the GP endorsement as a written invitation letter and was effective (Hewitson et al., 2011) while another study used the GP endorsement as a reminder text message and was not effective (Hirst et al., 2017). Thus, a more structured and systematic method for identifying the most effective implementations of each intervention is needed in order to better direct how research findings should be incorporated into national screening programmes.

Another limitation impeding the advancement of intervention development has been the minimal reporting of the behavioural processes or mechanisms by which interventions bring about behaviour change in articles describing interventions (Goodwin et al., 2019a). Although detailed explanations of the content and of what occurred during the intervention itself are provided, there is little explanation or demonstration regarding the process of change the intervention is attempting to enable. By identifying which processes and behavioural mechanisms lead to greater FOBT screening participation, a greater range of behavioural change targets can be established which will aid in new intervention design (Carey et al., 2018).

Finally, while research examining the specific attitudes and barriers invitees have towards FOBT screening has progressed, much less research has been conducted to understand the attitudes invitees have towards behaviour change strategies that may increase FOBT screening participation. It is vital that invitees themselves accept and perceive the benefit of an intervention so that they will engage with the intervention (DeSmet et al., 2019). This is of particular importance for mail-out screening interventions as there is little to no interpersonal communication or contact between those delivering and those receiving the intervention, meaning there is limited ability to clarify the purpose or utility of the interventions with the invitee.

User engagement is a key factor in determining if an intervention will reach its full potential effectiveness and one that is under-researched within this context. A greater understanding of invitees' preferences obtained prior to (and during) the design phase of new interventions is one way to ensure a user-centred approach to intervention design and implementation (Yardley et al., 2015).

1.9. Conclusions

National mail-out FOBT screening has the potential to detect early-stage bowel cancer, increase survival rates, and improve other health outcomes related to a more advanced stage of this disease. However, for complex and multifaceted reasons, participation in the Australian NBCSP, and similar programmes in other countries, is poor. This is evidenced by the varying participation rates across subpopulations and the wide range of barriers to screening experienced by different individuals (AIHW, 2020; Dressler et al., 2021). In addition, there is a lack of clear guidelines around designing and implementing interventions in this context despite the numerous strategies that have been trialled. Given the number of lives that can be saved with increased NBCSP participation, it is paramount that new interventions are developed that make use of the existing evidence base while simultaneously addressing the limitations within the FOBT intervention literature.

While there have been advances in FOBT programmes that have facilitated increases in participation, such as the use of advance notification letters and distributing FIT kits instead of gFOBT kits (e.g., Cole et al., 2007; Moss et al., 2016), these increases are relatively small to modest and leave the absolute participation rate far short of recommended bowel cancer screening goals (Goodwin et al., 2019a; Meester et al., 2015). Thus, more research is needed to understand how participation rates can be increased and how to create new intervention strategies.

In order to develop effective interventions, they need to be examined using a behaviour change lens, whereby investigations go beyond identifying which interventions work to a more nuanced understanding of *why* interventions work, what specific components are required for them to work, and how research should be translated and incorporated into existing programmes. This approach can be strengthened with a greater understanding of the invitee's attitudes towards behaviour change strategies to allow for greater intervention engagement. The goal of this program of research will be to address the gaps that are currently within the

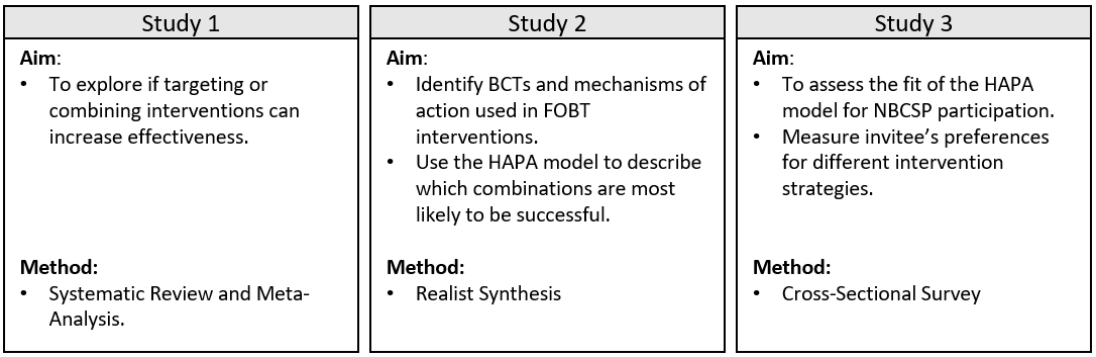
literature and establish recommendations for the construction of new interventions to increase mail-out FOBT screening participation.

1.10. Thesis Aims

The aim of the current research is to systematically identify the ways in which interventions to increase participation in mail-out FOBT screening programmes should be designed, targeted, and delivered to maximise effectiveness. A summary of the aims and methods are presented in Figure 1.1. This will be achieved through an examination of existing interventions, their combined effectiveness and relative effectiveness for various sub-groups (study one), a detailed examination of the behaviour change strategies and mechanisms employed in each of the existing interventions and synthesis of these across successful and unsuccessful interventions (study two), and finally, an investigation into NBCSP invitee's process of participation (and non-participation) along with their preferences regarding specific strategies (study three).

Figure 1.1.

Summary of Thesis Aims and Methods



To achieve these aims this thesis will report on the results of these three studies.

Study One - Ways to Use Interventions to Increase Participation in Mail-Out Bowel Cancer Screening: A Systematic Review and Meta-Analysis.

Through a systematic literature review (SLR) and meta-analysis of identified studies, the first study explored if the effectiveness of interventions aiming to increase participation in mail-out FOBT screening programmes can be enhanced by using specific interventions for certain subpopulations and/or combining interventions for a multifaceted behaviour change approach.

Study Two - Implementation Strategies for Interventions Aiming to Increase Participation in Mail-Out Bowel Cancer Screening Programmes: A Realist Review.

Using a realist synthesis approach, the second study examined the implementation differences of FOBT screening intervention by identifying the effective and ineffective intervention components and behaviour change mechanisms used in trials thus far and investigated how they should be combined.

Study Three - A Health Action Process Approach for Developing Invitee Endorsed Interventions to Increase Mail-Out Bowel Cancer Screening.

Through a cross-sectional survey of NBCSP invitees, study 3 assessed if the Health Action Process Approach (HAPA) would be a suitable psychological theory to describe mail-out bowel cancer screening behaviour and therefore could be used as a framework to create a multifaceted intervention strategy. The survey also collects data on invitees' preferences for various behaviour change strategies to allow for more user centre intervention design choices.

1.11. Thesis Outline

The three outlined studies will be presented in the following eight chapters. To ease navigation, these chapters are described below:

Chapter 2: Background for Study One

Chapter two presents the theoretical and empirical background for study one. Within this chapter, the justification for investigating targeting and combining approaches to intervention design is explained.

Chapter 3: (Study one) Ways to Use Interventions to Increase Participation in Mail-Out Bowel Cancer Screening: A Systematic Review and Meta-Analysis

Chapter 3 presents the published article relating to study one. The article reports on the methods and findings of an SLR and meta-analysis that evaluated how effective targeting or combining intervention strategies has been in the context of mail-out FOBT screening interventions.

Chapter 4: Background for Study Two

Chapter 4 introduces the realist synthesis method that is applied in study two. Additionally, the behaviour change techniques taxonomy v1, the theory and technique tool, and HAPA frameworks are introduced as they are subsequently utilised in the realist synthesis of study two.

Chapter 5: (Study two) Implementation Strategies for Interventions Aiming to Increase Participation in Mail-Out Bowel Cancer Screening Programmes: A Realist Review

Chapter 5 presents the published article relating to study two; a realist synthesis that applied the behaviour change frameworks and theories introduced in chapter four to identify and label the effective (and ineffective) components of FOBT screening interventions, their mechanisms of behaviour change, and how they can be incorporated into a larger theoretical framework.

Chapter 6: Background for Study three

Chapter 6 describes the development process (such as item refinement and content validation) of a survey designed to measure FOBT invitee preferences for different behaviour change interventions and constructs specified with the HAPA model applied in the context of mail-out FOBT screening that was used in study three.

Chapter 7: (Study three) A Health Action Process Approach for Developing Invitee Endorsed Interventions to Increase Mail-Out Bowel Cancer Screening

Chapter 7 presents the submitted manuscript (currently undergoing review at the Annals of Behavioural Medicine) that reports on the methods and findings of study three; a cross-sectional survey study investigating theoretical factors predicting FOBT participation and invitee's preferences for various behaviour change strategies.

Chapter 8: General Discussion

Chapter 8 presents a general discussion of, and conclusions drawn from, the findings from this body of research.

CHAPTER 2: BACKGROUND FOR STUDY ONE

This chapter introduces the theoretical and empirical background that motivated the aims and research method of study one. Through an SLR and meta-analysis, Goodwin et al. (2019a) identified several strategies (i.e., GP endorsement, advance notification, FOBT kit changes, and telephone contact) that consistently increased mail-out FOBT screening participation. However, given the modest effect sizes Goodwin et al. (2019a) estimated for these intervention types none of these in isolation could be utilised as a panacea for the low-participation rates found in mail-out FOBT screening programmes. Therefore, the purpose of study one was to investigate if the effectiveness of these interventions could be enhanced by using alternative delivery strategies. The effect sizes estimated within the Goodwin et al. (2019a) meta-analysis related to each intervention type separately without comparing variability in effects across subpopulations. It is possible that combining interventions together or only using certain intervention types for the subpopulations in which they have the largest effects (i.e., a targeting strategy) may be a more successful way to incorporate known interventions into screening programmes. However, without a re-analysis of these studies, it remains unknown if targeting subpopulations or combining multiple intervention strategies result in larger average effects. This new information can inform policy makers and those designing and delivering interventions of the most efficient and effective way to apply successful interventions tested to date. For instance, if the effect of a GP endorsement intervention were higher for males and the effect of reminder interventions were higher for females these interventions could be delivered to the subpopulation for which they are the most effective. It is important to note that both a targeting and combining strategy are inherently more complex and therefore have special considerations that need to be explored.

2.1. Targeting Subpopulations with Specific Interventions

Selecting and refining interventions to best match the recipient's unique individual psycho-social makeup is a nuanced way to increase the overall effectiveness of behaviour change strategies (Ryan et al., 2001). This method, often referred to as *tailoring,* is highly flexible and can address specific barriers experience by various individuals. Given research has shown that there are multiple barriers to FOBT screening, and different people experience different barriers, tailoring may be of particular use in this context. A meta-analysis of health promotion messaging

interventions found that tailoring health messages to specific individuals is an effective behaviour change strategy (Noar et al., 2007). However, these tailoring interventions are also very labour intensive, costly, and difficult to implement on large scales (Lairson et al., 2011). A pragmatic alternative is to use *targeted* interventions, where more broad information is collected from recipients (such as age or SES) and intervention selection is based on these demographic groupings (Lairson et al., 2011). Previous studies have directly compared the costs and effectiveness of targeted versus tailored interventions at promoting cancer screening behaviour; specifically scheduling a mammography or requesting an FOBT kit (Lairson et al., 2011; Lairson et al., 2008). In both studies, the targeted intervention was vastly less expensive and more effective than the tailored intervention strategy at promoting cancer screening behaviour (Lairson et al., 2011; Lairson et al., 2008).

When deciding which of these two approaches should be applied in the context of mail-out FOBT screening, it is also important to note that the NBCSP distributes over 3 million FOBT kits to individuals per year (AIHW, 2019). As such, a tailoring strategy would require detailed data to be collected for all 3 million people (e.g., data on individual psycho-social make-up and attitudes towards health behaviours). This is likely implausible to do at this scale and some individuals mistrust towards large health systems may further hinder efforts to collect this type of data. However, the demographic data required for a targeted intervention strategy (i.e., SES, age, or gender) is already collected and known in health care systems in which mail-out screening programmes take place. Therefore, a targeting intervention strategy may be feasible given the data currently available on mail-out bowel cancer screening program participants.

Data regarding NBCSP uptake also indicates that a targeting intervention approach may be suitable. The AIHW (2020) report clear distinctions between subpopulations in mail-out FOBT screening participation rates (e.g., males participate less than females). Given these demographic differences in participation, it is plausible that the effectiveness of interventions aiming to increase these participation rates may also change across subpopulations. For example, it is possible that lower socio-economic groups may not respond as well to technical interventions that require reading of complex materials or have multiple components and should be avoided within this subpopulation (Watson et al., 2013). Currently, the limited amount of research that has investigated differences in intervention effects across

subpopulations has focused solely on lower SES populations. Wardle et al. (2016) found that an enhanced reminder letter intervention showed a larger effect in the low SES subpopulation in the United Kingdom when compared to a higher SES subpopulation (Wardle et al., 2016), suggesting a targeting strategy could be used for this intervention within this low SES subpopulation. However, research into the differences in intervention effectiveness in other subpopulations and other intervention types has yet to be conducted. For a targeting intervention strategy to have a substantial impact in mail-out FOBT screening rates the most effective intervention type for each of the major demographic subpopulations need to be identified.

2.2. Evidence for Combining Interventions

There are multiple barriers to participation in mail-out FOBT programmes, ranging from personal health beliefs, attitudes towards health care systems, to practical difficulties specific to FOBT screening (Javanparast et al., 2012; Palmer et al., 2014). Therefore, combining intervention strategies to overcome these multiple barriers may be required to effectively produce behaviour change (Grimshaw et al., 2012). For instance, an intervention that changes the stool collection process to address disgust type barriers could be combined with an intervention that raises bowel cancer risk awareness to address necessity type barriers could be combined to create a multifaceted intervention strategy targeting two barriers. However, there are potential downsides to combining intervention strategies that should be considered. Often when combining interventions, the overall behaviour change strategy becomes complicated. This added complexity can increase the chance of errors occurring during the delivery phase, decreasing the fidelity of the intervention delivery, and can result in a less effective behaviour change strategy (Michie et al., 2009; Squires et al., 2014). For example, an intervention strategy that combines advance notification letters with GP endorsement letters, requires systems to deliver the advance notification and systems to link invitees to their GP. In this case, there would be a higher chance of a system failure occurring when compared to a less complex strategy. Additionally, in the context of mail-out FOBT screening interventions, a behaviour change strategy might require giving the invitee more materials (e.g., more information about health risks of bowel cancer plus a GP endorsement letter). This increase in written materials has been shown to reduce participation rates (Wardle et al., 2016). Therefore, it is not clear in principle if a

combined intervention strategy should or should not be used to increase FOBT screening rates.

The empirical evidence for the effectiveness of multifaceted interventions is inconsistent. For instance, a meta-analysis of internet-based interventions to promote a variety of health behaviour changes (ranging from dietary behaviour to smoking abstinence) showed that an increase in the number of behaviour change strategies employed in an intervention lead to an increase in effectiveness (Webb et al., 2010). The authors concluded that the increased cost and planning required for these elaborate interventions were justified in this circumstance as they generally lead to greater effects. On the other hand, a scoping review of interventions aimed to increase physical activity, healthy eating and decrease smoking in low-income groups, found that interventions with the fewest techniques had the greatest effect (Michie et al., 2009). Michie et al. (2009) argued that in the studies they reviewed, the interventions that selected a small specific set of well-suited behaviour change strategies and where the intervention delivery could be more easily managed and monitored were the most likely to be successful. The mixed evidence might suggest combining interventions is effective in some circumstances but not others.

With respect to interventions aimed at increasing participation in mail-out FOBT screening, it has yet to be established if increasing, or minimising, the number of techniques used in an intervention leads to greater or lesser participation rates. This information will aid policy makers and researchers in deciding how best to direct limited resources to increase mail-out FOBT screening participation. By understanding how combined intervention strategies have previously worked, clearer recommendations can be provided on whether national screening programmes will benefit from combining multiple intervention strategies to address a wide range of barriers associated with FOBT screening or whether a single-focused intervention approach is required.

2.3. Conclusions

The literature currently provides some insight into interventions that can successfully increase participation in mail-out FOBT screening, however, it is clear that further efforts are required to build interventions that will substantially increase participation rates. Targeting or combining approaches are possible ways to enhance the effectiveness of known intervention strategies that have worked in other health behaviour change contexts. However, evidence for either of these approaches has yet

to be examined in the context of mail-out FOBT screening. The aim of study one, therefore, was to assess whether intervention strategies could benefit from being targeted at subpopulations or combined.

CHAPTER 3: STUDY ONE (PUBLISHED ARTICLE)

Myers, L., Goodwin, B., March, S., & Dunn, J. (2019). *Ways to use interventions to increase participation in mail-out bowel cancer screening: a systematic review and meta-analysis.* Translational Behavioral Medicine. doi:10.1093/tbm/ibz081 (Q2: Applied psychology, H = 33)

3.1. Abstract

Background: The impact of colorectal cancer can be reduced through nationwide FOBT screening. Unfortunately, participation in screening programs are low with interventions only increasing participation modestly.

Purpose: This meta-analysis explores if intervention effectiveness can be increased by targeting specific subpopulations with specific interventions or by combining interventions.

Methods: Six databases were searched for studies aiming to increase participation in mail-out FOBT screening. To investigate if interventions are more effective for certain subpopulations, the difference in (log)*RR*s between alternate subpopulations (male vs female; low vs high SES; < 65 vs 65 ≥ years) was assessed. To investigate if interventions should be combined, uptake rates for single interventions were compared to uptake rates for combined interventions. Cochrane Collaboration tools were used to assess the risk of bias.

Results: Searches found 3436 articles, with 32 meeting the inclusion criteria. These contained 30 trials that reported uptake rates within subpopulations and 17 trials that combined interventions. Most differences in intervention effects between subpopulations were non-significant. Combining interventions led to greater participation, *RR* = 1.06, CI [1.03; 1.10].

Conclusions: As interventions rarely affect subpopulations differently, targeting them at specific subpopulations may be an ineffective strategy. While individual interventions show modest effects, these results indicate that future programs might overcome this by combining interventions together. Care is needed when selecting interventions to combine as adding some interventions (e.g., additional print materials) can reduce the effectiveness of a combined strategy. Future research should examine methods for effectively combining interventions in nationwide programs to maximise participation.

Keywords: Faecal occult blood test; Colorectal Cancer; Population screening; Systematic Review

3.2. Introduction

Colorectal cancer (CRC) is the second leading cause of cancer death and the third most commonly diagnosed cancer worldwide (Bray et al., 2018). These high incidence and mortality rates place considerable strain on both health care systems and individuals within these systems (AIHW, 2013). As such, many countries (e.g., Australia, England, France, South Korea, and Chile) have implemented a nationwide mail-out CRC screening program to increase the rate of early detection and thereby reduce these morbidity and mortality rates (Navarro et al., 2017).

A common screening method used in these national programs is to mail faecal occult blood tests (FOBT) directly to members of the population that are at a higher risk of developing CRC (i.e., those aged between 50-74 years; AIHW, 2018c; Schreuders et al., 2015). Individuals complete the test at home and anyone who yields a positive result (by the detection of blood in the stool sample) is referred on to receive a colonoscopy (Schreuders et al., 2015). This two-stage process is sensitive at detecting CRC and highly cost-effective (AIHW, 2018c).

Despite the success of these types of programs, participation remains below 50% (of invited individuals) in many countries (AIHW, 2018c; Swan et al., 2012). As such, there will be large proportions of the population in the future who will be diagnosed with CRC who could have been identified earlier if they had participated in a screening program. Consequently, numerous interventions have been trialled in an attempt to increase participation rates in mail-out FOBT screening programs.

A recent meta-analysis of these trials categorised studies into nine general intervention types and concluded that only interventions involving advance notifications, general practitioner (GP) endorsements, simplified testing procedures, and telephone contact resulted in significant improvements in participation (Goodwin et al., 2018a). However, the effect sizes of these interventions were small to moderate, equating to absolute increases in participation of approximately 5-7% (Goodwin et al., 2018a). Given participation rates are generally below 50%, these interventions will likely fail to bring about enough change to meet the 80% target for screening rates set by the National Colorectal Cancer Roundtable (Meester et al., 2015). As such further investigation on how to optimise interventions to increase future uptake is needed.

One plausible reason for the modest effect sizes seen in previous interventions may be that interventions work differently for various subpopulations.

For example, it is possible that lower socio-economic groups may not respond as well to technical interventions that require reading of complex materials (Watson et al., 2013). Thus, in highly controlled trials, which typically stratify or balance these subpopulations between intervention arms, greater effects may potentially be masked. Previous research has found that males, those who are socio-economically disadvantaged, and younger adults, are less likely to participate in mail-out FOBT programs (Mansouri et al., 2013). It is therefore plausible that the success of interventions aimed at improving these rates may also be impacted by these factors.

If such demographic factors were found to moderate the effectiveness of interventions, screening programs could then use this information by only applying interventions to the subpopulations in which they have been shown to be the most effective. This could lead to more efficient use of resources and potentially greater overall participation rates. However, a systematic review of interventions that work particularly well in specific subpopulations has yet to be conducted.

An alternate explanation for the modest effects reported recently is that the 2018 meta-analysis (Goodwin et al., 2018a) only examined the unique effects of individual intervention strategies. While many studies examined the use of only a single intervention strategy within their trial (e.g., using GP endorsement letters) (Benton et al., 2017) some studies combined intervention types within a trial arm in an attempt to achieve greater effects (e.g., using a GP endorsement letter and an enhanced procedural leaflet; Hewitson et al., 2011). It is commonly argued that combining interventions represents a sound approach to overcoming the many different barriers associated with health behaviours (Squires et al., 2014). However, it is also acknowledged that combining interventions can increase complexity; thereby increasing error proneness and decreasing the fidelity of the intervention's delivery (Squires et al., 2014). It has yet to be established—across studies—if combining intervention types has a beneficial or detrimental effect on FOBT screening uptake.

There are clear health and financial benefits that will result from improving the low participation rates in mail-out FOBT screening (AIHW, 2018c; Navarro et al., 2017; Swan et al., 2012). As such it is imperative that screening program organisers apply effective and evidenced-based interventions to increase participation rates. Participation in CRC screening varies greatly among subpopulations, and no single intervention can be relied upon to substantially

improve participation rates (Goodwin et al., 2018a). Program organisers, therefore, at present have two logical options available to them in terms of intervention distribution; either deliver different interventions to the specific subpopulations in which they are most effective, or to deliver many different interventions simultaneously to the whole population; assuming the effects of a multimodal approach will be greater than any of the individual interventions that it is comprised of.

This meta-analysis will synthesise the available evidence regarding these two options. Firstly, it will investigate if the effect sizes of different intervention types for improving CRC screening are greater for any particular subpopulation. In doing so, this study will assess whether targeting interventions to certain subpopulations will be an effective strategy. Secondly, it will assess whether adding intervention types together is associated with greater effect sizes. This will provide information to indicate whether a multimodal approach should be used in future. Based on these findings, evidence-based suggestions can be made as to the best way to distribute interventions aimed to increase participation in mail-out FOBT screening.

3.3. Methods

The search strategy for this review replicated those of a previous review (Goodwin et al., 2018a) with updated search dates completed on the 31st of October 2018 (see PRISMA diagram in Appendix A). This review protocol was registered under PROSPERO; number CRD42018088577. Article screening, data extraction, and risk of bias assessments were conducted by two independent researchers with any discrepancies being moderated by the larger research team. The review followed the PRISMA guidelines (Moher et al., 2009).

3.3.1. *Search Strategy*

Searches were conducted for all studies reporting on interventions aimed at increasing the participation rates of mail-out CRC screening programs. Databases used in this search included Pubmed, Scopus, PsycInfo, CINAHL, and ProQuest Dissertations and Theses. Full search terms can be found in Appendix B. Manual searches were also conducted using Google scholar and ancestry searches of articles gathered during the primary search.

Articles were included if (a) the studies reported on interventions aimed at improving participation in mail-out (FOBT) CRC screening, (b) the study mailed a CRC screening kit to the participants home without specific request from the

individual, and (c) quantitative data of the FOBT return rate was reported. Studies were excluded if (a) the FOBT kit was not mailed directly to the participant, (b) if studies required participants to request a kit or accept an invitation to receive a kit in the future or to be part of the study, (c) studies investigated other types of CRC screening (e.g., colonoscopy) and did not report specific outcomes for FOBT screening, and (d) if the full text was not available in English. These criteria were chosen as they best replicate the design of many national FOBT screening programs (Swan et al., 2012).

3.3.2. *Screening Process*

Articles were screened using a three-stage process with results being reported in the PRISMA flow-diagram (Appendix A). Firstly, all duplicates were removed from the database. Secondly, titles and abstracts were reviewed for relevance. Lastly, for the remaining articles, a full-text review was carried out. Screening decisions were based on the set inclusion and exclusion criteria. Accepted studies were then further separated depending on if they used multiple intervention types within trial arms or if they reported separate uptake rates within subpopulations within intervention arms. If the study did not report the latter, requests for this data were made to the corresponding author of the primary study.

3.3.3. *Risk of Bias Assessment*

For randomised trials, the risk of bias was assessed using the *revised Cochrane risk-of-bias tool for randomised trials* (ROB 2) and for non-randomised trials (n = 5/25) the *Risk of Bias in Non-randomised Studies - of Interventions* (ROBINS-I) tool was used (Higgins et al., 2016; Sterne et al., 2016). Using these tools, a risk of bias judgment is made regarding various elements of each study and the study overall ranging from low to high/critical risk. For both tools, the risk of bias judgments were made using the published signalling questions and suggested algorithms (Higgins et al., 2016; Sterne et al., 2016).

3.3.4. *Analysis*

For each intervention, summary data was extracted and is presented in Appendix C. This data included the author, year, intervention, sample size, age range of sample, country, available data, and risk of bias. Similar interventions were grouped together to form intervention types. Intervention effects were evaluated using unadjusted RRs based on an intention-to-treat analysis, with an alpha level of .05.

To determine if differential intervention effects were evident for subpopulations, pooled effect sizes were calculated for each intervention type according to age, gender, and SES brackets. In this manner, three two-level groups were compared; (a) males versus females, (b) younger versus older cohorts, and (c) low versus high SES. The difference between the two pooled effects (measured by the difference in *log* RRs) was tested for significance using a Wald-type test (Viechtbauer, 2017). Studies generally report SES according to five levels (i.e., quintiles). For this analysis, the lowest three and the highest two SES classes were combined to constitute the low and high SES groups respectively. Age categories and ranges varied markedly across studies. Therefore, in the current study, we applied age brackets that were the most consistent with what was reported across studies with < 65 years old constituting the younger cohort and ≥ 65 years old constituting the older cohort. When this grouping could not be applied, due to restrictions with the available data, age was categorised with <60 years old constituting the younger cohort and ≥ 60 years old constituting the older cohort. This secondary age categorisation strategy occurred in 21% of cases (n = 6 trials). The age brackets applied to each individual trial can be seen in Appendix C.

To determine whether combining interventions is associated with greater increases, or decreases, in screening participation, the rates of participation in trial conditions that included combined intervention types (e.g., GP endorsement letter *and* using a simplified testing procedure) were compared to those that included only one intervention type (e.g., only GP endorsement letter). In the cases where several interventions were combined (e.g., GP endorsement letter *and* using a simplified testing procedure *and* an information brochure), these participation rates were compared to the intervention arm that had one less intervention type (e.g., GP endorsement letter *and* using a simplified testing procedure). In this manner, the effect of adding interventions together could be examined. Pooled RRs were calculated across these comparisons. Given the variation in research methodologies used across studies, pooled effect-sizes were calculated using a random effects model with restricted maximum likelihood estimation (Borenstein, 2009). However, as one intervention used almost identical methodologies (i.e., advanced notification letters; discussed below) a fixed effect model was fitted for this intervention type (Borenstein, 2009). This analysis was conducted using the *metaphor* package in the R statistical program (R Core Team, 2014; Viechtbauer, 2010). The estimation of

residual heterogeneity was calculated using the I^2 statistic. I^2 values of 25%, 50% and 75% were described as *small*, *moderate*, and *large* respectively (Borenstein, 2009). To assess the possibility of small study effects (e.g., publication bias), Egger's regression test was used to test for funnel-plot asymmetries (Viechtbauer, 2010). This was calculated for every pooled RR calculated in this review.

3.4. Results

Appendix A (PRISMA flow chart) shows the results of the search and screening strategies. Thirty-two articles met inclusion criteria. Of these, 15 reported separate data for subpopulations and four further studies gave this data upon request. Of the remaining studies, some authors could not provide this data (n = 3), some authors did not respond to the request (n = 7), and the others could not be contacted (n = 3). From these 19 studies, there were 30 individual trials in which effects across subpopulations could be compared. Out of all the studies that met the inclusion criteria, nine studies used combined interventions which were comprised of 17 individual trials. A summary of all trials can be seen in Appendix C.

3.4.1. *Evidence for Demographic Differences in Effectiveness of Interventions*

The review found 30 individual trials in which effects could be compared between subpopulations. Within these, as in previous reviews (Goodwin et al., 2018a), several different intervention types were identified and categorised into four groups (descriptions are given below). There were also three interventions that did not fall into a relevant category and were only trialled once.

3.4.1.1. Advance Notification. There were two trials that tested the effect of advance notification letters on participation. These involved sending a letter 2-weeks prior to the FOBT kit arrival. The letter would inform the invitee they will be receiving an FOBT kit in the mail soon and what they should do when it arrives. Studies were from Australia (n = 1) and Scotland (n = 1; Cole et al., 2007; Libby et al., 2011). Both were randomised controlled trials (RCT) and had a low risk of bias. Separate uptake rates were available for age, gender, and SES (see Appendix C).

The total sample size for each subpopulation ranged from 23,039 – 41,204 (median = 31,936). Pooled effects can be seen in Table 3.1. Advance notification was associated with a significantly greater effect in males, *RR* = 1.13, CI [1.10; 1.16], compared to females, *RR* = 1.07, CI [1.05; 1.10], *(log)RR diff* = 0.046, p = .009. Advance notification letters did not show significant differences in effects between the younger, *RR* = 1.10, CI [1.08; 1.13], and older cohorts, *RR* = 1.09, CI [1.06;

1.12], *(log)RR diff* = 0.012, *p* = .50, or the low, *RR* = 1.10, CI [1.07; 1.13], and high SES groups, *RR* = 1.09, CI [1.07; 1.12], *(log)RR diff* = 0.003, *p* = .87. Large reductions in heterogeneity were found between comparative groups. The level of heterogeneity in RRs observed in females (I^2 = 0.0), the older cohort (I^2 = 0.0), and the low SES areas (I^2 = 0.0) was small. The three opposing categories, males (I^2 = 63.3), the younger cohort (I^2 = 72.1), and the high SES group (I^2 = 64.7), showed moderate to large amounts of heterogeneity (see Table 3.1). In testing for small study effects, all Egger's regression tests for the pooled RRs were non-significant, *p* > .05.

3.4.1.2. GP Endorsement. In total, five studies (six trials) used GP endorsement to increase participation (Benton et al., 2017; Cole et al., 2002; Hewitson et al., 2011; Hirst et al., 2016; Wardle et al., 2016). These involved sending a letter (or text) of recommendation for FOBT screening from the invitee's personal GP (or GP practice). Studies were conducted in Australia (n = 1) and England (n = 4). Subpopulation data was available for gender in six trials, for age in five trials, and SES in three trials (see Table 3.1). Five of the six studies were RCTs with a low risk of bias. However, one study (Benton et al., 2017) was a non-randomised trial (that used match comparisons) and had a serious risk of bias (see Appendix C).

The total sample size for each subpopulation ranged from 212,861 – 259,354 (median = 236,589). Pooled effects can be seen in Table 3.1. There was no significant difference in the effect size of the intervention between males, *RR* = 1.04, CI [1.00; 1.08], and females, *RR* = 1.07, CI [1.01; 1.13], (*log*)*RR diff* = -0.029, *p* = .40. There was no significant difference in the effect size between the younger, *RR* = 1.09, CI [1.01; 1.19], and older cohorts, *RR* = 1.03, CI [0.99; 1.07], (*log*)*RR diff* = 0.059, *p* = .21. There was also no significant difference in the effect size of the GP endorsement intervention between low SES group, *RR* = 1.04, CI [0.99; 1.09], and the high SES group, *RR* = 1.03, CI [0.98; 1.08], (*log*)*RR diff* = 0.012, *p* = .73. All demographic groups showed moderate to large levels of heterogeneity ranging from 53.6% - 90.3% (see Table 3.1). The Egger's regression test showed significant small study effects for the pooled RRs of the male group, *p* = .013, female group, *p* = .006, and younger cohort, *p* < .001, the remaining tests were non-significant.

3.4.1.3. Simplified Testing Procedure. In total there were six studies (seven trials) that simplified the testing procedure to increase participation (Blom et al., 2018; Cole et al., 2003; Digby et al., 2013; Moss et al., 2016; Santare et al., 2015; van Rossum et al., 2008). These trials removed the dietary restrictions and/or

required fewer samples to increase participation rates. Data was available for gender and age in all studies, however, SES data was only available for four of the seven trials (see Table 3.1). Studies were from the Netherlands (n = 1), Australia (n = 1), Scotland (n = 1), England (n = 1), Sweden (n = 1), and Latvia (n = 1). Four of these studies were RCTs with one (Cole et al., 2003) showing some concerns of bias and the remaining having a low risk of bias. Two studies were non-randomised trials, with one showing moderate risk of bias (Blom et al., 2018) and the other showing serious risk of bias (Digby et al., 2013; see Appendix C).

The total sample size of each subpopulation ranged from 834,394 – 1,307,106 (median = 1,155,063). Pooled effect sizes can be seen in Table 3.1. There was no significant difference in the effect sizes between the male, *RR* = 1.31, CI [1.16; 1.48], and female groups, *RR* = 1.21, CI [1.09; 1.35], (*log*)*RR diff* = 0.079, *p* = .34. There was no significant difference in the effect sizes between the younger, *RR* = 1.30, CI [1.18; 1.44], and older cohorts, *RR* = 1.22, CI [1.11; 1.35], (*log*)*RR diff* = 0.063, *p* = .38. There was also no significant difference in the effect sizes for simplifying the testing between the low, *RR* = 1.23, CI [1.04; 1.45], and high SES groups, *RR* = 1.24, CI [1.03; 1.49], (*log*)*RR diff* = -0.009, *p* = .94. All subpopulations showed large levels of heterogeneity (all $I^2 > 98\%$). The Egger's regression tests showed significant small study effects for the pooled RR of females, *p* = .015, the older cohort, *p* = .002, the low SES group, *p* = .032, and the high SES group, *p* < .001. The remaining tests were non-significant.

3.4.1.4. Added Print Materials. There were seven studies (12 trials) that added print materials to the standard invitations to increase participation in mail-out FOBT screening (e.g., a simplified explanation or extra information about CRC risks; Cole et al., 2007; Hewitson et al., 2011; Libby et al., 2011; Neter et al., 2014; O'Carroll et al., 2015; Wardle et al., 2016; Watson et al., 2013). Studies were from England (n = 3), Scotland (n = 2), Australia (n = 1), and Israel (n = 1). Subpopulation data was available for gender in all studies, whereas age and SES data were not available for one study (see Table 3.1). These studies were all RCTs, with six showing a low risk of bias and one (Watson et al., 2013) showing a high risk of bias (see Appendix C).

The total sample size for each subpopulation ranged from 466,151 – 546,682 (median = 506,890). Pooled effect sizes can be seen in Table 3.1. There was no significant difference found in effect sizes between the male, *RR* = 1.00, CI [0.98;

1.02], and female groups, *RR* = 1.00, CI [0.97; 1.03], (*log*)*RR diff* < 0.001, *p* = .99. There was no significant difference in the effect size between the younger, *RR* = 0.99, CI [0.97; 1.02], and older cohorts, *RR* = 1.00, CI [0.98; 1.01], (*log*)*RR diff* = -0.001, *p* = .93. There was also no significant difference in the effect sizes between the low, *RR* = 0.99, CI [0.95; 1.03], and high SES groups, *RR* = 1.00, CI [0.98; 1.01], (*log*)*RR diff* = -0.006, *p* = .77. Large amounts of heterogeneity were found for all subpopulations, with I^2 values ranging from 63.8% - 96.1%. The Egger's regression test showed significant small study effects for the low SES group, *p* = .011, with the remaining tests being non-significant.

3.4.1.5. Collection Paper. One trial (Denters et al., 2013) used collection paper, that was designed to make collecting the stool sample easier, to increase participation. This study was an RCT conducted in the Netherlands and had a low risk of bias (see Appendix C). Subpopulation data was available for gender and age but not SES. The sample size of each subpopulation ranged from 4,109 – 11,363 (median = 7,816). The effect size for each subpopulation can be seen in Table 3.1. The effect size associated with sending the collection paper with the FOBT kit was not significantly different between the male, *RR* = 1.00, CI [0.95; 1.06], and females groups, *RR* = 0.99, CI [0.94; 1.03], (*log*)*RR diff* = 0.017, *p* = .66. There was also no significant difference in effect sizes between the younger, *RR* = 1.00, CI [0.96; 1.05], and older cohorts, *RR* = 0.97, CI [0.90; 1.04], (*log*)*RR diff* = 0.035, *p* = .41.

3.4.1.6. Financial Incentive. One trial, conducted by Gupta et al. (2016), offered small financial incentives ($5 - $10 Walmart gift cards) for participation. This was an RCT conducted in the USA and had a low risk of bias (see Appendix C). The study reported data for gender and SES data but not for age. The sample size each subpopulation ranged from 4,361 – 7,281 (median = 5,660). The effect size for each subpopulation can be seen in Table 3.1. The effect of offering a small financial incentive was not significantly different between the male, *RR* = 0.99, CI [0.89; 1.12], and female groups, *RR* = 1.06, CI [0.98; 1.14], (*log*)*RR diff* = -0.061, *p* = 39. The effect size was also not significantly different between the low, *RR* = 0.95, CI [0.86; 1.04], and high SES groups, *RR* = 1.08, CI [0.98; 1.18], (*log*)*RR diff* = -0.129, *p* = .06.

3.4.1.7. Community Drop-Off Location. One trial (Sandiford et al., 2018) offered an alternate community-based drop-off location along with the traditional mail-return system to increase participation. This was a non-randomised trial

conducted in New Zealand that showed a moderate risk of bias (see Appendix C). The study reported data for gender and age but not SES. The sample size of the subpopulations ranged from 38,396 – 89,995 (median = 62,203). The effect size for each subpopulation can be seen in Table 3.1. Offering community drop-off location had a significantly larger effect in males, *RR* = 1.03, CI [1.01; 1.05], when compared to females, *RR* = 1.00, CI [0.98; 1.02], (*log*)*RR diff* = 0.029, *p* = .045. The effect was also significantly larger in the younger cohort, *RR* = 1.03, CI [1.01; 1.05] when comparted to the older cohort, *RR* = 1.00, CI [0.98; 1.02], (*log*)*RR diff* = 0.028, *p* = .043.

Table 3.1.

Pooled Statistics for Different Sub-Groups Within Different Intervention Types

		Demographic$_a$				Demographic$_b$					
Intervention	*k*	*n*	RR	95%CI	I^2 (%)	*n*	RR	95%CI	I^2 (%)	(log) Difference	*p*
Advance Notification											
Gender (male$_a$/female$_b$)	2	30 584	1.13	[1.10; 1.16]	63.3	33 659	1.07	[1.05; 1.10]	0.0	0.046	.009
Age (younger$_a$/older$_b$)	2	41 204	1.10	[1.08; 1.13]	72.1	23 039	1.09	[1.06; 1.12]	0.0	0.012	.50
SES (low$_a$/high$_b$)	2	30 546	1.10	[1.07; 1.13]	0.0	33 287	1.09	[1.07; 1.12]	64.7	0.003	.87
GP Endorsement											
Gender (male$_a$/female$_b$)	6	227 832	1.04	[1.00; 1.08]	53.6	245 346	1.07	[1.01; 1.13]	79.7	-0.029	.40
Age (younger$_a$/older$_b$)	5	212 861	1.09	[1.01; 1.19]	90.3	259 354	1.03	[0.99; 1.07]	67.5	0.059	.21
SES (low$_a$/high$_b$)	3	248 279	1.04	[0.99; 1.09]	84.3	217 000	1.03	[0.98; 1.08]	75.3	0.012	.73
Simplified Testing Procedure											
Gender (male$_a$/female$_b$)	7	1 156 245	1.31	[1.16; 1.48]	99.6	1 265 282	1.21	[1.09, 1.35]	99.6	0.079	.34
Age (younger$_a$/older$_b$)	7	1 091 639	1.30	[1.18; 1.44]	99.3	1 307 106	1.22	[1.11; 1.35]	99.3	0.063	.38
SES (low$_a$/ high$_b$)	4	1 153 881	1.23	[1.04; 1.45]	98.9	834 394	1.24	[1.03; 1.49]	99.5	-0.009	.94
Added Print Material											
Gender (male$_a$/female$_b$)	12	494 573	1.00	[0.98; 1.02]	80.9	523 347	1.00	[0.97; 1.03]	93.2	< 0.001	.99
Age (younger$_a$/older$_b$)	11	509 254	0.99	[0.97; 1.02]	92.3	504 525	1.00	[0.98; 1.01]	83.2	-0.001	.93
SES (low$_a$/ high$_b$)	11	546 682	0.99	[0.95; 1.03]	96.1	466 151	1.00	[0.98; 1.01]	63.8	-0.006	.77
Collection Paper											
Gender (male$_a$/female$_b$)	1	7 385	1.00	[0.95; 1.06]	na	8 247	0.99	[0.94; 1.03]	na	0.017	.66
Age (younger/older)	1	11 363	1.00	[0.96; 1.05]	na	4 109	0.97	[0.90; 1.04]	na	0.035	.41
Financial Incentive											
Gender (male$_a$/female$_b$)	1	4 361	0.99	[0.89; 1.12]	na	7 281	1.06	[0.98; 1.14]	na	-0.061	.39
SES (low$_a$/ high$_b$)	1	5 710	0.95	[0.86; 1.04]	na	5 610	1.08	[0.98; 1.18]	na	-0.129	.06
Community Drop-off Location											
Gender (male$_a$/female$_b$)	1	56 723	1.03	[1.01; 1.05]	na	67 682	1.00	[0.98; 1.02]	na	0.029	.045
Age (younger$_a$/older$_b$)	1	89 995	1.03	[1.01; 1.05]	na	38 396	1.00	[0.98; 1.02]	na	0.028	.043

Note. *k* = number of studies, *n* = total number of participants in comparison , Differences and significance testing between the two groups were determined by a Wald-type test.

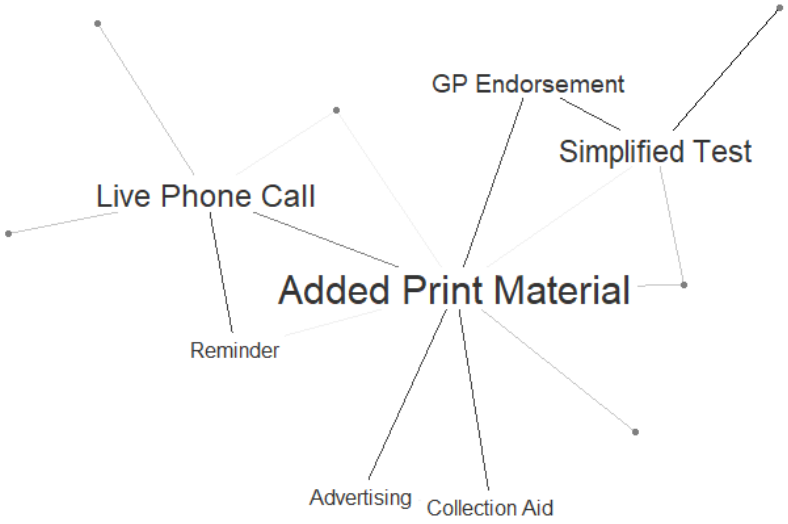
3.4.2. *Evidence for Combining Interventions*

Studies that combined interventions (n=9) were produced in England (n = 3), Scotland (n = 2), USA (n = 2), Australia (n = 1), and Latvia (n = 1). Eight of these studies were RCTs with five showing low risk of bias and three showing some risk of bias (King et al., 1992; Myers et al., 1991; Verne et al., 1993). There was also one non-randomised (White et al., 2015) trial that had a critical risk of bias (see Appendix C).

The sample size of these trials ranged from 588 – 63,441 (median = 1,127). A description of these trials can be found in (see Appendix C). Figure 3.1. shows the co-occurrence network of interventions that have been trialled together. As shown in Figure 3.1, the large majority of combinations included the addition of print materials (n=9). There was no obvious clusters or trend to combine certain intervention types and only in one study were similar intervention strategies combined more than once (Verne et al., 1993). Across these studies, there were 12 comparisons involving one against two interventions, four comparisons involving two against three interventions, and two comparisons of three against four interventions.

Figure 3.1.

Co-Occurrence Network of Trialled Interventions

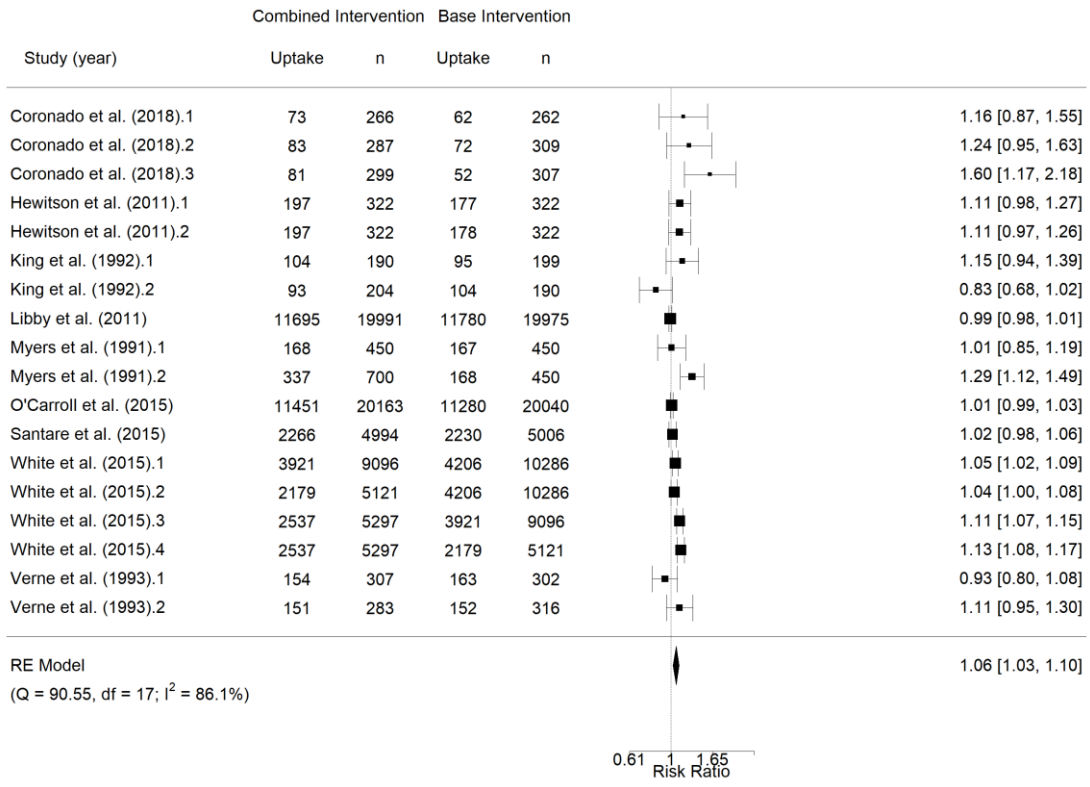


Note. The size of the text represent the relative amount each intervention has been used, with larger texts representing more frequent use. The darkness of the lines depicts how often the interventions have been combined, with darker lines representing a higher frequency. For simplicity, the unlabelled nodes represent interventions that have below the median weight in the network.

Overall, there was a significant increase in participation when they contained an added intervention, *RR* = 1.06, CI [1.03; 1.10]. There was a large amount of heterogeneity, I^2 = 86.1% (see Figure 3.2). As a robustness test, the risk of bias for the included studies was tested for moderating effects. All studies with a low risk of bias were categorised as low and the remaining were categorised as high for this analysis. The results showed a non-significant effect of the risk of bias as a moderator, *QM*(1) = 0.31, *p* =.58. In doing this the level of residual heterogeneity remained similar, I^2 = 83.3%. The Egger's regression test did not show significant small study effects, *p* = .07.

Figure 3.2.

Forest Plot of Trials that Contained Combined Interventions



Note. Effect sizes (RR) are represented in exponentiated terms such that one represents the null effect and greater than one represents greater participation in the trial that combined interventions. Bracketed values are the 95% confidence interval.

As many of these trials added extra print materials when combining intervention strategies and previous research has shown that the addition of print materials does not—by itself—significantly increase participation (Goodwin et al., 2018a), a post-hoc exploratory analysis was conducted to examine the specific effect

of adding print materials to an intervention strategy. Trials were dummy coded as either having the added intervention being the addition of print materials or not. Using this dummy code as a moderator showed not using additional print material as the added intervention significantly increases participation in combined trials, *RR* = 1.09, CI [1.05; 1.13], and this effect was significantly reduced if the additional print materials was the added intervention (*log*)*RR diff* = -0.071, *p* = .030.

3.5. Discussion

The results of this systematic review and meta-analysis highlight potential distribution strategies that CRC screening program organisers can implement to increase participation. Most of the studies reviewed were RCTs with a low risk of bias, thus increasing confidence in the findings. Overall, these results suggest that existing interventions are unlikely to be optimised through the targeting of specific subpopulations such as gender, age, and SES groups, however, combining interventions may have a positive effect in increasing participation.

This review found that the majority of trialled interventions did not have differential effects on participation within gender, age, and SES subpopulations. Meaning, targeting certain subpopulations with specific interventions is unlikely to be a successful strategy to increase participation in nationwide mail-out FOBT programs. There were some exceptions. This review found the use of advance notification letters and the offering of community drop-off locations had greater effects when sent to males over females, with the community drop-off locations also having a greater effect in the younger cohort over the older cohort (the primary study's authors also note greater effect for those indigenous to the area, i.e., Māori and Pacific Islanders people; Sandiford et al., 2018). These effects are promising as these subpopulations often show lower general participation rates (Mansouri et al., 2013; Sandiford et al., 2018). However, the differences in these effects were small; ranging from approximately 1.5 – 2.5%. Further, many countries already send advance notification letters (e.g., Australia and England; AIHW, 2018c; NHS England, 2016), and offering the community drop-off locations to everyone requires no further work than offering it only to a certain subpopulation as the infrastructure remains the same. As such using a targeting strategy with these interventions is not likely to result in heavy savings or be a novel addition to existing programs.

Combining intervention strategies has been trialled in various health behaviour change contexts with mixed results regarding its benefit (Squires et al.,

2014). The current study's findings, however, suggest that in the context of mail-out FOBT screening, distributing more than one intervention with FOBT invitations might be a useful strategy for increasing participation rates. This review found, on average, an additional 2.5% - 3% greater participation within combined intervention trials. Interestingly, the majority of combined intervention trials included the addition of print materials; a largely unsuccessful strategy when delivered independently thus far (Goodwin et al., 2018a). In examining the effect of combining an additional print material strategy to an intervention, this review found doing so significantly reduced the effect of combining intervention strategies. This would indicate that if researchers do combine intervention strategies in the future, they might have greater success if they choose interventions that have been shown to work independently.

Combined interventions may be effective at increasing participation because a multifaceted strategy can address the numerous barriers people report in regard to FOBT screening (Hall et al., 2015). For example, interventions aimed to improve professional performance in a healthcare setting have been found to be more effective if the intervention addressed previously determined barriers (Baker et al., 2010). In the context of mail-out FOBT screening, it remains unknown which set of barriers can be addressed through a multifaceted intervention strategy. It is also unknown if combining interventions has a simple 'dose effect' whereby for every intervention added to a strategy a steady increase in effectiveness is achieved. In order to assess whether there is a consistent dose effect of adding interventions together more factorial randomised trials (e.g., Hewitson et al., 2011) need to be conducted.

Importantly, none of the nine studies that combined interventions provided strong theoretical reasons why these interventions should be combined. Authors do posit theoretical reasons for the efficacy of individual strategies, such as advance notification letters allowing invitees to think about screening before they make a decision when the kit arrives (Cole et al., 2003), but there was no such discussion regarding why certain interventions strategies should be trialled together. As such, the relatively modest improvements made by delivering multiple interventions might reflect interventions that do not complement each other theoretically, with respect to their mechanisms of behaviour change. To ascertain this, a greater understanding of the behaviour change mechanisms responsible for each intervention's efficacy is needed as well as an application of a larger theoretical framework to understand what

behaviour change mechanisms can work synergistically. For example, the Transtheoretical model (TTM) of behaviour change suggests that invitees can be categorised into five stages, precontemplation, contemplation, preparation, action and maintenance, with only the last two stages involving participation. Velicer et al. (2000) argue that different strategies are effective at progressing people through the different stages of behaviour change. Awareness raising interventions (such as GP endorsement letters giving persuasive information from a credible source; Benton et al., 2017) are likely to encourage attitudinal change, thereby leading to contemplation of kit use, whereas stimulus control interventions (such as physical changes to kits) are more suited to people who have made the decision to participate, but have failed to act (Velicer et al., 2000). A multi-faceted approach can therefore address barriers experienced at each stage of change.

3.5.1. *Strengths and Limitations*

This is the first study to use meta-analytic techniques to better understand what distribution strategies are most likely to be successful at increasing participation in mail-out FOBT programs. This study was able to go beyond broad effects and examine how intervention types work for different subpopulations. While past research has focused on the effect of singular interventions, this study was able to build on these findings by examining the effects of combined interventions. This type of information is valuable for the organisers of mail-out FOBT programs who wish to use these interventions to increase participation rates. However, some limitations are worth noting. Not all studies reported uptake rates within intervention arms for the separate subpopulations. This meant that it was not always possible to assess the intervention effect within these subpopulations. While best efforts were made to obtain further data from the researchers, we were unable to gather this information directly for 13 studies. This highlights a need for authors to retain and make data available for researchers wanting to conduct such investigations, or to routinely report on participation rates across common subpopulations. Eight pooled RRs showed some signs of publication bias when significant small study effects were detected. This may largely be attributable to the subset of trials included in this analysis that fit the specific purpose of the study, however, the conclusions drawn from the pooled RRs should still be made with caution. Finally, there were also moderate to large levels of heterogeneity found for the majority of RR estimates.

This leaves open the question as to what real differences between studies would lead to this level of heterogeneity.

3.5.2. *Conclusion*

The determinants of a person engaging in mail-out FOBT programs are complex and multi-faceted (Hall et al., 2015). It is therefore not surprising that a one-size-fits-all solution has yet to be found. This review found little evidence that targeting interventions at specific subpopulations will improve overall mail-out FOBT participation rates. Adding intervention strategies together tended to improve participation rates in the reviewed studies, however, this is not the case for all interventions. Specifically, our results show that adding some interventions (e.g., additional print materials) will reduce the effectiveness of combining interventions. Therefore, national bowel cancer screening programs are unlikely to see large increases in participation through targeted distribution of interventions, rather intervention developers and policy makers should focus their efforts on creating interventions that combine several complimentary strategies.

CHAPTER 4: BACKGROUND FOR STUDY TWO

The results of study one indicated that combining intervention types together generally led to increased levels of effectiveness, and therefore, a combined intervention approach may be more suitable than a single intervention approach in the context of mail-out bowel cancer screening interventions. It was also found that the selection of intervention types mattered for this strategy, as using some types of interventions (i.e., using additional print material) attenuated the effect. However, there are several limitations within the current literature that prevent policy makers and intervention designers from capitalising on the benefits of a combined intervention strategy. Currently, psychological theory is underutilised in the development of combined intervention strategies. This becomes an issue for intervention selection as it is hard to know what interventions need to be combined to create a multifaceted strategy that targets all aspects of behaviour change. Further, it is not clear what the active components are within these successful intervention strategies or what behavioural mechanism underlies the behaviour change they bring about. A greater understanding of the specific active components and behaviour change mechanisms within successful interventions will allow intervention designers to identify the aspects of interventions that should be incorporated into their design (Pawson et al., 2004). Therefore, the aims of study two were to identify the effective components within behaviour change strategies, along with the behavioural mechanisms responsible for change, and to use psychological theory to understand how intervention components should be combined with one another to be as effective as possible. The purpose of chapter 4 is to introduce the research methods, frameworks, and background literature required to reach the aims of study two.

4.1. Realist Review Methods

Realist reviews are a relatively new approach to synthesising research findings. They are a theory-driven approach that aims to explain *why* an intervention works as opposed to *if* an intervention works. As such, realist reviews go beyond the question of what works, to "what is it about this program that works for whom in what circumstances?" (p. 22, Pawson et al., 2005). The goal of realist reviews is to understand the mechanisms by which interventions bring about behaviour change (or fail to do so) and explore what specific contextual and implementation factors affect the overall success of the intervention strategy (Wong et al., 2012). To achieve this, realist reviews use psychological theory and behaviour change frame works to guide the creation of explanatory descriptions of how interventions work and use a broader scope of information (such as government reports and intervention materials) to refine these explanatory descriptions and understand the role context has in an intervention's success (Pawson et al., 2004). Findings from realist reviews are often used to supplement findings from more traditional research synthesis such as Cochran reviews, SLRs, and meta-analyses; an example of which is given below.

4.1.1. *Illustration of Realist Review in Practice*

An illustration of the utility of realist reviews can be seen in the evaluation of school feeding programs. In this example, Kristjansson et al. (2007) conducted a Cochrane review of the outcomes associated with school feeding programmes that provide their pupils with food during school days in disadvantaged areas (Kristjansson et al., 2007). It was found that school feeding programmes had a positive impact and increased the children's weight, height, math ability, and attendance. However, there were varying levels of effectiveness across different feeding programmes and the wide range of social settings, cultures, and political contexts in which these programmes took place makes generalising any of the primary study's findings to future and different contexts difficult. The methods used in the Cochrane review could not describe how these feeding programmes brought about these improvements and what crucial factors dictate the varying success of these feeding programmes (Greenhalgh et al., 2007). Therefore, the Cochrane review finding, that on average feeding programmes were successful, was not enough to inform policy makers on how feeding programmes should be implemented in future (Greenhalgh et al., 2007).

By conducting a subsequent *realist review*, Greenhalgh et al. (2007) were able to construct explanatory models of why some specific feeding programmes were more successful than other feeding programmes and describe the mechanisms by which feeding programmes induced positive change within the school children. The realist review synthesised data regarding intervention delivery (e.g., intensity and timing), comments made by staff regarding changes made to the feeding programmes, the history and cultural factors of the school in which the program took place, and any mechanism or theory postulated by the authors of the primary studies explaining what facilitated and hindered the feeding program's success. In short, Greenhalgh et al. (2007) found that feeding programmes are most likely to be successful when the target group has a clear nutritional deficiency, is pilot tested with the children to increase their acceptability towards the program, and measures are in place to ensure the food is actually being consumed. Additionally, the key mechanisms uncovered by Greenhalgh et al. (2007) was that school feeding programmes brought about positive change within children by correcting long term nutritional deficiencies and improved children's performance at school by creating a pleasant social environment where the children eat together as well as reducing distractions caused by short-term hunger.

Thus, the combination of the Cochran review and the realist review allowed a comprehensive understanding of school feeding programmes and how they should be implemented. The quantitative Cochran review established that feeding programmes can indeed produce positive change within school cohorts in disadvantaged areas and the realist review showed the important contextual factors that need to be considered and highlighted the mechanisms new feeding programmes should aim to implement to increase effectiveness. This level of understanding is needed if policy makers want to effectively incorporate interventions strategies into established mail-out FOBT screening programs to increase participation.

In the remainder of this chapter, the behaviour change frameworks and psychological theories that were used in study two will be introduced. It will be explained how they can be used to describe the mechanisms responsible for behaviour change in FOBT interventions and how they can guide the construction of new multifaceted behaviour change strategies.

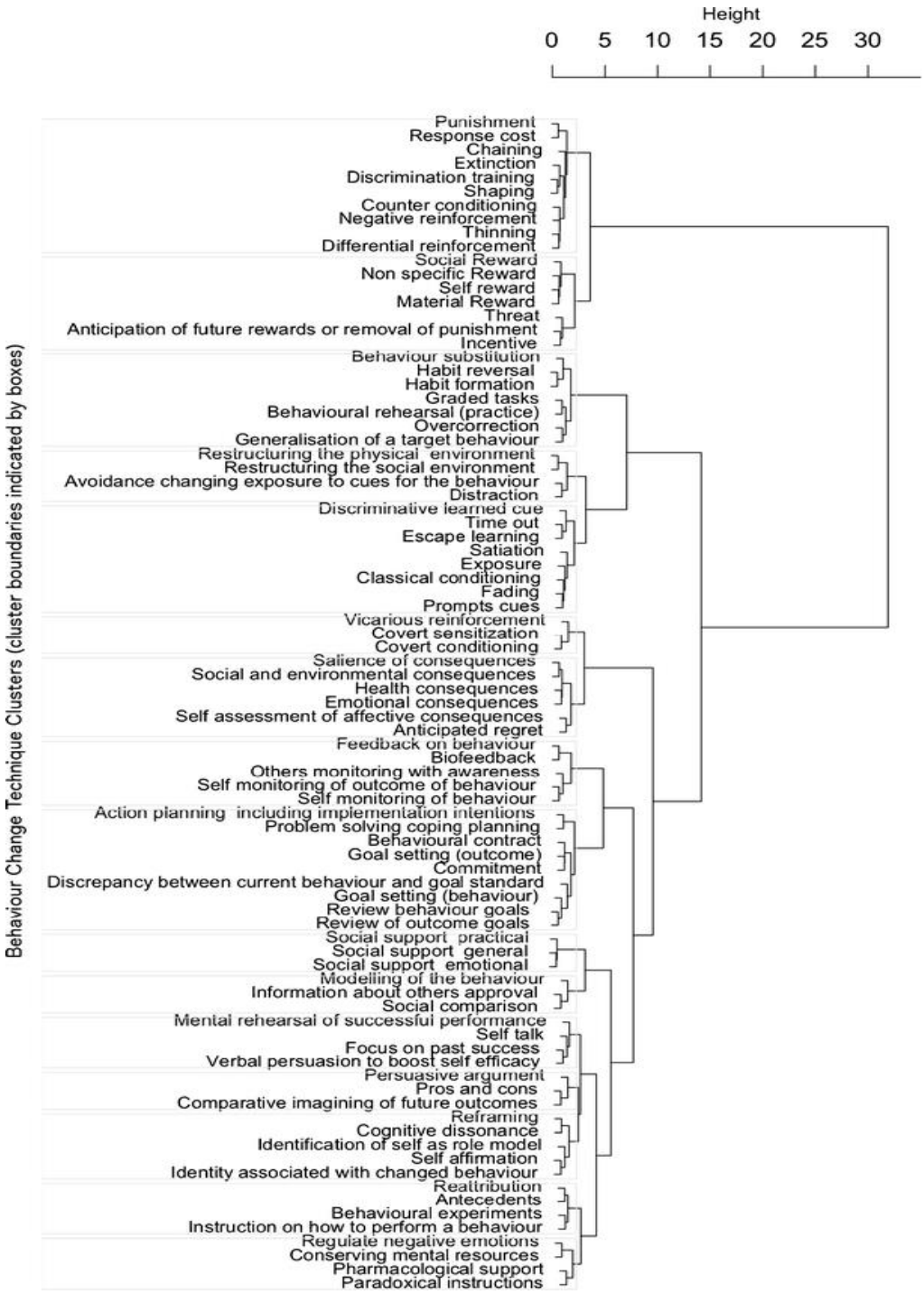
4.2. Behaviour Change Techniques and Mechanisms of Action

One obstacle to creating a multifaceted behaviour change strategy is deciding what aspects of interventions should be combined (Michie et al., 2013). For example, two separate interventions to increase FOBT kit use provided an endorsement statement from the invitee's personal GP (Hewitson et al., 2011; Hirst et al., 2017). While similar language was used to describe the different interventions, they were in fact quite different regarding their implementation. One GP endorsement intervention focused on delivering health messages (Hewitson et al., 2011) while the other GP endorsement intervention acted only as a reminder to complete and return the kit (Hirst et al., 2017); with only the former resulting in a significant increase in participation. Without a deeper understanding of what the active elements of each intervention strategy are, it becomes difficult to select successful strategies for FOBT screening programmes.

One popular framework designed to reliably identify the active elements (otherwise known as Behaviour Change Techniques; BCTs) within behaviour change interventions is known as the BCT-taxonomy v1 (Michie et al., 2013). By bringing together six different classification systems, the BCT-Taxonomy v1 contains 93 non-redundant BCTs that can be hierarchically clustered into 16 groups (e.g., the BCTs 'imaginary punishment', 'imaginary reward', and 'vicarious consequences', are grouped within the 'covert learning' BCT group). These BCT clusters can be found in Figure 4.1. Each BCT within the taxonomy has a unique definition that describes an "observable, replicable, and irreducible component of an intervention designed to alter or redirect causal processes that regulate behaviour" (p. 23, Michie et al., 2013). By using this taxonomy, each intervention strategy can be accurately described in terms of its individual components. In this manner, interventions can either be subtly changed to fit a new context without changing its active elements or interventions can more accurately be categorised and compared using this agreed upon language (Michie et al., 2013).

Figure 4.1.

Dendrogram of BCT Clusters Reported in Michie et al. (2013)

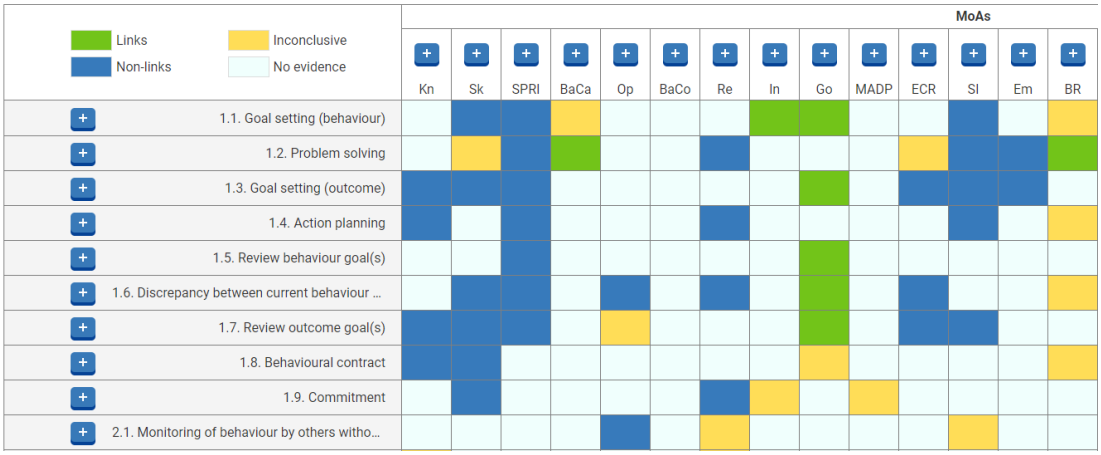


Online training is available to aid the use of the BCT-taxonomy v1. The training helps users familiarise themselves with each item within the taxonomy, provides definitions for each BCT, and gives examples for users to practice identifying and coding BCTs from real-world research extracts. This online training has been shown to improve the accuracy of BCT identification and labelling, increase the reliability of the tool, instil confidence in the users, and improve agreement with behaviour change experts (Wood et al., 2014).

While the BCT-taxonomy v1 can accurately describe interventions that bring about behaviour change, it cannot describe the underlying mechanism that is responsible for the behaviour change; otherwise known as the mechanism of action (Michie et al., 2017). The mechanism of action can be considered as the mediating factor between the intervention and behaviour change (Johnston et al., 2018). The *Theory and Technique tool* is a framework that explicitly links BCTs to their possible mechanism of action and it was created to facilitate intervention design. Firstly, it can enhance the evaluation of previous research via an improved understanding of how interventions bring about behaviour change. Secondly, it shows which BCTs should be utilised to elicit certain mechanisms of action (Carey et al., 2018). The Theory and Technique tool was created through a combined effort of literature synthesis and expert consensus regarding theoretical links between BCTs and mechanisms of action (Carey et al., 2018). The triangulation of the findings of these two research methods resulted in the current Theory and Technique tool (Johnston et al., 2018). An excerpt from the theory and technique tool can be seen in Figure 4.2.

Figure 4.2.

A Subset of the Theory and Technique Tool



Note. Theory and technique tool can be found at https://theoryandtechniquetool.humanbehaviourchange.org/. The column on the left shows each BCT and the top row show each mechanism of action. The colours of the joining cells show the level of evidence for each link between that columns BCT and that rows mechanisms of action.

The tool itself shows the level of evidence for all possible links between 74 BCTs and 26 mechanisms of action, with 1,924 total possible links (Johnston et al., 2018). Through the convergence of the literature review and expert consensus panel, each combination of BCT and mechanism of action was classified as either being

linked, definitively having no link, being inconclusive, or not having any evidence (Carey et al., 2018; Johnston et al., 2018). Using this tool researchers creating new interventions can decide which mechanisms of action are most likely to be effective and choose the linked BCTs best suited for the context and any behaviour change model they may be using. Conversely, researchers wanting to better understand how previous interventions brought about behaviour change can identify which BCTs were used within the intervention than use the tool to find the linked mechanism of action (Johnston et al., 2018).

Currently, neither the BCT-taxonomy v1 nor the Theory and Technique tool have been used in describing intervention design or for synthesising evidence across intervention trials in the context of FOBT screening participation. By using this framework to articulate the specific BCTs and mechanisms of action that have been successful at increasing mail-out FOBT participation, new behaviour change strategies can be created to retain the active elements of past trials with the flexibility to suit the new context in which they are being applied. Therefore, all previous mail-out screening interventions will be coded using this framework in study two to aid the translation of successful BCTs and mechanisms of action into practice.

4.3. Behaviour Change Theory

While identifying which BCTs and mechanisms of action are effective at increasing participation in FOBT screening programmes will aid the translation of research findings into practice, they do not provide a framework for how they should be combined with one another. Psychological and behaviour change theory can provide such a framework. When designing new and effective behaviour change strategies, research has shown that interventions based on psychological theory are more effective than interventions that have no theoretical bases (Glanz & Bishop, 2010). Further, those that use multiple concepts within these theories to build multifaceted intervention strategies are also associated with greater effects (Glanz & Bishop, 2010). Psychological theories and models of behaviour change can be used to firstly, explain the influential factors involved in many health behaviours, and secondly, direct the construction of interventions such that they target all of these influential factors (Michie et al., 2017). However, there are many different models of health behaviour change and selecting the most appropriate one for any given health behaviour is often challenging (Glanz & Bishop, 2010).

4.3.1 *Types of Behaviour Change Theory*

Models of behaviour change can be broadly categorised as either continuum-based or stage-based (Lippke & Ziegelmann, 2008; Schwarzer, 2008). Continuum-based models attempt to find a parsimonious set of variables that predict intentions to engage in the specified health behaviour (e.g., attitudes, subjective norms, and perceived behavioural control predict intentions in the Theory of Planned Behaviour; Ajzen, 1991). The goal of interventions within these continuum-based frameworks is to move people along these predictors to increase intentions which in turn increases the likelihood of a person engaging in the health behaviour (Schwarzer, 2008). A major limitation of these models is that there is often a gap between a person's level of intention and a person's actual behaviour, with intention only explaining approximately 28% of the variation in behaviour (Sheeran, 2002). Meaning increasing people's intention is often not enough to change people's behaviour.

Alternatively, there are stage-based models. These models describe behaviour change as a person progressing through a series of stages, with each stage being qualitatively different from the others, and each stage having specific barriers and processes. For example, the Transtheoretical model typically breaks health behaviours into five stages (precontemplation, contemplation, preparation, action, and maintenance; Prochaska & Velicer, 1997). Here the gap between developing intentions and performing the behaviour is an explicit part of the model. Interventions designed within these stage-based frameworks aim to identify what behavioural stage the person is in and deliver a stage-specific intervention to help the person overcome the specific barriers that are associated with that stage of change (Prochaska & Velicer, 1997).

Some argue that health behaviours are often more complicated than the stage-based models suggest and that stage-based models rarely consider the psychological and sociological factors that affect health behaviours (Adams & White, 2004). Additionally, for a stage-based intervention to be effective, there needs to be a valid and reliable tool available to correctly identify what stage of change a person is in so the appropriate stage-based intervention can be delivered. While some tools have been created for this purpose (e.g., Calfas et al., 1997), their psychometric properties have not been confirmed causing doubt as to how accurately they can classify individuals' into their correct stage of change (Adams & White, 2004).

A modern alternative to both continuum-based and stage-based theories that addresses their respective limitations, is a model which combines both. The Health Action Process Approach (HAPA) models behaviour change as two stages, a motivational stage where a person develops intentions to perform a behaviour and then a volitional stage where the person translates these motivations into action (Schwarzer, 2008). However, this model also uses a different set of continuum-based predictors, for each of the motivational and volitional stages separately (Schwarzer, 2008). In this manner, the HAPA model is able to delineate between the intentions and actions stages (what is missing in continuum-based models) as well as incorporate psychological and sociological factors that are absent in stage-based models. Research into the experience of FOBT screening invitees—particularly that of invitees who do not participate—does indicate that the HAPA model may be an appropriate framework to describe the process of FOBT screening and one from which new multifaceted intervention could be designed.

It has been suggested that broadly speaking, people who do not complete and return their FOBT kits can be categorised into two distinct groups. These are, those who know about the program but refuse to participate and those who intend to participate but certain barriers prevent them from doing so (Goodwin et al., 2019b; Hall et al., 2015; Palmer et al., 2014). Invitees who simply refuse to participate show low levels of motivation to screen. They tend to doubt the need for, and validity of, mail-out FOBT screening as well as report more negative reactions to receiving the testing kits (e.g., feeling old when it arrives in the mail). In contrast, invitees who intend to participate, but do not, report having high motivations to complete and return their FOBT kit, however, volitional issues involving forgetting and procrastinating tend to prevent their participation (Goodwin et al., 2019b; Hall et al., 2015; Van Rijn et al., 2008). These two "sticking points" for nonparticipants can be directly related to the two stages theorised in the HAPA model, that being the motivational stage and volitional stage respectively. As such the HAPA model is a strong candidate for a theoretical framework as the invitee's negative experiences align with what is already posited in the model. The remaining of this chapter provides a deeper account of the HAPA model and evidence regarding its utility.

4.3.2. *The HAPA Model*

According to Schwarzer (2008), the HAPA model was developed by integrating social-cognitive theory (Bandura, 1986), the theory of reasoned action

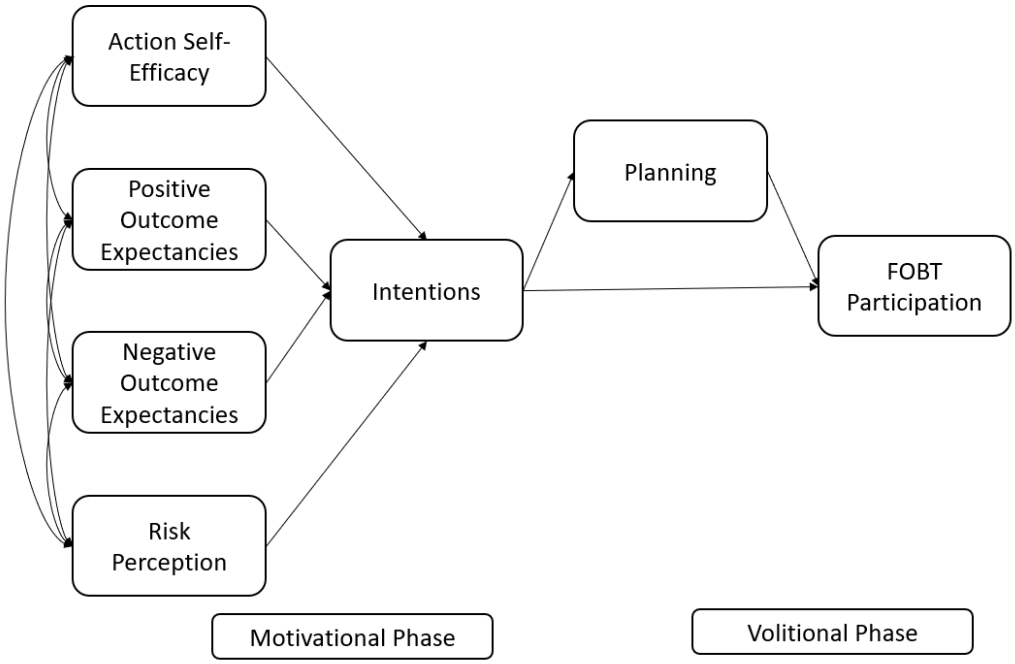
(Fishbein & Ajzen, 1977), and the volitional theories of Heckhausen and Gollwitzer (1987) and Kuhl (1985). One of the main goals of the HAPA model was to incorporate mediating factors to account for the gap between high intentions and action; a crucial aspect missing from the health behaviour models that came before it (Schwarzer, 2008). To do this, the HAPA model argues that engaging in a health behaviour is a process consisting of first a motivational stage, followed by a volitional phase.

Those in the motivational stage of change are in the process of developing intentions as to whether they will perform the behaviour or not (in this case complete and return their FOBT kit). The HAPA model posits that there are four "social-cognitive" predictors that are influential in this motivational stage. For the context of mail-out FOBT screening behaviour, these include their perceived susceptibility of being affected by bowel cancer (known as risk perception); beliefs of positive outcomes occurring if they participate in the screening program (e.g., improved survivability of a bowel cancer diagnosis; known as positive outcome expectancies); beliefs about negative outcomes occurring if they participate in the program (e.g., having to be in close contact with faecal matter; known as negative outcome expectancies); and beliefs regarding their capability of completing the FOBT kit (known as action self-efficacy). When one has strong intentions to participate, they are thought to be past the motivational stage and enter a volitional stage where intentions are transformed into action (i.e., completing and returning the FOBT kit). In this volitional stage, the level to which the person has an effective plan for how they are going to perform the behaviour (i.e., action planning) and to overcome the practical barriers associated with the behaviour (i.e., coping planning) are the influential factors that mediate the relationship between intentions and action (Schwarzer et al., 2011). It should be noted that the HAPA model is typically used to describe health behaviour change where the behaviour should be ongoing or regular (e.g., increasing physical daily activity; Parschau et al., 2014). As such, factors of the HAPA model that relate to the maintenance of continuing the behaviour are not applicable in the context of mail-out FOBT screening, where although it is hoped that the recipient will continue to participate in future rounds of screening, as such a long-time elapses between FOBT kit invitations (i.e., two-years), it is considered here as a 'one-off' behaviour. A truncated version of the HAPA model has been

previously applied for other such ‘one-off’ health behaviours (Ernsting et al., 2013) and will be used in study two and three (see Figure 4.3).

Figure 4.3.

Truncated Version of the HAPA Model



4.3.2.1. The HAPA Model Explaining Behaviour. The two-stage process specified in the HAPA model, along with the psychological determinants within each stage, has shown utility in explaining a wide range of health behaviours. Typical applications of the HAPA model aim to describe the uptake and maintenance of enduring health behaviours, in particular, increased levels of physical activity. Schwarzer et al. (2007) found in a longitudinal study of a general population sample that the factors and processes of the HAPA model could account for 21% of the variance in physical activity and that planning was a key mediating factor. The ability for the HAPA model to explain variation in levels of physical activity is very generalisable as it has shown similar utility within various subpopulations such as adults with obesity (Parschau et al., 2014), people with multiple sclerosis (Chiu et al., 2011), and those with type 2 diabetes mellitus (Rohani et al., 2016a). The HAPA model can also successfully explain behavioural variation in a wide range of other enduring health behaviours including, but not limited to, hygienic food handling behaviour (Mullan et al., 2010), fruit and vegetable intake (Richert et al., 2010), seatbelt use (Schwarzer et al., 2007), and dental flossing (Schwarzer et al., 2007). In

addition to enduring health behaviours, the HAPA model has been successfully used to explain the one-off health behaviour of receiving a flu vaccination (Ernsting et al., 2013). A meta-analysis of 105 samples (95 studies) was conducted by Zhang et al. (2019) to assess the effectiveness of the HAPA model across the literature. The meta-analytic structural equation modelling showed, across studies, that the HAPA model had an acceptable fit, could explain 17.5% of behaviour, and could explain 26.1% of behavioural intention. The inter-correlations among HAPA factors were found to be small to medium with the exception of those relating to risk perception, which had small effects with confidence intervals that overlapped zero (i.e., non-significant). The effect planning had on bridging high intentions with actual behaviour was also found to be consistent and significant (Zhang et al., 2019). This study provided comprehensive evidence that the HAPA model can be used to explain a wide range of health behaviours.

The application of the HAPA model to explain behaviours related to cancer screening is limited. One study of Iranian women did find that the HAPA model could explain 60% of the variation in mammography screening behaviour (Pourhaji et al., 2021). The HAPA model was also found to predict both testicular and breast self-examinations (Barling & Lehmann, 1999; Luszczynska & Schwarzer, 2003). Given the wide range of health behaviours the HAPA model can account for, further application of the HAPA model in the context of cancer screening is warranted.

4.3.2.2. HAPA Model-Based Interventions. The HAPA model is now beginning to play a role in health intervention design. One multicomponent intervention based on the HAPA model was significantly more effective than a control in promoting factors relating to self-management of health care for those with tuberculosis (e.g., medication adherence and promotion of healthy lifestyles; Chen et al., 2020). The HAPA intervention facilitated positive outcome expectances through informing the tuberculosis patients of the health benefits of maintaining medication adherence and healthy lifestyle (i.e., balanced diet and regular exercise) and promoted self-efficacy and planning by including a self-management therapy session where individuals with their therapist established short-term, medium-term, and long-term plans for how they are going to maintain their medication adherence and healthy lifestyle. The control group in this study only received an education booklet regarding health care self-management. Chen et al. (2020) found that those in the intervention group had higher motivations for self-management, had more

confidence in their self-management abilities, and had a better plan for how they were going to maintain their self-management.

Another example of a HAPA based intervention aimed to reduce sedentary behaviour in university students. The intervention had a one-on-one session, where information regarding the risks of sedentary behaviour and positive outcomes of reduced sedentary behaviour were provided to them (i.e., risk perception and positive outcome expectancy components). However, the main focus of this session was to have the participants complete an action plan specifying when and how they are going to reduce sedentary behaviour (i.e., planning component). Compared to a passive control group, those who received the HAPA based intervention had significantly more time standing and stretching (Dillon et al., 2021). Crucially, for both these interventions, it was key that the intervention contains both motivational components to have the participants engage in the health behaviour and volitional components where the participants planned how they were going to do the health behaviour and how they were going to overcome any barriers that arise.

4.3.2.3. HAPA Model Conclusions. The HAPA model has demonstrated its utility in describing a variety of health behaviours and provides a framework from which new multifaceted interventions can be designed. Importantly, the HAPA model provides clear behaviour change targets for mail-out screening interventions whereby interventions should aim to increase the invitee's motivation to participate and also implement planning strategies that lower the specific volitional barriers to FOBT screening. These efforts together will cultivate high FOBT screening intentions and aid the translation of these intentions into participatory action. No interventions to increase participation in FOBT kit use have been specifically designed following the HAPA framework. However, we might expect that previous interventions containing BCTs that incidentally target the social-cognitive factors of both the motivational and volitional stages of FOBT screening, should have the highest likelihood of being successful when compared to other interventions that only target one stage of change. As such, the aim of study two was to assess how successful interventions were if they targeted both stages of change specified in the HAPA model.

4.4. Chapter 4 Conclusions

The evidence thus far indicates that combining interventions will be an effective approach for future intervention design. However, due to the lack of behaviour change theory reported on in the intervention literature, it is difficult to determine which aspects of interventions should be used and how should they be combined. By using realist review methodologies, behaviour change frameworks and theories can be applied to answer these questions. Specifically, using the BCT taxonomy-v1, the theory and technique tool, and the HAPA model within a realist review will allow for the identification of the active elements within each intervention, establish the mechanisms by which these interventions bring about change, and evaluate the effectiveness of targeting multifaceted intervention strategies at either (or both) the motivational and volitional stages of behaviour change.

CHAPTER 5: STUDY TWO (PUBLISHED ARTICLE)

Myers, L., Goodwin, B., Ralph, N., Castro, O., & March, S. (2020). *Implementation Strategies for Interventions Aiming to Increase Participation in Mail-Out Bowel Cancer Screening Programmes: A Realist Review.* Frontiers in oncology, 10, 1799. doi: 10.3389/fonc.2020.543732 (Q1: Oncology, H = 71)

5.1. Abstract

Background: Bowel cancer is the third most commonly diagnosed cancer and the third most common cause of cancer-related death with 1,849,518 new cases of bowel cancer diagnosed, and 880,792 deaths reported globally in 2018 alone. Survival can be improved through early detection via national mail-out bowel cancer screening programs; however, participation remains low in many countries. Behaviour change is therefore required to increase participation. This realist review aims to (a) identify the BCTs used in each intervention, (b) understand the mechanisms of action responsible for the BCTs effectiveness, and (c) apply a behaviour change model to inform how BCTs and mechanisms of action can be combined to increase screening participation.

Methods: We systematically reviewed the literature for interventions aiming to increase participation in mail-out bowel cancer screening. We used a four-stage realist synthesis approach whereby; (1) interventions were extracted from each study; (2) BCTs applied in each intervention were identified and coded using the BCT taxonomy-v1; (3) the Theory and Techniques tool was used to link BCTs to their mechanisms of action; and (4) BCTs and mechanisms of action were categorised according to their effectiveness and what Health Action Process Approach (HAPA) stage of change they would affect.

Results: We identified 68 intervention trials using 26 unique BCTs and 13 mechanisms of action to increase participation. Sixteen BCTs and 10 mechanisms of action were identified within the interventions that successfully increased participation rates. Interventions targeting both stages of the HAPA model had a higher success rate (80%) than those targeting one stage of change (51%). When targeting only one stage, interventions targeting the volitional stage had a higher success rate (71%) than interventions only targeting the motivational stage of change (26%).

Conclusion: Importantly, this review identified a suite of BCTs and mechanisms of action that are effective for increasing participation in mail-out bowel cancer

screening programs. With increased participation in bowel cancer screening leading to improved survival, our findings are key to informing the improvement of policy and interventions that aim to increase screening using specific strategies at key stages of health decision-making.

Keywords: *Bowel Cancer Screening, HAPA, behaviour change techniques, Realist Review.*

5.2. Introduction

Bowel cancer has the third-highest incidence rate and the third-highest mortality rate of all cancers worldwide (International Agency for Research on Cancer, 2020). If detected early enough approximately 90% of cases are cured (AIHW, 2019b). To aid in early detection population-based screening are now commonplace in developed countries. At least 24 countries have now adopted national bowel cancer screening programs including Australia, Canada, and the UK, with faecal occult blood testing (FOBT) the most effective population screening tool for detecting early signs of bowel cancer (AIHW, 2019b; De Klerk et al., 2018; Navarro et al., 2017).

Typically, FOBT kits are sent directly to the recipient's homes (Navarro et al., 2017). Invitees are asked to collect small stool samples using the FOBT kit provided and mail the samples back for processing (Schreuders et al., 2015). It is recommended that those over 50 years old (i.e., the average-risk population) do this once every two years (Navarro et al., 2017). If the test is positive, the individual is then referred to further diagnostic tests such as colonoscopy and biopsy (AIHW, 2018c; NHS England, 2016). This two-stage process is highly cost-effective and sensitive at detecting bowel cancer (Ananda et al., 2016; Wong et al., 2008).

Nevertheless, low participation in FOBT screening is frequently reported, with countries such as Australia, France, Czech Republic, Germany, Latvia, and Croatia reporting less than one in two invitees return the test (AIHW, 2018c; Klabunde et al., 2015; Navarro et al., 2017; Swan et al., 2012). Correspondingly, bowel cancer mortality remains disproportionately high in these countries, in part due to poor screening uptake and later diagnosis and treatment (Lew et al., 2017). Increasing participation is, therefore, a common focus in the literature with a range of interventions trialled. Findings from two recent systematic reviews (Goodwin et al., 2019a; Myers et al., 2019) highlight four key implications for improving the implementation of bowel cancer screening programs:

(a) Some interventions consistently increase participation rates (e.g., advance notification letters, simplified testing procedures, telephone contact, and use of General Practitioner [GP] endorsement) but their effects are small to moderate (Goodwin et al., 2019a).

(b) There are large levels of heterogeneity in these effects due to the variation in implementation (Goodwin et al., 2019a).

(c) Using multiple intervention strategies is associated with larger effects (Myers et al., 2019).

(d) Little is known about how these interventions work and an overarching framework for how interventions should be combined has yet to be established (Myers et al., 2019).

These heterogeneous and modest intervention effects are unsurprising given the large variation in the reasons provided by invitees for non-participation. Reasons for non-participation are diverse and include (but are not limited to): emotional disgust in the process, seeing the test as unnecessary, procrastination, and fear of a cancer diagnosis (Goodwin et al., 2019b; Hall et al., 2015; Palmer et al., 2014). Studies have also noted distinct groups of people within those choosing not to participate in FOBT screening, those that have no motivation to do the test altogether, and those that intend to do the test but do not, often due to procrastination, forgetting, or inconvenience (Goodwin et al., 2019b; Hall et al., 2015). Thus, for interventions to be effective in population-based screening programs, they need to overcome various and multiple barriers to have the greatest effect and facilitate screening for distinct groups of people (Myers et al., 2019). This can be systematically accomplished by establishing a comprehensive behaviour change framework to address the nuances of nonparticipation in FOBT screening programs.

Policymakers and organisers of mail-out FOBT screening programmes must make use of suitable evidence-based interventions to increase participation. However, evidence gaps are hindering these efforts. Firstly, differences in how interventions are described in the literature make it difficult to decide which elements are the “active ingredients” (otherwise known as behaviour change techniques; BCTs) and should be incorporated into national screening programs. For example, two separate interventions to increase FOBT kit use provided an endorsement letter from the invitee’s personal GP (Hewitson et al., 2011; Hirst et al., 2017). While seemingly similar, one letter focused on delivering health messages as the endorsement (Hewitson et al., 2011) while the other acted only as a reminder to return the kit (Hirst et al., 2017); with only the former significantly increasing participation rates. This demonstrates the need to go beyond assessing if an intervention as a whole can significantly increase participation rates, to identifying and evaluating the individual intervention components that are responsible for

behaviour change. In this manner, the most effective intervention components can be established and implemented within national bowel cancer screening programs.

Secondly, knowing that an intervention component can bring about behaviour change does not necessarily assist in identifying the underlying behavioural mechanisms responsible for the behaviour change; with these being known as mechanisms of action (Michie et al., 2017). These mechanisms of action can be seen as the mediating factor between the intervention itself and the behaviour change (Carey et al., 2018). It is important to understand the mechanisms of action by which the interventions work so adaptations can be made to fit the given context and effectively design new interventions (Carey et al., 2018). Identifying the effective mechanisms of action is of additional importance in the context of FOBT screening as these interventions predominately involve sending extra information to the invitees. Previous research has shown that an overload of the information sent to invitees can result in a decrease in FOBT screening participation (Watson et al., 2013). It is therefore important to make the most efficient use of any materials sent to invitees. For example, providing health information about bowel cancer as an intervention may work through multiple mechanisms; such as increasing the invitee's perception of the risk of developing the disease and/or increasing the invitee's belief that they can take preventative action. If only one of these mechanisms are likely to bring about behaviour change, interventions should focus on delivering messages that evoke that one mechanism and disregard superfluous information-based interventions that may lead to an information burden that produces a counter-active effect.

One framework that has been constructed to address these issues of intervention reporting and discerning their related mechanism of action is the combined use of the BCT taxonomy-v1 (Michie et al., 2013) and the Theory and Technique tool (Carey et al., 2018; Johnston et al., 2018). The BCT taxonomy-v1 is a comprehensive list of BCTs that have been trialled in health behaviour interventions. It was designed to create an agreed-upon language that can be used to describe the active components within interventions (Michie et al., 2013). These BCTs can be linked to certain mechanisms of action using The Theory and Techniques Tool (*Theory and Technique Tool*, 2019). mechanisms of action describe the process by which these BCTs bring about behaviour change (Carey et al., 2018; Johnston et al., 2018). This combined framework allows for a systematic and reliable way to

describe the active elements within intervention strategies and understand *how* interventions bring about behaviour change.

It is also important to consider strategies within a larger theoretical framework to identify which BCTs and mechanisms of action can be used to construct an effective multifaceted intervention. When designing new and effective behaviour change strategies, research has shown that interventions based on psychological theory can be more effective than interventions that have no theoretical bases; with those that target multiple constructs within these theories being even more effective (Glanz & Bishop, 2010). One prominent framework is the Health Action Process Approach (HAPA) which models behaviour change as two stages; first, a motivational stage where people develop intentions to engage in a behaviour, then a volitional stage where people translate these intentions into behaviour (Schwarzer & Luszczynska, 2008). For example, in the context of FOBT use, recipients who refuse to participate would be described as being in the motivational stage whereas those who wish to screen but have not due to procrastination would be described as being in the volitional stage. According to the HAPA model BCTs and mechanisms of action can work synergistically when they facilitate change across both the motivational and volitional stages of change (Schwarzer et al., 2010). To date, trials that have combined intervention strategies (i.e., multiple BCTs and mechanisms of action) did so without reporting any theoretical grounds for combining those specific interventions together (Myers et al., 2019). Greater use of behaviour change theory could assist in developing an effective intervention strategy that could bring about substantial improvements in bowel cancer screening participation and subsequently reduce the burden associated with this disease.

5.2.1. *Aims*

This realist review aims to understand the behavioural mechanisms that are effective in increasing screening participation and identify what combination of BCTs might work most effectively. Specifically, this review will identify all trials that reported on an intervention aiming to increase participation in mail-out FOBT screening programmes. The objectives are to:

1. Identify the specific BCTs that have successfully been used within interventions.

2. Link these BCTs with mechanisms of action to understand the potential process of behaviour change in screening participation.
3. Use the HAPA stages of change to examine what combinations of BCTs and mechanisms of action tend to be effective.

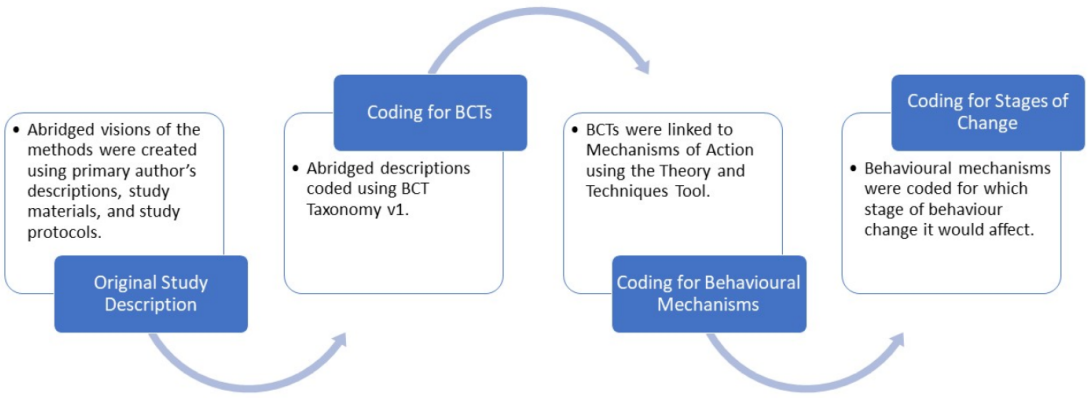
5.3. Method

The current research aims were addressed using a realist synthesis methodology. Rather than focusing on making judgments about *if* an intervention works (like traditional systematic reviews and/or meta-analysis), a realist review is more *explanatory* in nature and uses a generative model to infer *how* an intervention brings about behaviour change (for a full description of this technique see Pawson et al., 2005). Realist reviews go beyond the question of what works, to "what is it about this program that works for whom, in what circumstances?" (p. 22, Pawson et al., 2005). Consequently, findings from realist reviews tend not to be concise, such as meta-analytic point estimates, but rather the findings are complex, intricate, and holistically address the multi-factorial nature of health behaviours (Pawson et al., 2004).

The Realist and Meta-narrative Evidence Synthesis: Evolving Standards (RAMESES) guidelines were used to conduct this review (Wong et al., 2013). See Appendix D for the RAMESES II reporting standards for the realist evaluations checklist. After the systematic search process was complete, we adopted a novel four-stage realist synthesis approach to identify what makes an intervention successful at increasing participation in mail-out FOBT screening programs and how they bring about behaviour change (depicted in Figure 5.1).

Figure 5.1.

Four-Stage Realist Synthesis Approach



5.3.1. *Search Strategy and Screening*

The search strategy followed the same procedure as a 2018 systematic review of interventions aiming to increase participation in mail-out FOBT screening (Goodwin et al., 2019a) with an updated date range to include dates up to the 20th of June 2019. Included studies (a) reported on interventions aimed at improving participation in mail-out bowel cancer screening, (b) involved the mailing of a screening kit to the participants' homes without a specific request from the individual, and (c) included quantitative data that reported on the FOBT return rate.

Studies were excluded if (a) the screening kit was not mailed directly to the participant, (b) if studies required participants to request a kit or accept an invitation to receive a kit in the future or to be part of the study, (c) studies investigated other types of bowel cancer screening (e.g., colonoscopy) and did not report specific outcomes for FOBT screening, and (d) if the full text was not available in English.

These searches were conducted with six databases; PubMed, Scopus, PsycInfo, CINAHL, Google Scholar, and Proquest Theses and Dissertations. See Figure 2 for document flow chart and Appendix E for detailed search strategy (Goodwin et al., 2018a; Myers et al., 2019).

5.3.2. *Stage 1: Data Extraction*

For each study, short descriptions of the procedures and intervention materials were extracted. When available, these descriptions were further informed by study protocols and online versions of the materials. In cases where this information was not readily available, best efforts were made to contact the original authors for a copy of their materials.

5.3.3. *Stage 2: Coding BCTs*

To address the first research objective, stage 2 identified what techniques were used within interventions to affect participation rates, using the BCT taxonomy-v1 [19]. The BCT taxonomy-v1 contains 93 non-redundant BCT (e.g., the BCTs *'imaginary punishment*', *'imaginary reward'*, and *'vicarious consequences'*). Each BCT has a unique definition that describes an "observable, replicable, and irreducible component of an intervention designed to alter or redirect causal processes that regulate behaviour" (p. 23, Michie et al., 2013). By using these definitions, and the instructions available at the website (https://www.bct-taxonomy.com), each BCT present within each intervention were identified. BCT identifications were made from the description within the methods section of each article and when possible the

intervention materials themselves. BCTs that were part of 'usual care', as opposed to being part of an intervention strategy, were not recorded or analysed.

5.3.4. *Stage 3: Linking BCTs to Mechanisms of Action*

The purpose of stage 3 was to address the second research objective; to understand the process by which these BCTs did and did not bring about behaviour change (Carey et al., 2018). The Theory and Techniques tool was used to link BCTs identified in stage 2 to their mechanism of Action (Carey et al., 2018; Johnston et al., 2018). The Theory and Techniques tool suggests links between 74 BCTs and 26 mechanisms of action. These links were established through a synthesis of research literature and the consensus of experts in the field of behaviour change (Carey et al., 2018; Johnston et al., 2018). In the Theory and Techniques tool, each mechanism of action may have one or more linked BCTs with varying evidence for the suggested link (e.g., the mechanism of action '*reinforcement*' has a link to the behaviour change technique *'material incentive'*, an inconclusive link to the behaviour change technique *'associative learning'*, and a non-link to the behaviour change technique *'information about health consequences'*). In the current review, the information and procedure provided by the Theories and Techniques tool along with the context of the given application were used to decide on a link between the BCTs identified in stage 2 and their mechanisms of action.

5.3.5. *Stage 4: Identifying Stages of Behaviour Change*

Stage 4 addresses the third research objective and examines what combinations of BCTs and mechanisms of action tend to be effective. Stage 4 used the HAPA model to categorize how the individual BCTs and mechanisms of action might work synergistically to address the variety of barriers that occur at various stages of change experienced during the process of receiving, using, and returning an FOBT kit (Schwarzer, 2008). The HAPA model posits two-stages of change relevant to bowel cancer screening, (1) a motivational stage and (2) a volitional stage, with different factors being influential at the different stages. The model also includes factors related to maintenance and recovery of the health behaviour, however, these are not relevant in the context of FOBT screening; a 'one-off/occasional' behaviour. The HAPA model suggests that people need to develop risk perceptions, outcome expectations, and task self-efficacy (i.e., the confidence a person has in performing the action) to develop the motivation to engage in any health behaviour. While factors such as action planning, coping planning, and maintenance self-efficacy (i.e.,

confidence the person has in overcoming barriers) are influential in the volitional stage. The HAPA model argues that interventions should first increase people's motivation (e.g., providing information regarding the benefits of bowel cancer screening) then help the person translate this motivation into action (e.g., by developing useful action plans; Schwarzer & Luszczynska, 2008). By using the HAPA model in conjunction with the Theory and Techniques tool, it can be determined what mechanisms of action are effective for the different stages of change and which mechanisms of action should be combined so that both stages of change are targeted by an intervention strategy. Thus, in stage 4, the mechanisms of action within each intervention were coded according to whether they were likely to affect the motivational or volitional stage of change as described by the HAPA model.

5.3.6. *Coding, Synthesis, and Analysis of Findings*

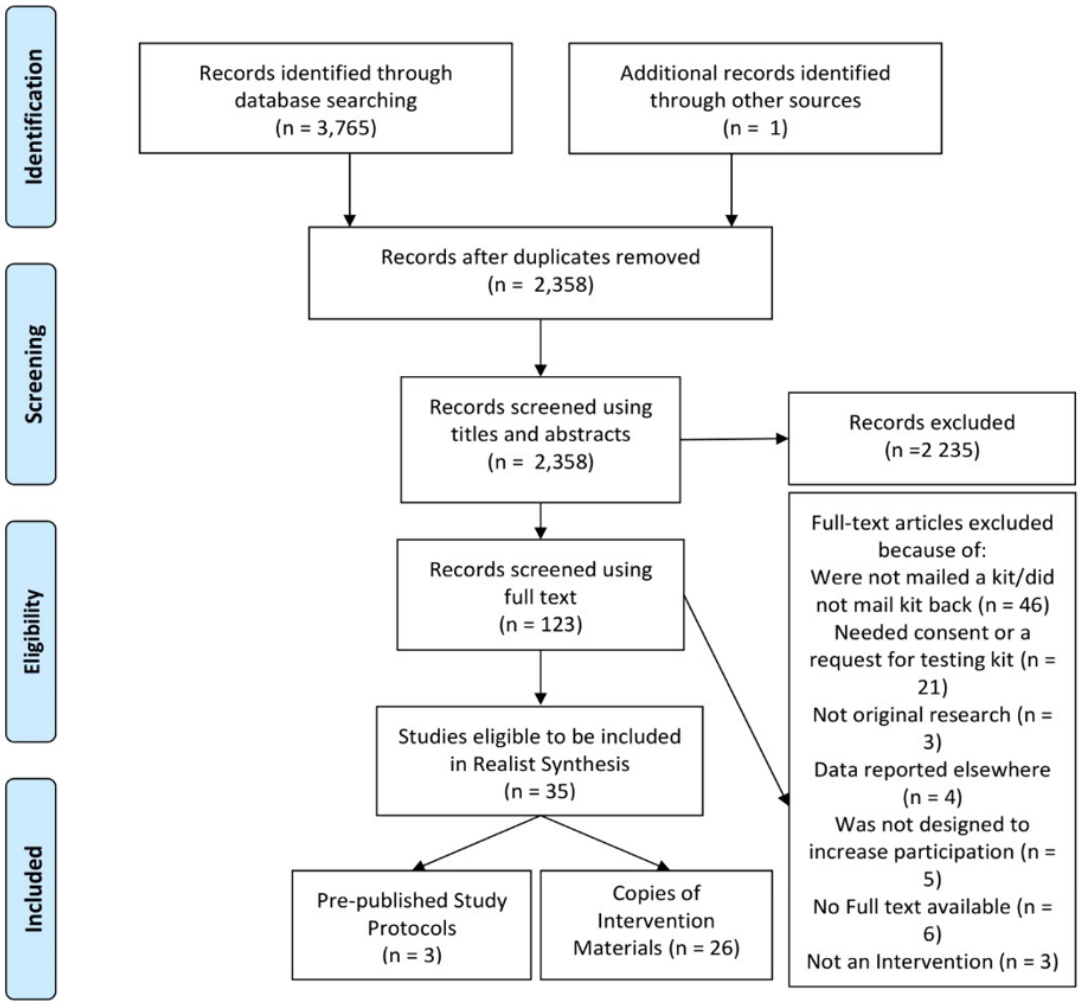
Researchers performed coding independently at all stages of the review (L.M. & O.C. for stage 2; L.M. & B.G. for stages 3, and L.M. for stage 4). All reviewers responsible for coding the intervention content for BCTs have completed the online BCT taxonomy training ("behaviour change technique Taxonomy-v1 Online Training," 2019). Discrepancies between reviewers at any of these stages were resolved by a consensus discussion with the wider research team.

Two methods were applied to synthesize findings. Firstly, the BCTs and mechanisms of action identified were grouped according to whether or not they were applied in an intervention trial that significantly increased participation rates. Comparisons were then made regarding the frequencies of BCTs and mechanisms of action and how often they were part of a successful intervention. Secondly, individual trials were also grouped according to the HAPA model stage/s the mechanisms of action in that intervention addressed and whether the intervention significantly increased participation rates. This was analysed to descriptively examine if the HAPA model stage addressed by an intervention had any association with the likelihood of the intervention being successful at increasing participation rates.

5.4. Results

Figure 5.2.

Document Flow Diagram



5.4.1. *Stage 1 and Document Characteristics*

As seen in Figure 5.2, 35 articles were found that met the inclusion and exclusion criteria. This included a total of 68 intervention trials. All 68 individual intervention trials were included in this analysis (see Appendix F for a summary of these interventions). In addition to the published articles, 11 studies (30.6%) had the intervention materials readily available, four studies (11.1%) gave these materials on request, seven studies (19.4%) could not provide the materials (due to lost files or language other than English), and 14 studies (38.9%) could not be contacted or did not respond to the request. In total, intervention materials were available for 26 trials. Three published protocols were also found relating to these studies (Hirst et al., 2016; Mehta & Doubeni, 2015; O'Carroll et al., 2013).

Studies took place in eight different countries; United Kingdom (n = 14), Australia (n = 7), Netherlands (n = 5), United States of America (n = 5), Israel (n = 2), Latvia (n = 1), and New Zealand (n = 1). A risk of bias assessment was conducted on this set of studies using the Cochrane Risk of Bias tools (Higgins et al.,

2016; Higgins et al., 2011; Sterne et al., 2016) and methods are detailed in previous systematic reviews (Goodwin et al., 2019a; Myers et al., 2019). Briefly, 17 articles were of low risk of bias (Cole et al., 2002; Cole et al., 2003; Coronado et al., 2018; Coronado et al., 2019; de Klerk et al., 2019; Deutekom et al., 2010; Gupta et al., 2016; Hirst et al., 2016; Libby et al., 2011; Mehta et al., 2019; Moss et al., 2016; Neter et al., 2014; O'Carroll et al., 2013; Ore et al., 2001; Wardle et al., 2016; Watson et al., 2013), three studies were of moderate risk of bias (Blom et al., 2018; Durkin et al., 2019; Sandiford et al., 2018), nine studies were of unclear risk of bias (Cole et al., 2007; Denters et al., 2013; King et al., 1994; Lo et al., 2014; Myers et al., 1991; Robinson et al., 1994; Santare et al., 2015; Van Roon et al., 2011; Verne et al., 1993), four were of high risk of bias (Benton et al., 2017; Hughes et al., 2005; King et al., 1992; White et al., 2015), and two articles were of serious risk of bias (Digby et al., 2013; Schreuders et al., 2019).

5.4.2. *Stage 2: BCTs*

Across the 68 interventions, 26 unique BCTs were identified with the frequency of use displayed in Figure 5.3. Overall, this review found that there was no single BCT that could be recommended as a necessary component to be implemented in all mail-out FOBT programs. Rather, this review found a suite of BCTs that are flexible in their implementation, can be part of an effective strategy, and should be utilized together. For instance, the most frequently used BCT was the provision of *'Information about health consequences'* (n = 24). Depending on the information provided, this BCT changed behaviour through two distinct mechanisms; informing people about the risks of bowel cancer (mechanism of action '*Perceived susceptibility'*) and/or informing people of the reduced risks if they participate in the program (mechanism of action '*Beliefs about consequences*'). This BCT was often used in conjunction with the second and third most frequently identified BCTs; delivering messages from a '*credible source'* (e.g., personal GP or health network; mechanism of action *'Attitude towards the behaviour',* n = 21) and issuing '*prompts/cues*' (n = 17) to remind invitees to complete and return the kit (mechanism of action *'Behavioural cueing'*). While a large proportion of interventions that used these three BCTs were successful (see Figure 5.3), approximately 20-30% of these trials did not increase participation rates. This suggests that the frequently used BCTs '*Information about health consequences'*, '*credible source'*, and '*prompts/cues*' often are, and should be, part of an effective strategy, however, there are

circumstances under which they may not bring about increases in FOBT participation.

As seen in Figure 5.3, six BCTs were associated with increased participation rates in 100% of their uses and are strong candidates to be implemented in FOBT screening programs. All interventions that included the following significantly increased participation; had invitees make a *'Commitment'* (n = 7) to return the completed FOBT, gave *'Feedback on behaviour'* (n = 6) that the invitee had yet to return the FOBT kit, used live *'Social support (practical)'* (n = 5) to give instructions on how to complete the FOBT kit, used live *'Social support (unspecified)'* (n = 5) to encourage people to complete the FOBT kit, had invitees engage in *'Problem-solving'* (n = 4) to overcome barriers associated with FOBT participation, and involved *'Restructuring the physical environment'* (n = 1) by accepting completed FOBT kits in community drop off locations as well as mailed returns.

However, several caveats need to be considered before implementing the above-mentioned BCTs. *'Restructuring the physical environment'* has only been trialled once and replication of the finding is needed before its efficacy can be established (Sandiford et al., 2018). The remaining five of these BCTs *'Commitment'*, *'Feedback on behaviour'*, *'Social support (practical)'*, *'Social support (unspecified)'*, and *'Problem-solving'*, were predominately delivered using live telephone calls. While the relatively small samples in these studies (n < 590) meant that this was feasible (Coronado et al., 2018; Coronado et al., 2019; Myers et al., 1991), national screening programs typically send millions of FOBT kits every year (AIHW, 2018c). Thus, employing a strategy that requires live telephone calls may not be scalable. Nonetheless, these BCTs do show promise in controlled contexts and future research should focus on how to implement these key components on a larger scale.

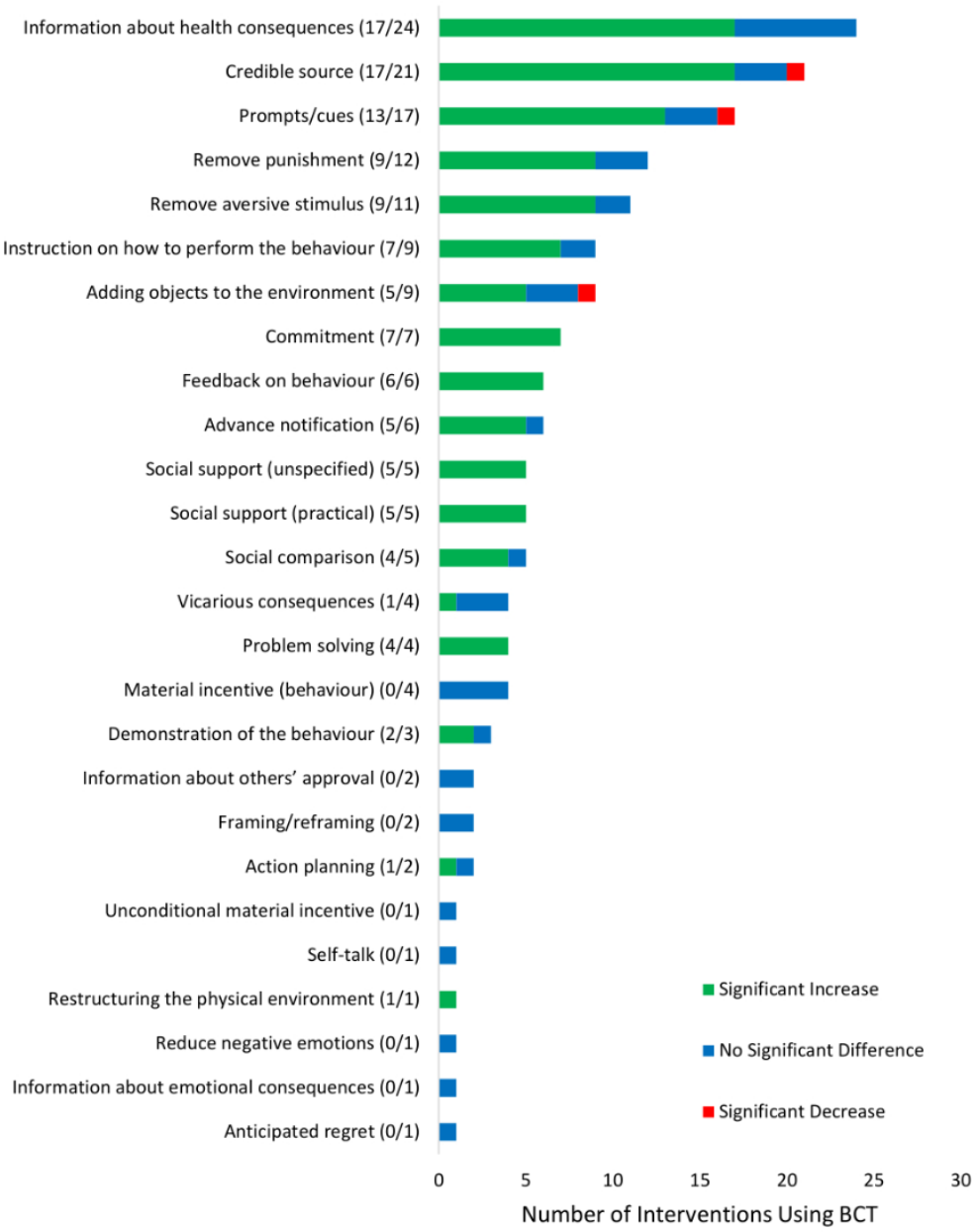
An important finding from this review was that 69 BCTs listed in the BCT taxonomy-v1 were not trialled in any of the reviewed studies. This provides a significant opportunity to create novel intervention strategies. For example, BCTs such as having invitees create a *'Pros and cons'* list, sign a *'Behavioural contract'*, or increasing the *'Salience of consequences'* has yet to be trialled in the context of mail-out FOBT screening and are possible avenues for future research to increase participation. When deciding which novel BCTs to trial researchers should base their judgments on the known barriers to screening (Goodwin et al., 2019b; Hall et al.,

2015; Javadzade et al., 2014) and what BCTs can be applied in the context of mail-out FOBT screening.

It should be noted that two BCTs did not fit any of the descriptions within the BCT taxonomy-v1 and were designated their own categories. One of these strategies involved notifying invitees weeks prior that an FOBT kit will be arriving soon (Cole et al., 2007; Coronado et al., 2019; Libby et al., 2011; Santare et al., 2015; Van Roon et al., 2011). This was labelled *'Advance notification'*. The other strategy involved sending a $10 gift voucher with the FOBT invitation (not conditional on FOBT completion) as an incentive to complete the FOBT kit (Mehta et al., 2019). This was labelled '*Unconditional material reinforcement'*.

Figure 5.3.

BCT Used in Reviewed Interventions



Note. (/) = Number of successful trials/Total number of trials

5.4.3. *Stage 3: Linked Mechanisms of Action*

In total, 13 different mechanisms of action were linked to the BCTs utilized in the given interventions; these are displayed in Figure 5.4. The most commonly employed mechanism of action was to change the '*Environmental Context and Resources*' (n = 28) available to the invitee which reduced the barriers commonly related to FOBT screening. This mechanism of action was successful in 78.6% of cases, with differences in implementation appearing to drive the variability in

efficacy. The BCTs that successfully used this mechanism of action to increase participation rates did so by reducing the number of screening tests needed (BCT; *'remove aversive stimuli'*; e.g., Deutekom et al., 2010; Digby et al., 2013) and/or removing the need for any dietary restriction (BCT; *'remove punishment'*; e.g., Blom et al., 2018; Cole et al., 2003; Hughes et al., 2005). Overall, the efficacy of the mechanism of action changing the *'Environmental context and Resources'* predominately reflect the success of programs that have switched to a newer FOBT kit (known as a faecal immunochemical test; FIT) that require fewer samples and no dietary restrictions. However, many countries already use these newer FIT kits and participation rates are still in need of improvement. Additional strategies will, therefore, be needed to increase participation rates.

In contrast, studies that changed the '*Environmental Context and Resources'* by making the sampling procedure easier (e.g., by use of collection aids; BCT; *'adding object to the environment'*), either did not increase participation rates or was only successful when delivered with another mechanism of action (Denters et al., 2013; White et al., 2015). As the sampling procedure itself is a reported barrier to screening (Goodwin et al., 2019b; Hall et al., 2015), further investigation is needed to improve the design of the screening kits to facilitate participation.

As screening programs may have limited capacity to change the FOBT kit (or the abovementioned effective changes have already been made), other mechanisms of action can be used to increase participation rates and do not require changing the testing kit or procedure. One of these mechanisms of action that are highly effective is to use *'Behavioural cuing'* to remind/prompt invitees to complete the FOBT. This can be successfully implemented through various mediums such as media campaigns, live telephone calls, or direct mailed reminders (Benton et al., 2017; Coronado et al., 2018; Durkin et al., 2019). Media campaigns, in particular, have been shown to be a cost-effective way to deliver these messages (Durkin et al., 2019; White et al., 2015; Worthington et al., 2020a), however, there is some evidence to suggest that these campaigns need to be of high intensity (i.e., multiple mediums over multiple times) to be effective (Durkin et al., 2019). It should be cautioned that those interventions that used text messages or automated phone calls as a medium for their *'behavioural cuing'* did not increase participation (Coronado et al., 2018; Hirst et al., 2017). These findings suggest that prompts and cues should be delivered using media campaigns, live telephone calls, or direct mailed reminders to be effective.

Helping people develop *'Intentions'* was also a mechanism of action that was frequently associated with increased participation rates. This was done either implicitly, through sending letters weeks in advance of the testing kit instructing the invitee in what to do when it arrives (BCT '*Advance notification'*), or explicitly, through asking invitees during a phone call to verbally commit to completing the kit (BCT *'Commitment'*) or having invitees set a time and date for when they will do the test (BCT *'Action planning'*). This latter BCT of *'Action planning'* was only successful when the invitees completed their own action plan; when the same strategy was used but with pre-filled responses to the planning questions, no difference was found in participation (Lo et al., 2014; Neter et al., 2014). Screening programs that enhance intentions and help invitees create their own specific plans and commitments seem more likely to be effective.

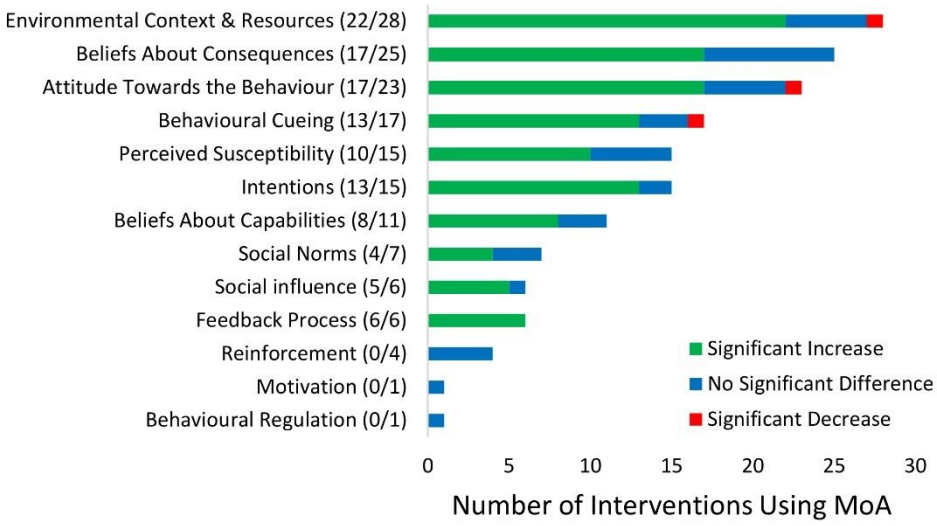
Providing feedback to the invitee that they have not completed their test (mechanism of action *'Feedback process'*; BCT *'Feedback on behaviour',* n = 6) is recommended to be included in screening programs as it was a highly successful mechanism and was the only mechanism of action that was associated with increased participation in 100% of its trials. Again, this was predominantly done through live telephone calls which limits the potential scalability. However, this mechanism of action has also been coupled with a reminder letter (mechanism of action *' behavioural cuing'*) and that implementation successfully increased participation rates (Benton et al., 2017). This may provide a way to implement this highly successful mechanism at the scale of a national screening program.

A further 13 behavioural mechanisms are listed in the Theory and Technique tool and were not trialled in any of these interventions. However, 12 of these mechanisms of action either appear not to be applicable (e.g., *'knowledge and existence of something'* and *'skill acquired through practice'*) or similar mechanisms of action have been trialled instead (e.g., the mechanism of action *'norms'* has not been trialled but *'Social norms'* has been trialled). This suggests that most mechanisms of action have been trialled and research should focus on new BCTs and combinations of BCTs to better engage the mechanisms of action that have been found to be effective. One untried mechanism of action that may be effective is the use of the invitee's *'Self-image'* (One's conception and evaluation of oneself) to increase participation rates. Invitees often find the arrival of the FOBT kit as a negative reminder of their age and this acts as a barrier to participate (Goodwin et al.,

2019b). Thus, informing invitees that FOBT screening is for the young and old may be a potential way to utilize the mechanism of action of *'Self-image'* and reduce this barrier and increase participation.

Figure 5.4.

Mechanisms of Action Used in Reviewed Studies



Note. (/) = Number of successful trials/Total number of trials

5.4.4. Stage 4: HAPA Stages

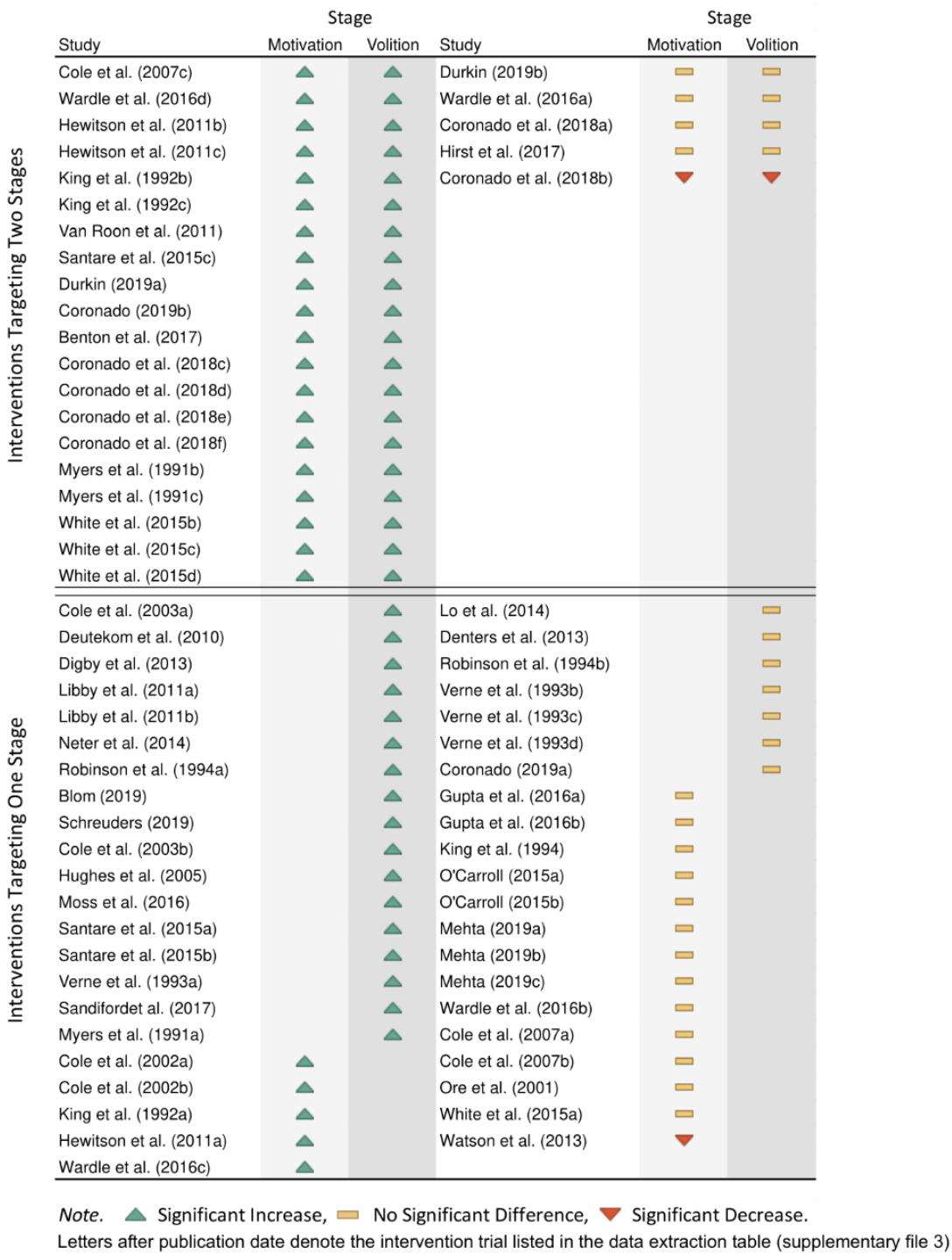
Figure 5.5 shows a heat map of each intervention trial which indicates the stage of change the trial targeted and if the trial significantly increased participation rates. As seen in Figure 5.5, 36.8% (n = 25) of interventions targeted both the motivation and volition stages together; 80% (n = 20) of which significantly increased participation rates. In contrast, 63.2% of trials targeted only one stage of change (n = 43); of which 51.2% (n = 22) significantly increase participation rates. These findings suggest that interventions should attempt to increase the invitee's motivation to participate in screening as well as facilitate the screening process itself to maximize the likelihood of success. These findings are consistent with previous research that suggests interventions should be combined to enhance impact (Myers et al., 2019) and provides a framework for deciding which interventions should be combined and how.

Furthermore, the findings of this review are in line with previous qualitative findings that propose two distinct categories of non-participants in mail-out FOBT screening programs; those who intend to participate in the program but whose intentions have not yet translated into action (i.e., those in the volitional stage) and those who decide not to participate from the outset (i.e., those in the motivational stage; Goodwin et al., 2019b; Hall et al., 2015). Interventions that target both the motivational stage and the volitional stage may be more likely to be effective because they facilitate change for both groups of invitees by addressing the specific barriers that are present for the distinct groups (Schwarzer & Luszczynska, 2008; Velicer et al., 2000).

When examining interventions that targeted only one stage of change, those that solely targeted the volitional stage had a higher success rate (70.8%, n = 17) than interventions that solely targeted the motivation stage (26.3%, n = 5). Past research has shown that strategies targeting the motivational stage may indeed be successful at increasing motivation to screen but doing so will only move the participant along to a volitional stage where new barriers arise (such as the need for planning; Schwarzer & Luszczynska, 2008). As such, interventions that only increase motivations do not necessarily help invitees overcome the new volitional barriers that arise when transforming motivations into action. Alternatively, intervention strategies that only target the volitional stage are likely to be successful in progressing those already with strong motivations to screen (i.e., those in the volitional stage) through to test completion, thus deeming the intervention successful (Weinstein et al., 1998). It is important to note that whilst volitional interventions appear more efficacious, there are still many people in the target population that do not have motivation to screen because they misunderstand the risks of bowel cancer and/or the need for medical screening for early detection (Goodwin et al., 2019b; Hall et al., 2015). As such both motivational and volitional interventions are needed to overcome barriers for the entire change process.

Figure 5.5.

Heat Map of Interventions Targeting HAPA Factors



Note. ▲ Significant Increase, ▬ No Significant Difference, ▼ Significant Decrease.
Letters after publication date denote the intervention trial listed in the data extraction table (supplementary file 3)

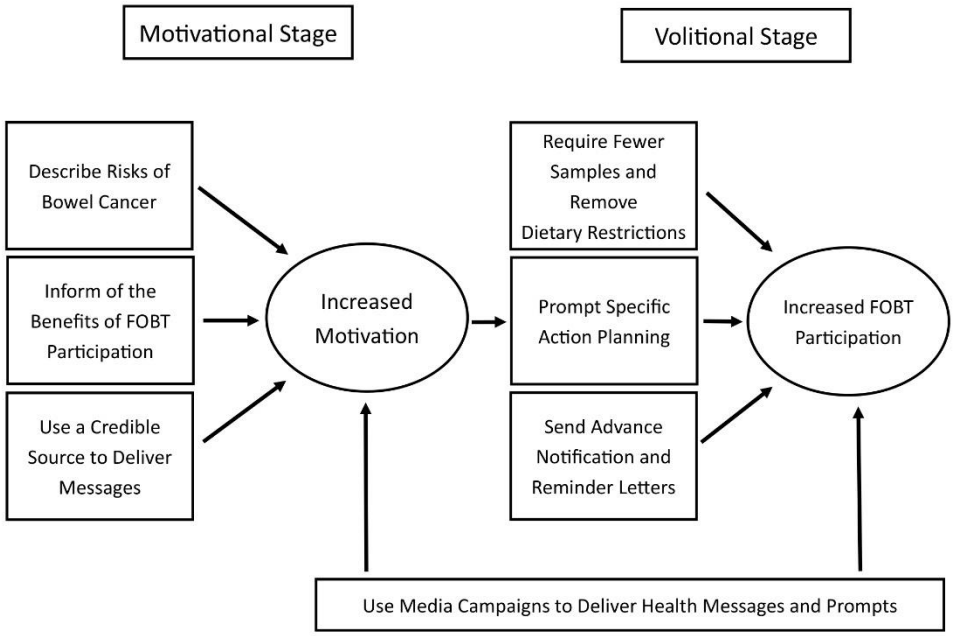
5.5. Discussion

By identifying effective strategies for increasing participation, findings from this review address a key gap in the literature and provide a platform for implementing interventions that increase chronic low participation rates in bowel cancer screening programs across the world. We found strategies that increased participation predominately do so by (1) changing the resources available to reduce the burden of participation, (2) changing invitees' beliefs about the consequences of screening and their perceived risk of developing bowel cancer; and (3) providing effective cues. The specific BCTs that were most consistently associated with increases in participation in mail-out FOBT screening programs included; providing information about the health risk of bowel cancer, using credible sources to deliver these health messages, providing prompts or cues to remind people to complete the test, and changing to a FIT kit to reduce the number of samples needed and removing dietary restrictions. Importantly, interventions that increase motivations to screen as well as facilitate the screening process itself are most likely to be successful.

It is clear that there is no 'one-size-fits-all' solution to increase participation rates in mail-out FOBT screening programs. Additionally, the exact type of intervention strategy adopted by screening programs will depend on what currently exists within the screening program itself. However, the findings from this review can be used to guide policymakers in their decisions as to which behaviour change strategies should be implemented and combined to increase participation rates (See Figure 5.6).

Figure 5.6.

Implementation Recommendations from Realist Analysis



First, FOBT screening programs should aim to implement strategies that sufficiently motivate people to participate. To do this, the findings from this study suggest that messages should inform invitees of the high risks associated with bowel cancer as well as how FOBT screening reduces these risks. According to the HAPA model, it is crucial that both these risk perception messages and positive outcome messages are included to sufficiently create motivation (Schwarzer & Luszczynska, 2008). Further, findings from this study also suggest additional strategies may successfully enhance the motivational power of such health messages. Motivations can be boosted if the health-related messages come from a trusted health professional, ideally from the invitee's personal GP (Benton et al., 2017; Goodwin et al., 2019c; Hewitson et al., 2011). While this information can be sent directly to the invitee along with the FOBT kit, these motivational strategies can also be supplemented by large scale media campaigns (Durkin et al., 2019; White et al., 2015).

Second, and in line with the assertions of the HAPA model, the findings of this study show that only increasing motivation to screen will not be optimal when attempting to impact participation rates. Rather, FOBT screening programs should

also implement strategies that facilitate the transition of these motivations into action (i.e., completing and returning the FOBT kit). Specifically, intervention strategies should aim to help invitees overcome barriers (often through the reduction of barriers) and enable the creation of specific action plans for performing the behaviour (Schwarzer & Luszczynska, 2008). To address the barriers associated with FOBT screening, programs should supply the newer FIT kits that do not require any dietary restrictions and need fewer samples to be taken, while still being more accurate than gFOBT (Lin et al., 2016; Moss et al., 2016; Tinmouth et al., 2015). However, more research is needed on how to reduce barriers to faecal sampling in individuals eligible for screening. This has been noted as a barrier to participating and previous attempts to improve the sampling procedure have not been effective (Denters et al., 2013; Goodwin et al., 2019b) thus represent a direction for future research. Additionally, helping people develop and commit to a specific action plan can reduce the number of people not participating due to procrastination or forgetting (Hagger & Luszczynska, 2014). The findings from this study show this can be done by prompting people to commit to a specific time and date for when they want to complete the test and having them set a plan for where they are going to keep the kit when it arrives (Neter et al., 2014). Finally, sending reminder letters to those that have not returned their FOBT kit can act as a type of feedback process and prompt more participation (e.g., Benton et al., 2017).

It should be cautioned that many of these behaviour change strategies involve sending information to the invitee and overloading invitees with information that can reduce participation rates (Watson et al., 2013). As such informational messages should be spread across an advance notification letter, the invitation that includes the FOBT kit, and a reminder letter weeks after the FOBT kit's arrival. Not only have advance notification letters and reminder letters been shown to increase participation rates themselves (Benton et al., 2017; Cole et al., 2007; Libby et al., 2011), they give an opportunity to disperse the information load across time points reducing the risk of information burden hindering participation (Watson et al., 2013).

Accordingly, it is vital that comprehensive behaviour change strategies are implemented to increase participation and that mail-out FOBT screening programs deliver a strategy that includes both motivational and volitional behaviour change components. Policymakers can draw from the specific BCTs and mechanisms of

action highlighted in this review to guide new interventions to facilitate participation within their programs.

5.5.1. *Strengths and Limitations*

This review is the first to examine what aspects of interventions are associated with increases in screening participation for mail-out FOBT screening. By making use of realist methodologies and a theory of behaviour that models the distinct changes involved with FOBT screening participation, this review identifies the mechanisms that bring about behaviour change and how these mechanisms relate to these distinct stages. Also, by using the BCT taxonomy-v1 and the Theory and Techniques Tool, the active elements and mechanisms of action of each intervention are able to be coded in a rigorous, transparent, and replicable manner aided by direct reference to intervention materials. Additionally, we ensured accuracy in coding the BCTs from both published studies and intervention materials, through dual coding and coder training (Wood et al., 2014).

Nonetheless, study findings need to be interpreted with some limitations in mind. One being that many of the BCTs were trialled within the same intervention making it difficult to draw firm conclusions regarding the efficacy of each individual BCT. While it can be identified that certain BCTs form a part of a successful strategy when combined it is not possible to infer with confidence which BCT led to the intervention's success. Additionally, intervention materials were not available for all trials so BCT coding relied on the reporting in the original research article. As such, for these articles, it is possible some BCTs were either not identified or misidentified.

5.5.2. Conclusion

The results from this review present a range of BCTs and mechanisms of action that, when included in an intervention, are likely to lead to increased participation rates in mail-out FOBT screening programs. Importantly, findings suggest that BCTs and mechanisms of action should aim to increase the invitee's motivation to participate in the screening program as well as facilitate the translation of these motivations into active participation. Organizers of population mail-out FOBT screening programs should aim to identify which of the suggested BCTs and mechanisms of action are not already present within their programs and work to incorporate them such that all stages of change are targeted if they wish to improve participation rates.

CHAPTER 6: INSTRUMENT DEVELOPMENT AND BACKGROUND FOR STUDY THREE

The findings from this body of research thus far indicate that intervention strategies should be combined, that previous trials can be broken down in terms of their specific BCTs and mechanisms of action, and that these should be combined in a manner that targets both the motivational and volitional stages of FOBT screening. This latter finding supporting behaviour change stages theorised within the HAPA model. However, it has yet to be shown whether all of the social-cognitive factors theorised to affect each stage of change in the HAPA model are actually influential in the context of mail-out bowel cancer screening. For instance, no data has been collected to demonstrate that the invitee's level of risk perception, positive outcome expectancies, negative outcome expectancies, and self-efficacy are related to FOBT screening intention or if the invitee's level of planning mediates the relationship between these intentions and FOBT participation. As it is possible that some, none, or all of the relationships specified in the HAPA model fit the context of mail-out FOBT screening, a full evaluation of the HAPA model needs to be conducted. Knowing if the HAPA model fits the context of FOBT screening, and which specific components fit, can help guide future researchers to develop theory-based intervention strategies. In that, interventions can be designed to contain BCTs that affect each of the influential HAPA social-cognitive factors, thus making a multifaceted approach to promote FOBT screening intention and an additional multifaceted approach to target all the volitional factors of the HAPA model.

Once the HAPA model has been evaluated as a theoretical basis for intervention design, the next step is to identify the specific BCTs that should be implemented to target each influential social-cognitive factor. Several relevant BCTs that have been part of previously successful strategies are discussed in Chapter 5 that could be used for these purposes. However, in addition to identifying influencing factors and intervention strategies to target these, it is also important to examine the likelihood that these will be taken up by participants. Whether invitees themselves perceive a strategy as being helpful or beneficial should be considered. It is vital that invitee's themselves perceive the benefit of an intervention so that they will engage with it. If invitees do not respond positively to proposed interventions, they are unlikely to engage with the intervention rendering it ineffective (DeSmet et al.,

2019). Therefore, user engagement is a key factor determining if an intervention will reach its full potential efficacy (Yardley et al., 2015).

Given the need to better understand (1) whether screening behaviour can be explained by the HAPA model and (2) measure the acceptance of potential intervention from a consumer perspective, study three sought to develop and apply two instruments to quantitatively address each of these aims. The first, the *Process Approach to Mail-out Screening* (PAMS), measured each construct within the HAPA model to determine if they have utility in explaining mail-out FOBT participation (or non-participation). The second, the *User Ratings of Mail-Out Screening Interventions* (UR-MSI), assessed which intervention strategies (based on specific BCTs) NBCSP invitees believe will increase participation in FOBT screening. These together can be used to inform user-centred design for future intervention development. This chapter describes the development and content validation of these two instruments.

6.1. Measurement Development

To create a valid survey instrument, the individual items used need to be generated in a principled and methodologically reproducible manner (Zamanzadeh et al., 2015). Specifically, during the early development phase of any measurement tool, the goal is to generate items that have content validity. Content validity is the degree to which the measure fully represents the target construct/s. In other words, content validity is a measure of how well a construct has been operationalized by a set of survey items (Drost, 2011). To ensure the items used the PAMS and the UR-MSI instruments have content validity, a series of steps proposed by Zamanzadeh et al. (2015) were followed.

6.2. Survey Development Method

6.2.1. *Stage One: Establishing the Content Domain*

The first stage in developing the measures for study three was determining the content domain. This involved arriving at set definitions for the constructs the instruments aimed to measure and establishing clear boundaries for these content domains (Karros, 1997). The content domain for the constructs being measured by the PAMS survey was based on pre-existing definitions described by the HAPA model (Schwarzer, 2008). Within the HAPA model, seven construct domains are relevant to mail-out FOBT screening behaviour. The name and definition of these constructs can be seen in Table 6.1.

Table 6.1.

Definitions of the HAPA Constructs

Construct	Definition
Risk Perception	How much the person perceives that a given health condition is a threat to themselves (e.g., how threatening the person believes bowel cancer is to themselves).
Positive Outcome Expectancies	The benefit the person believes they will receive if they engage in the given health behaviour (e.g., finding bowel cancer at its earliest stage and successfully treating it).
Negative Outcome Expectancies	The direct negative consequences the person believes will occur if they engage in the health behaviour (e.g., having to be in close contact with fecal matter to complete the FOBT kit).
Action Self-Efficacy	The degree to which the person believes they can overcome barriers associated with the health behaviour (e.g., how much the person believes they can overcome their discomfort of fecal sampling and complete the test).
Intention	A desire to engage in the health behaviour (e.g., deciding that they will complete the FOBT kit).
Planning	A detailed action plan for when, how, and where they are going to engage in the health behaviour (e.g., the person planning on returning their FOBT kit by the end of the week).
Action	The completion of the health behaviour (e.g., completing and returning the FOBT kit in the mail).

Note. These constructs and definitions were paraphrased from Schwarzer (2008).

For the UR-MSI instrument, the content domain was established using the BCT-taxonomy v1 (Michie et al., 2013). Guided by the findings from study two (Chapter 5), each BCT that is relevant to the mail-out FOBT screening process was identified and their corresponding definition was extracted. In total there were 32 BCTs identified that fit within the mail-out FOBT screening context (see Table 6.2).

Table 6.2.

Definition of BCTs Used in the UR-MSI

BCT	Definition
Action planning	Prompt detailed planning of performance of the behaviour (must include at least one of context, frequency, duration and intensity). Context may be environmental (physical or social) or internal physical, emotional or cognitive) (includes 'Implementation Intentions').
Adding objects to the environment	Add objects to the environment in order to facilitate the performance of the behaviour.
Anticipated regret	Induce or raise awareness of expectations of future regret about the performance of the unwanted behaviour.
Behavioural contract	Create a written specification of the behaviour to be performed, agreed on by the person, and witnessed by another
Commitment	Ask the person to affirm or reaffirm statements indicating a commitment to change the behaviour
Comparative imagining of future outcomes	Prompt or advise the imagining and comparing of future outcomes of changed versus unchanged behaviour
Credible source	Present verbal or visual communication from a credible source in favour of or against the behaviour

Demonstration of the behaviour	Provide an observable sample of the performance of the behaviour, directly in person or indirectly e.g. via film, pictures, for the person to aspire to or imitate.
Discrepancy between current behaviour and goal	Draw attention to discrepancies between a person's current behaviour (in terms of the form, frequency, duration, or intensity of that behaviour) and the person's previously set outcome goals, behavioural goals or action plans (goes beyond self-monitoring of behaviour)
Feedback on behaviour	Monitor and provide informative or evaluative feedback on the performance of the behaviour (e.g. form, frequency, duration, intensity).
Framing/reframing	Suggest the deliberate adoption of a perspective or new perspective on behaviour (e.g. its purpose) in order to change cognitions or emotions about performing the behaviour (includes 'Cognitive structuring').
Goal setting (behaviour)	Set or agree on a goal defined in terms of the behaviour to be achieved.
Identification of self as role model	Inform that one's own behaviour may be an example to others.
Imaginary reward	Advise to imagine performing the wanted behaviour in a real-life situation followed by imagining a pleasant consequence.
Information about emotional consequences	Provide information (e.g. written, verbal, visual) about emotional consequences of performing the behaviour.
Information about health consequences	Provide information (e.g. written, verbal, visual) about health consequences of performing the behaviour.
Information about others' approval	Provide information about what other people think about the behaviour. The information clarifies whether others will like, approve or disapprove of what the person is doing or will do.
Information about social and environmental consequences	Provide information (e.g. written, verbal, visual) about social and environmental consequences of performing the behaviour.
Instruction on how to perform a behaviour	Advise or agree on how to perform the behaviour (includes 'Skills training').
Material incentive (behaviour)	Inform that money, vouchers or other valued objects will be delivered if and only if there has been effort and/or progress in performing the behaviour (includes 'Positive reinforcement').
Problem solving	Analyse , or prompt the person to analyse, factors influencing the behaviour and generate or select strategies that include overcoming barriers and/or increasing facilitators (includes 'Relapse Prevention' and 'Coping Planning').
Prompts/cues	Introduce or define environmental or social stimulus with the purpose of prompting or cueing the behaviour. The prompt or cue would normally occur at the time or place of performance.
Pros and cons	Advise the person to identify and compare reasons for wanting (pros) and not wanting to (cons) change the behaviour (includes 'Decisional balance').
Reduce negative emotions	Advise on ways of reducing negative emotions to facilitate performance of the behaviour (includes 'Stress Management').
Remove aversive stimulus	Advise or arrange for the removal of an aversive stimulus to facilitate behaviour change (includes 'Escape learning').
Remove punishment	Arrange for removal of an unpleasant consequence contingent on performance of the wanted behaviour (includes 'Negative reinforcement').
Restructuring the physical environment	Change, or advise to change the physical environment in order to facilitate performance of the wanted behaviour or create barriers to the unwanted behaviour (other than prompts/cues, rewards and punishments).

Restructuring the social environment	Change, or advise to change the social environment in order to facilitate performance of the wanted behaviour or create barriers to the unwanted behaviour (other than prompts/cues, rewards and punishments).
Salience of consequences	Use methods specifically designed to emphasise the consequences of performing the behaviour with the aim of making them more memorable (goes beyond informing about consequences).
Self-incentive	Plan to reward self in future if and only if there has been effort and/or progress in performing the behaviour.
Self-talk	Prompt positive self-talk (aloud or silently) before and during the behaviour.
Social comparison	Draw attention to others' performance to allow comparison with the person's own performance.

6.2.2. *Stage Two: Sampling from the Content Domain*

Once the content domain was established, survey items were generated through an iterative process. For the PAMS instrument, the initial set of items were generated using the instructions given by the HAPA models creators (Schwarzer, 2008; Schwarzer et al., 2003) and amending survey items from previously validated surveys based on the HAPA model such that they fit the context of mail-out FOBT screening behaviours (Barg et al., 2012; Barling & Lehmann, 1999; Ghofranipour, 2018; Hattar et al., 2016; Lippke & Plotnikoff, 2014; Lippke et al., 2009; Parschau et al., 2014; Paxton, 2016; Payaprom et al., 2011; Rohani et al., 2016b; Sniehotta et al., 2005). To guide the amendments to these previous items to fit the context of mail-out FOBT screening, previously published qualitative findings of invitee's experience with mail-out FOBT screening were referred to along with the expert opinion of the primary research team based on their experience in the field (Goodwin et al., 2019b; Goodwin et al., 2019c; Hall et al., 2015; Javanparast et al., 2012). Once this initial set of PAMS items was generated, they were reviewed and refined by the members of the primary research team (L.M, S.M, and B.G) until no further changes were deemed necessary.

To create items for the UR-MSI, example interventions were generated from each BCT identified in stage one (see Table 6.2.). Example interventions based on each BCT were used instead of the BCT itself to make it more applicable to the end-user and the context of FOBT screening. For instance, if the BCT was 'Adding objects to the environment (definition; Add objects to the environment in order to facilitate the performance of the behaviour), one example intervention might be 'providing invitees with longer collection devices (longer stick) to make faecal sampling easier'. Many of these example interventions were based on behaviour

change strategies that have previously been trialled to increase mail-out FOBT participation (see Chapter 5). Where existing intervention strategies to address a BCT did not exist in the literature novel examples were generated based on the BCT by the primary research team. This process was guided by the previous research into the barriers and facilitators of mail-out FOBT screening (Goodwin et al., 2019b; Goodwin et al., 2019c; Hall et al., 2015; Javanparast et al., 2012). The feasibility of each example intervention was also considered, as for any intervention to be implemented it had to be possible to deliver on a national scale (i.e., in the order of reaching millions of people per year). This was an iterative process of generation and refinement until no further changes were deemed necessary by the primary research team.

6.2.3. *Stage Three: Expert Judgment*

The third stage of the instrument development process was to have an expert panel external to the primary research team, assess each item and the instruments overall. The expert panel consisted of eight public health experts/professionals including researchers and health promotion specialists. Of these, four panel members (O.C., K.D., S.B., and A.M.) have extensive knowledge in behaviour change and BCTs, and the remaining four (S.K., R.B., F.C., and N.T.) are experts in health promotion, specialising in cancer screening, and are familiar with the NBCSP and its processes. The goal of this stage was to reach a consensus from a panel of experts regarding the content validity of the instruments and establish if any further amendments were needed.

The expert panel were asked to assess all items, from both instruments, for how relevant they were in reference to the definition provided and how clear the wording of each item was. The panel was instructed that their task was to indicate how relevant each proposed item and response scale is (1 = *not relevant*, 2 = *item needs some revision*, 3 = *relevant but needs minor revisions*, and 4 = *very relevant*) and how clear each proposed item and response scale is (1 = *not very clear*, 2 = *item needs some revision*, 3 = *clear but needs minor revision*, and 4 = *very clear*). The relevancy rating for each item is in reference to the definition provided for each construct. The clarity rating for each item was based on the exact wording of each item. Finally, for each construct in the PAMS survey (e.g., risk perception, positive outcome expectancies, etc.) the expert panel was to assess how comprehensively each set of items covers the definition of each construct (1 = *no*, 2 = *a little, needs*

major revision, 3 = *yes, needs minor revision*, and 4 = *yes*). For each numerical response given, the expert panel could provide a written statement to add further commentary (e.g., suggested change of item wording). All responses and comments were provided through the Qualtrics survey platform (Qualtrics, 2015). The responses given by the expert panel were anonymized.

6.3. Analysis of Judges Responses

To analyze the data provided by the expert panel a content validity index (CVI) was calculated for each item in both instruments and for each comprehensiveness rating for the constructs in the PAMS instrument. To calculate the CVI, the number of judges that gave a rating of 3 or 4 was divided by the total number of judges (Zamanzadeh et al., 2015). Thus, the CVI expresses the proportion of judges that rate the item/s as relevant, clear, or comprehensive. If the CVI is greater than 79% the item, or set of items, was retained, if it was 70 – 79% it was amended, and if it was below 70% it was completely changed (Zamanzadeh et al., 2015). The expert panel consultation process was approved by the University of Southern Queensland (USQ) Human Research Ethics Committee (H20REA119).

6.4. Results

There were 25 items generated for the PAMS survey. Of these, nine did not meet the pre-determined CVI threshold. The comments left by the expert panel also suggested that all items relating to negative outcome expectancies should be reworded to fit a consistent format. For example, an original item of "I feel disgusted at the idea of reaching into the toilet" was changed to "If I complete my FOBT kit, I am concerned I would feel disgusted reaching into the toilet to collect a stool sample" such that it better reflects a consequence of the behaviour. In total 11 items from the UR-MSI were reworded and sent back out to the expert panel for review. Through this process, all items except for the one item relating to social support were above the CVI threshold. As social support is seldom used in scales based on the HAPA model it was removed. Finally, after this process, each set of items measuring the different components of the HAPA model surpassed the 79% agreement threshold for comprehensiveness. The final set of 25 PAMS items can be seen in Appendix G.

There were 49 example interventions generated for the UR-MSI survey. Of all example interventions, three did not meet the pre-determined CVI threshold. Based on the suggestion of the expert panel these items were reworded and revaluated.

After this process, all UR-MSI items surpassed the 79% agreement threshold. The final set of 49 UR-MSI items can be seen in Appendix H.

6.5. Conclusions

The design of interventions to increase mail-out FOBT screening participation can be informed and improved through a greater understanding of the behavioural process underpinning FOBT screening participation along with the perceived usefulness of interventions from the invitee's perspective. Through an iterative process of internal review by the primary research team and external review from a panel of field relevant experts, the items within the PAMS and UR-MSI were deemed to be of high content validity. In addition, the set of items in the PAMS instrument that measure the individual constructs of the HAPA model were evaluated to be comprehensive. The following chapter is a manuscript that has been submitted for publication that includes a summary of the scale development process and details regarding the survey study.

CHAPTER 7: STUDY THREE (UNDER PEER-REVIEW FOR PUBLICATION)

Myers, L., Goodwin, B., Ralph, & March, S. A Health Action Process Approach for Developing Invitee Endorsed Interventions to Increase Mail-Out Bowel Cancer Screening. (submitted to Annals of Behavioural Medicine)

7.1. Abstract

Background: Population mail-out faecal occult blood test (FOBT) screening can markedly improve bowel cancer survival. However, participation in these programs is low and user-centred theory-based interventions are needed to increase participation rates. This article describes a study assessing the theoretical fit of the health action process approach (HAPA) for the context of home FOBT screening and measured FOBT screening invitees' preferences for different intervention strategies.

Methods: A cross-sectional sample (*n* = 377), aged 50-74 years, was recruited through online advertising and community posts, completed both surveys. The process approach to mail-out screening (PAMS) scale measured HAPA factors and processes for the context of FOBT screening and the user-ratings of mail-out screening interventions (UR-MSI) scale were developed for this study. Structural equation modelling (SEM) was used to assess the fit of PAMS scale responses to the HAPA model and binomial tests were used to measure preferences for interventions on the UR-MSI scale.

Results: PAMS responses showed acceptable fit with the HAPA model, CFI = .968, TLI = .964, RMSEA = .050, and explained 49.9% of the variation in FOBT screening participation. Endorsement ratings of interventions ranged from 15.95%, 95% CI [12.82, 19.50], an intervention prompting planning to complete the FOBT kit (BCT: Action planning), to 56.44%, 95% CI [51.92, 60.89], an intervention promoting the positive health outcome associated with FOBT screening (BCT: Information about health consequences).

Conclusion: Intervention strategies should be combined such that they target all factors specified within the HAPA model. User-centred intervention design, and the use of appropriate BCTs, should be used to effectively promote and facilitate FOBT uptake.

Keywords: Bowel cancer, HAPA, BCTs, user-centred interventions.

7.2. Introduction

In relation to the global cancer burden, bowel cancer has the third-highest incidence rate and is the second leading cause of cancer-related deaths (Bray et al., 2018). If detected early, before noticeable symptoms emerge, the 5-year relative survival rate is as high as 93% (Lew et al., 2017; Siegel et al., 2017). Many countries now implement population-based bowel cancer screening programs that aim to increase the rate of early detection, improve survival, and reduce the impact of the disease on health services (AIHW, 2020; Navarro et al., 2017). These programs typically involve mailing faecal occult blood test (FOBT) kits to all members of the population aged between 50 – 74 years, as this age group have a higher risk of developing bowel cancer (Navarro et al., 2017). Invitees are asked to collect small stool samples using these kits and mail them back to a pathology lab for processing. If the test is positive, this may be a sign of bowel cancer and the person is referred to their general practitioner for follow-up, at which point a colonoscopy is usually scheduled for a comprehensive diagnosis (Australian Government, 2017).

This two-stage approach of national bowel cancer screening has been shown to be highly cost-effective and sensitive at detecting early-stage bowel cancer (Ananda et al., 2016; Lew et al., 2018). Population mail-out screening programs have been shown to substantially increase bowel cancer survival rates, decrease cancer burden, and reduce treatment costs (Lew et al., 2017; Meester et al., 2015; Wong et al., 2015). However, low participation rates limit their efficacy. For example, the current participation rate for the Australian National Bowel Cancer Screening Program (NBCSP) is only 42% (AIHW, 2019b). If participation in the NBCSP were to be increased to 60%, it is estimated that over the next 25 years an additional 24,800 bowel cancer deaths would be prevented and $2 billion saved in health care costs (Lew et al., 2017). To improve the early detection of bowel cancer and reduce the burden of this disease, behaviour change interventions need to be developed to increase participation in mail-out bowel cancer screening.

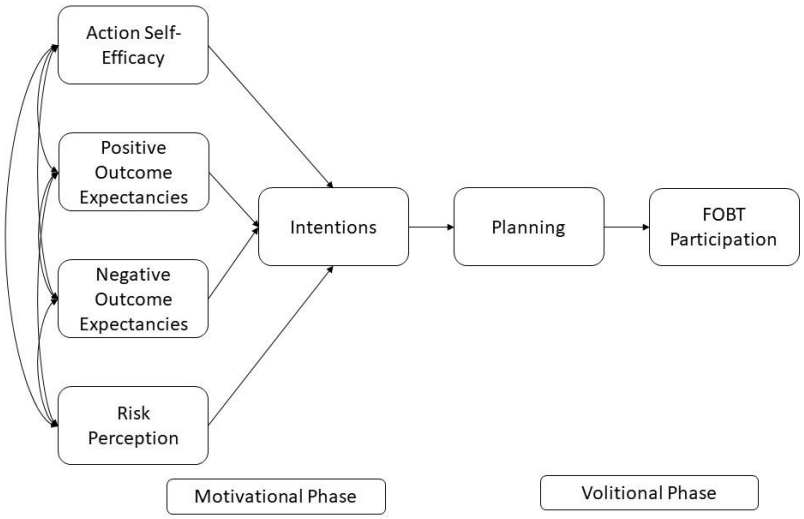
Interventions based on psychological and behaviour change theory are consistently reported as more effective than those without a theoretical basis (e.g., Diep et al., 2014; Taylor et al., 2012) with initiatives that target all determinates of behaviour change specified within these theories being particularly effective (Glanz & Bishop, 2010). While several multi-faceted interventions have been developed and applied to increase participation in mail-out bowel cancer screening programs, their

developers rarely report basing their intervention design on behaviour change theory (Myers et al., 2019). As most interventions aimed at increasing bowel cancer screening have only yielded a small to moderate impact on participation rates, a lack of theoretically informed interventions may explain the modest effects reported to date (Goodwin et al., 2019a; Myers et al., 2019).

The Health Action Process Approach (HAPA) model presents as one potential theory that could be applied when designing new interventions for increasing participation in bowel cancer screening, see Figure 7.1. The model suggests that individuals progress through two distinct stages when engaging in a health behaviour, firstly a motivational phase where intentions to perform a health behaviour are established, and secondly a volitional phase where these intentions are translated into action (Schwarzer, 2008). Crucially, behavioural intentions are thought to be dependent on four key factors that make up the 'motivational stage' of behaviour change (Schwarzer & Luszczynska, 2008); (a) risk perception (i.e., perceived susceptibility of being affected by bowel cancer); (b) positive outcome expectancies (i.e., beliefs of positive outcomes occurring if they participate in the screening program; e.g., better bowel cancer prognosis); (c) negative outcome expectancies (i.e., beliefs of negative outcomes occurring if they participate in the screening program; e.g., coming in close contact with faecal matter); and (d) action self-efficacy (i.e., beliefs regarding their capability of completing the FOBT kit). According to the HAPA model, when these factors are satisfied individuals will be motivated to engage in the behaviour and will enter a 'volitional stage' where intentions are transformed into action. In the context of bowel cancer screening, this "action" is completing and returning their FOBT kit. The HAPA model posits that the key mediating factor between intention and action is the level to which the person has an effective plan for how they are going to perform the behaviour (Schwarzer et al., 2011).

Figure 7.1.

Amended HAPA Model to Fit the Mail-Out FOBT Screening Context



The HAPA model has been previously used to successfully model a variety of enduring health behaviours, such as increases in physical activity, sunscreen use, and dietary behaviour (Craciun et al., 2012; Hattar et al., 2016; Parschau et al., 2014; Schwarzer et al., 2007), as well as one-off preventative health behaviours such as flu vaccinations (Ernsting et al., 2013). It has also been retrospectively shown that interventions are more likely to increase participation in mail-out FOBT screening programs if they target both the motivational and volitional stages akin to the HAPA model (Myers et al., 2020). For example, one trial that successfully increased participation rates combined behaviour change strategies of providing bowel cancer screening related health messages (motivational component) with a reminder to complete the FOBT kit if the invitee had not done so within 30-days (volitional component; Benton et al., 2017). These findings indicate that the HAPA model may be an appropriate framework to explain the variation in FOBT participation and to inform intervention design, however, to our knowledge the HAPA framework has not been explicitly considered in designing interventions to increase mail-out bowel cancer screening.

Additionally, when designing effective behaviour change interventions, a "user-centred" approach is strongly recommended (Yardley et al., 2015; Zebrack, 2014). This involves understanding the preferences and experiences of the target end-user has for different interventions and designing behaviour change interventions to accommodate them (e.g., DeSmet et al., 2019). It is vital that invitees themselves accept and perceive the benefit of an intervention so that they will engage with it

(DeSmet et al., 2019). This is of particular importance in mail-out screening interventions, as there is little to no interpersonal communication or contact between the deliverers of the intervention and the recipients. Therefore, user engagement is a key factor in determining if an intervention will reach its full potential effectiveness (Yardley et al., 2015). The majority of research to date has focused on barriers that prevent FOBT screening participation and research into end-user preferences for behaviour change interventions that may enable participants to overcome these barriers is seldomly researched (e.g., Goodwin et al., 2019b; Hall et al., 2015). Research that focuses on intervention development grounded in behaviour change theory combined with user co-design has significant potential impact.

7.2.1. *Aims*

This study describes the development, testing, and application of two survey measures designed to assist in intervention development to increase bowel cancer screening participation. The first is the *Process Approach to Mail-out Screening* (PAMS); designed to measure the constructs proposed by the HAPA model in the context of mail-out FOBT participation. The second is the *User Ratings of Mail-Out Screening Interventions* (UR-MSI) scale, designed to identify which intervention strategies invitees believe will make it more likely for them to participate in mail-out bowel cancer screening. In conjunction, these measures will be used to better understand which interventions can be applied to address the various barriers that occur during the process of participating in mail-out bowel cancer screening as described by the HAPA model. Findings can be used to co-design a theory-informed multifaceted intervention strategy that should have high end-user engagement.

7.3. Methods

7.3.1. *Scale Design*

7.3.1.1. Item Generation. PAMS and UR-MSI scale items were established through an iterative process. This process consisted of initial item generation by the primary research team, followed by content validation and refinement by an external panel of experts (as recommended in Zamanzadeh et al., 2015).

The initial set of items in the PAMS scale were based on the definitions of the HAPA constructs and instructions on how to create HAPA related scales published by the model's creators such that they fit the context of mail-out FOBT screening (Schwarzer et al., 2011; Schwarzer & Luszczynska, 2008). There are seven

constructs in the HAPA model that apply to mail-out FOBT screening; they along with their definitions can be found in Table 7.1.

Table 7.1.

HAPA Model Construct Definitions

HAPA Model Construct	Definition
Risk perception	How much a participant perceives bowel cancer as a threat to themselves.
Positive outcome expectancies	The benefits the participant believes they would receive if they complete and return their FOBT kit.
Negative outcome expectancies	The direct negative consequences the participant believes will occur if they complete and return their FOBT kit.
Action self-efficacy	How much the participant believes there were able to overcome barriers associated with participating in mail-out FOBT screening.
Planning	The degree to which the participant had a plan for when, how, and where they are going to complete and return their last mailed FOBT kit.
Intentions	The participant's desire to complete and return their last mailed FOBT kit.
Participation	If the participant completed and returned their last mailed FOBT kit or not.

Note. Definitions amended from Schwarzer (2008) to fit the context of mail-out FOBT screening.

The UR-MSI scale items consist of a series of example interventions based on BCTs listed in the BCT Taxonomy v1 (Michie et al., 2013) that are applicable in the context of mail-out FOBT screening. The example interventions in the UR-MSI were either based on interventions that have already been trialled (see Myers et al., 2020) or were adaptations of BCT definitions such that they fit the context of mail-out FOBT screening.

7.3.1.2. Content Validity. After the initial item generation and refinement was completed by the primary research team, an expert panel assessed each item and the scales overall for content validity. The expert panel consisted of eight public health experts/professionals including researchers and health promotion specialists. Of these, four panel members had extensive knowledge in behaviour change and BCTs, and the remaining four were experts in health promotion, specialising in cancer screening, and are familiar with the NBCSP and its processes.

The expert panel rated each item on a 4-point scale in terms of its relevancy (1 = not relevant, 2 = item needs some revision, 3 = relevant but needs minor revisions, and 4 = very relevant) and in terms of its clarity (1 = clear, 2 = item needs some revision, 3 = clear but needs minor revisions, and 4 = clear). The panel was advised that when rating the relevancy of items on the UR-MSI scale there were to consider

the BCT definition the item was based on. When rating the relevancy of items on the PAMS scale, they were to consider the definition of the HAPA construct the item was intended to measure (i.e., risk perception, positive/negative outcome expectancies, action self-efficacy, intention, and planning). Additionally, for the PAMS scale the panel rated if the set of items measuring each HAPA construct was comprehensive on a 4-point scale (1 = no, 2 = a little, needs major revision, 3 = yes, needs minor revision, and 4 = yes). A separate content validity index (CVI) was calculated for relevancy, clarity, and comprehensiveness whereby the number of judges that gave a rating of 3 or 4 was divided by the number of judges; giving the proportion of judges that deemed the item, or items, as relevant, clear, or comprehensive. Items that received a CVI > .79 for both relevancy and clarity were kept (Zamanzadeh et al., 2015) and items with a lower CVI were amended and resubmitted to the content validity expert panel for re-evaluation until a .79 CVI was reached (Zamanzadeh et al., 2015). The set of PAMS sub-scale items were deemed to comprehensively cover each HAPA factor if the CVI for comprehensiveness exceeded .79 (Zamanzadeh et al., 2015).

7.3.1.3. Content validity results. There were 25 items generated for the PAMS scale. Of these, nine did not meet the pre-determined CVI threshold in the first expert panel round. Subsequently, amendments were made to these nine items based on the panel's feedback and one additional item was added. These 10 items were then re-evaluated by the panel and all items except for one, relating to social support, exceeded the CVI threshold. As social support is seldom used in scales based on the HAPA model (e.g., Barg et al., 2012; Lippke & Plotnikoff, 2014; Paxton, 2016) and an agreement was not reached among the expert panel as to the item's relevancy or clarity, this item was removed. The comprehensiveness for each HAPA factor with the PAMS scale exceeded .79. The final set of 25 PAMS items can be found in Appendix G. There were 40 example interventions generated for the UR-MSI. Two items did not initially meet the .79 CVI threshold. Subsequently, revisions were made to these items based on the panel's feedback and after revaluation, all UR-MSI items demonstrated a CVI greater than .79. The final set of UR-MSI items can be found in Appendix H.

7.3.2. *Survey Recruitment and Procedure*

Participants were recruited through paid Facebook advertising and contacting community groups that are frequented by adults aged between 50 – 74 years, such as,

bowls clubs, men's support groups, retired service leagues, and social clubs. Invitees were offered an opportunity to win one of three grocery vouchers, to the value of $20 to $50 as an incentive to participate. Only Australian residents, from all states and territories, aged between 50 – 74 years (i.e., eligible participants of the NBCSP) were eligible to participate. The survey was delivered via the Qualtrics survey platform (Qualtrics, 2015). Completion of the survey took approximately 30 minutes. Participants provided informed consent and ethical approval for this research was provided by a university-based Human Research Ethics Committee (ref: H19REA291).

7.3.3. *Measures*

7.3.3.1. The PAMS Scale. The PAMS scale was intended to capture seven factors reflecting components of the HAPA model.

Risk Perception. There were four items assessing the degree to which participants consider bowel cancer a risk to their health. On a 6-point scale, participants were asked to respond to items such as "The threat of bowel cancer to your health is…" (from 1 = "very low" to 6 = "very high").

Positive Outcome Expectancies. There were four items assessing the degree to which participants expected a positive consequence from participating in mail-out bowel cancer screening. Participants were asked to rate how much they agree or disagree with statements such as "If I complete my FOBT kit, this will decrease my chance of dying from bowel cancer", on a 6-point scale (from 1 = "strongly disagree" to 6 = "strongly agree").

Negative Outcome Expectancies. There were five items assessing the degree to which the participant expected a negative consequence from participating in mail-out bowel cancer screening. Participants were asked to rate how much they agree or disagree with statements such as "If I complete my FOBT kit, I am concerned I would feel disgust while collecting a stool sample", on a 6-point scale (from 1 = "strongly disagree" to 6 = "strongly agree").

Action Self-efficacy. There were five items assessing how confident the participant was in overcoming barriers associated with mail-out bowel cancer screening. Participants were asked to rate how truthful statements such as "I would be able to complete the FOBT kit even if I had to overcome some of the disgust that might arise from collecting stool samples" were for them on a 6-point scale (from 1 = "not at all true" to 6 = "very true").

Intention. The participant's desire to complete and return their FOBT kit was measured by asking a single question "When you first received your last FOBT kit in the mail did you *intend* to complete and return it?" on a 5-point scale (from 1 = "I didn't intend to complete and return it" to 5 = "I had a very strong intention to complete and return it"). As FOBT screening participation is a very specific behaviour, single items can be a valid way to measure constructs related to it (Schwarzer & Luszczynska, 2007).

Planning. There were five items assessing the level of planning the participant had engaged in to complete their last mailed FOBT kit. Participants were asked to rate how truthful statements were for them on a 6-point scale (from 1 = "not at all true" to 6 = "very true"). For example, "The last time I received an FOBT kit I had a plan for where I was going to keep the kit".

Participation. Participation in the NBCSP was assessed with the single item "Last time you received an FOBT kit did you complete and return it?". Participants could either respond with a "yes" or "no".

Measures of internal consistency for the multiple indicator factors on the PAMS scale can be found in Table 7.3.

7.3.3.2. The UR-MSI Scale. Intervention examples were divided into three sections with different question stems to reflect the wording of the item. The first group of example interventions (n = 20) reflected "messages" and had the question stem "Would you be more likely to complete and return your next FOBT kit if the following messages were included in the blue oval" [with a blue oval superimposed on an image of the envelope used in the NBCSP to send the FOBT kit; see Figure 7.2]. Example items included "90% of bowel cancers are treatable if detected early, doing this test will greatly reduce your risk of dying from bowel cancer" and "Concerned about your health? People often have a sense of relief when they get their result saying everything is all clear". The second group of example interventions reflected provisions/items that could be added to the NBCSP (n = 18) and had the question stem "Would you be more likely to complete and return your next FOBT kit if you received the following with your next screening invitation?". Example items included "A sticky note you can put around the house to remind you to complete the FOBT kit" and "A series of pictures demonstrating each stage of the testing procedure". The third group of example interventions reflected services that could be provided alongside the NBCSP (n = 2) and had the question stem of

"Would you be more likely to complete and return your next FOBT kit if the following services were available with your next screening invitation?". Items included "A text-based messaging service you can use to get clear instructions on how to complete and return your FOBT kit" and "Places in your community where you can physically return your FOBT kit instead of mailing it back". Participants were asked to respond using a 5-point scale (1 = no, this would prevent me from participating, 2 = no, this would make me less likely to participate, 3 = this would make no difference, 4 = Yes, this would encourage me to participate, and 5 = Yes, this would definitely make me participate).

Figure 7.2.

Image of The NBCSP FOBT Kit to Depict Where the Example Intervention Messages of the UR-MSI Would be Placed

Note. Images sourced from www.cancerscreening.gov.au.

7.3.3.3. Demographic Information. Participants were asked to report their gender, age, income, highest education level, relationship status, country of origin, and residential postcode. Residential postcode was used to classify participants by geographic remoteness and socioeconomic status according to the Australian Bureau of Statistics, Australian Statistical Geography Standard, and Socio-Economic Indexes for Areas classification systems (Australian Bureau of Statistics, 2011a, 2011b).

7.3.3.4. Bowel Cancer Screening History. Participants were asked whether they received a home test kit through the NBCSP ("yes" or "no") and how recently (in months).

7.3.4. *Data Analysis*

Recoding of data, demographic frequencies, and percentages were calculated using IBM Statistics Package for Social Sciences (SPSS v.27). Confirmatory factor analysis (CFA) and structural equation modelling were conducted to assess the

measurement model and the structural model of the PAMS scale respectively. This was conducted with the Lavaan (Rosseel, 2012) R package using the bootstrapped diagonally weighted least squares estimator to account for the ordinal endogenous variables (i.e., level of intention and NBCSP participation) and the known non-normal distribution of indirect effects (MacKinnon et al., 2004). For the factors in the PAMS scale that have multiple indicator variables (i.e., risk perception, positive and negative outcome expectancies, action-self efficacy, and planning) McDonald's omega was calculated to assess their reliability using the semTools R package (Pornprasertmanit et al., 2015). McDonald's omega is a preferred reliability estimate over the traditional Cronbach's alpha, as it does not assume all items measure the latent factor with equivalent precision (and generalises to Cronbach's alpha if that assumption holds; Hayes & Coutts, 2020).

For analysis of the UR-MSI, responses to the example intervention were collapsed into a binary outcome with ratings of one, two, or three (i.e., responses of "no, this would prevent me from participating" thru to "this would make no difference") being recoded as zero reflecting a non-endorsement of the intervention and ratings of four or five (i.e., responses of "Yes, this would encourage me to participate" and "Yes, this would definitely make me participate") being recoded as one reflecting an endorsement of the intervention. The percentage of participants that endorsed the intervention was calculated for the subsets of people who did and did not return their last FOBT kit. Each example intervention was coded according to the factor of the HAPA model it was intended to relate to. For instance, the example intervention of delivering the message "90% of bowel cancers are treatable if detected early, doing this test will greatly reduce your risk of dying from bowel cancer" was coded under positive outcome expectancies. Interventions within each HAPA factor were ranked according to their level of endorsement. These endorsement percentages and respective 95% confidence intervals (CI) of positive responses to the UR-MSI items were calculated using the R statistical program (R Core Team, 2014) and plotted using GGplot 2 (Wickham, 2011).

7.4. Results

7.4.1. *Sample Characteristics*

Data was collected from 485 participants between the 11th of September 2020 and the 21st of December 2020. However, only 377 people completed all of the items on the PAMS scale and 354 completed all of the items in the UR-MSI scale. Missing

data were excluded in a listwise manner for the SEM analysis and a pairwise manner (i.e., per item) in the analysis comparing UR-MSI items. Non-completion of the PAMS scale was not significantly associated with gender (p = .815), education level (p = .673), age (p = .223), remoteness (p = .373), socio-economic status (SES, p = .113), or past participation (p = .449). In terms of non-completions of UR-MSI scale (which appeared later in the survey), missingness of data was not significantly associated with gender (p = .090), education level (p = .508), remoteness (p = .468), or SES (p = .867), however, it was significantly associated with increased age (p = .049) and past NBCSP non-participation (p = .034). The overall demographic characteristics can be seen in Table 7.2. The average age of the participants was 62.52 years (SD = 7.12).

Table 7.2.

Sample Characteristics

	n	(%^)
Gender		
Male	103	(28.7)
Female	253	(70.5)
Other	3	(0.8)
Past NBCSP Participation		
Yes	259	(68.0)
No	122	(32.0)
Born in Australia		
yes	256	(74.2)
no	93	(25.8)
In a relationship		
yes	222	(63.2)
no	129	(36.8)
Highest education level		
<Year 11	22	(6.1)
Year 11 – 12	34	(24.2)
TAFE/Apprenticeship	66	(18.3)
University degree	199	(40.7)
Other	39	(10.8)
Socio-economic status		
1st quintile (lowest)	40	(11.2)
2nd quintile	57	(16.0)
3rd quintile	96	(27.0)
4th quintile	76	(21.3)
5th quintile (highest)	87	(24.4)
Geographic remoteness		
1 (least remote)	227	(63.6)
2	101	(28.3)

3	28	(7.8)
4	1	(0.3)
5 (Most remote)	0	(0)

^ valid percentage

7.4.2. *PAMS*

7.4.2.1. Measurement Model. For all the constructs within the PAMS scale that have multiple indicators (i.e., action self-efficacy, positive/negative outcome expectancies, risk-perception, and planning) a CFA was fit to assess how each item loaded onto its respective factor and to assess the overall fit of the measurement model. One of the risk perception items ("To what level of severity would the health-related problems associated with bowel cancer be if they weren't attended to, or if they remained undiscovered?") had a low standardised factor loading and low communality (loading = .271, h^2 = .074) and was removed from the analysis. The remaining items had standardised factor loadings of above .60 and communalities greater than .40 (see Figure 3). The measurement model showed acceptable fit; $\chi 2$ (220) = 579.46, p < .001, CFI = .938, TLI = .928, RMSEA = .066, 90%CI [.059, .072]. The internal consistency for each of these constructs was ≥ .80 as shown in Table 7.3.

Table 7.3.

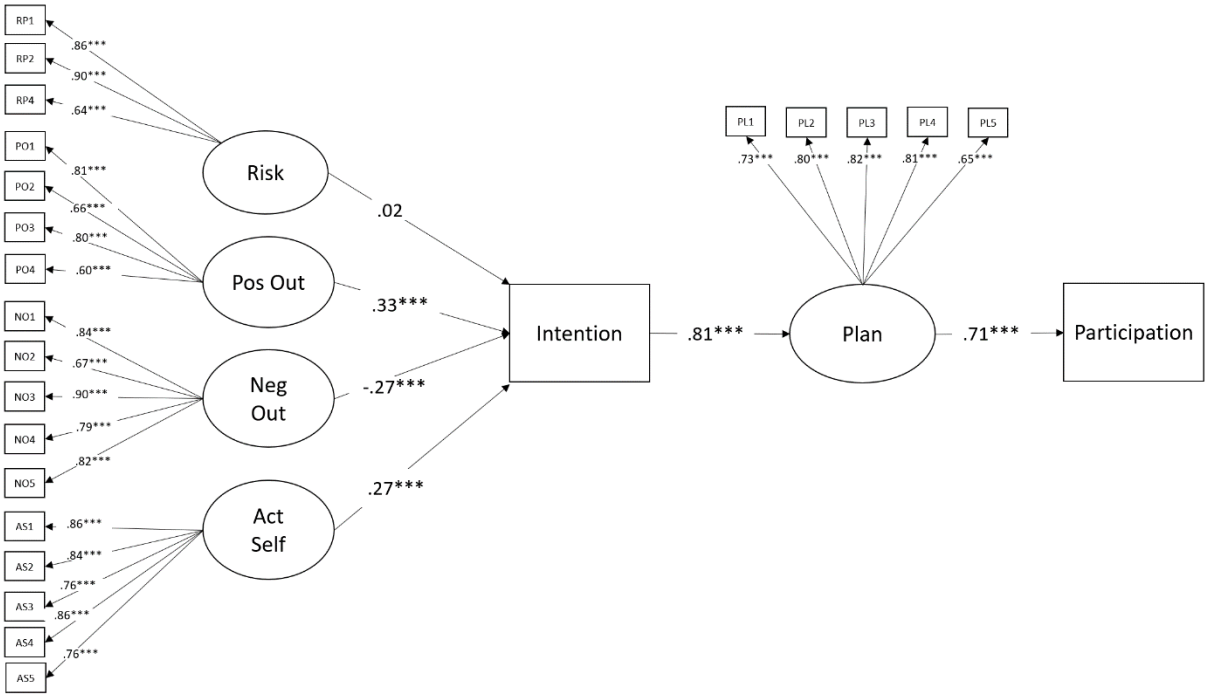
Internal Consistency of PAMS Factors with Multiple Indicators

PAMS Factor	ω
Risk perception	.82
Positive outcome expectancies	.80
Negative outcome expectancies	.89
Action self-efficacy	.91
Planning	.93

7.4.2.2. Structural Model. The structural model of the PAMS scale is shown in Figure 7.3. The structural model also showed acceptable fit, $\chi 2$ (242) = 466.08, p < .001, CFI = .968, TLI = .964, RMSEA = .050, 90%CI [.043, .056]. As seen in Figure 7.3, the only non-significant direct path was from risk perception to intention. The indirect paths from intention, positive outcome expectancies, negative outcome expectancies, and action self-efficacy to participation were all significant and the indirect path from risk perception to participation was non-significant (see Table 7.4). Overall, the model accounted for 39.5% of the variation in FOBT screening intention and 49.9% of the variation in FOBT participation.

Figure 7.3.

Standardised Coefficients and Factor Loadings of the PAMS Scale



Note. *** = significant at the .001 level.

Table 7.4.

Summary of Indirect Paths to FOBT Participation

Indirect Path	*B*	*SE*	95% CI	*p*
Intention → Planning → Participation	0.57	0.03	[0.51, 0.63]	< .001
Risk Perception → Intention → Planning → Participation	0.01	0.03	[-0.05, 0.07]	.718
Positive Outcome → Intention → Planning → Participation	0.19	0.03	[0.12, 0.25]	< .001
Negative Outcome → Intention → Planning → Participation	-0.15	0.03	[-0.25, -0.10]	< .001
Action Self-efficacy → Intention → Planning → Participation	0.15	0.03	[0.10, 0.21]	< .001

Note. *B* = standardised indirect effect, *SE* = Standard Error, 95% CI = standardised 95% confidence interval.

7.4.3. UR-MSI

All example interventions and their respective endorsement ratings can be seen in Appendix G. The example intervention that had the highest endorsement rating overall was delivering the message "90% of bowel cancers are treatable if detected early, doing this test will greatly reduce your risk of dying from bowel cancer " (BCT: Information about health consequences) with the FOBT kit, 56.44%, 95% CI [51.92, 60.89]. This was also the highest endorsed example intervention for both those that did return their last FOBT kit, 75.68%, 95% CI [69.98, 80.77], and for those that did not return their last FOBT kit, 50.00%, 95% CI [40.81, 59.18]. The example intervention that had the lowest endorsement rating overall was delivering the message "You are more likely to do something if you have a plan! Write down exactly where you are going to keep the kit, when you are going to complete the kit,

where you are going to store the samples and when you are going to return the kit" (BCT: Action planning) with the FOBT kit, 15.95%, 95% CI [12.82, 19.50]. This was also the lowest endorsed example intervention for those that did return their last FOBT kit, 18.14%, 95% CI [13.65, 23.39]. However, for those that did not return their last FOBT kit, the example intervention with the lowest endorsement rating was delivering the message "Encourage yourself to complete and return your FOBT kit, say out loud or silently 'As soon as I can, I will take my first sample!...And as soon as possible after that I will take my second sample" (BCT: Self-talk) with the FOBT kit, 13.11%, 95% CI [7.69, 13.11].

The three example interventions that had the highest endorsement rating within each HAPA factor can be seen in Figure 7.4. As shown in Figure 7.4, the highest endorsed example intervention within each HAPA factor and associated endorsement rating were as follows. Providing "A leaflet simply and clearly explaining how to complete each stage of the FOBT screening process" (BCT: Instruction on how to perform a behaviour, action self-efficacy). Delivering the message "90% of bowel cancers are treatable if detected early, doing this test will greatly reduce your risk of dying from bowel cancer" (BCT: Information about health consequences; positive outcome expectancies), 56.44%, 95% CI [51.91, 60.89]. Delivering the message "'Only 2 out of 100 people who complete this FOBT kit will be referred to have further testing, such as a colonoscopy. The vast majority of people who complete the FOBT kit require no further testing" (BCT: Information about health consequences; negative outcome expectancies), 37.01%, 95% CI [32.72, 41.46]. Delivering the message "Bowel cancer is one of Australia's most common cancers, even more so for people over 50. Early detection is your best chance of survival" (BCT: Information about health consequences; risk perception), 55.62%, 95% CI [51.09, 60.08]. Giving the prompt of "If you have not completed and returned the FOBT kit within two weeks, receiving a text message containing feedback that you have not completed and returned the FOBT kit" (BCT: Feedback on behaviour; planning), 48.06%, 95% CI [43.55, 52.59].

Figure 7.4.

Highest Endorsed Example Intervention from the UR-MSI Categorised by HAPA Factor

7.5. Discussion

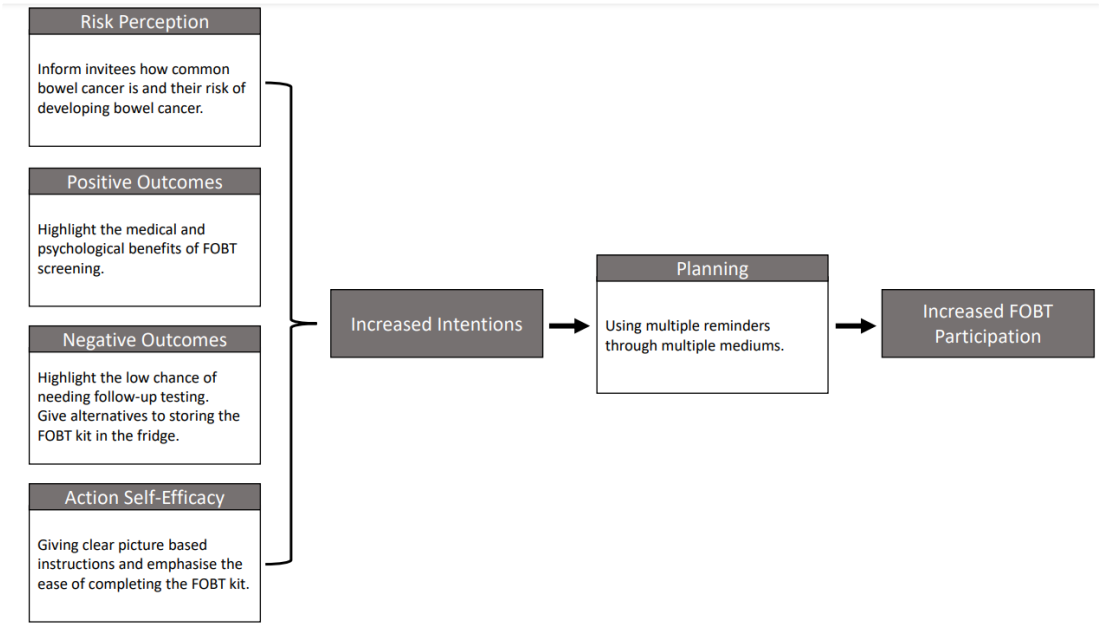
The findings from this study pose substantial clinical implications for mail-out bowel cancer screening programs. Two important discoveries to emerge from our study are that: (1) the HAPA model is an appropriate framework for describing and measuring the psychological and behavioural process involved in participating in mail-out bowel cancer screening programs, and (2) there are several consumer-endorsed interventions that should be trialled as they may induce a positive change

relating to each factor within the HAPA model and therefore an increase in participation rates for mail-out bowel cancer screening programs.

The findings from the PAMS scale suggest that using the HAPA model can explain half of the variation in FOBT participation, meaning risk perception, positive and negative outcome expectancies, action self-efficacy, and planning play an important role in mail-out bowel cancer screening behaviour. Furthermore, these results are consistent with the notion that participation in mail-out bowel cancer screening involves a clear two-stage process consisting of (1) a motivational stage, whereby an intention to participate is formed, followed by (2) a volitional stage, where these intentions are translated into action (Goodwin et al., 2019b; Myers et al., 2020). The findings from the UR-MSI scale indicate that providing information regarding the invitee's elevated risks of bowel cancer, sending text message-based reminders, and providing alternative locations to return their FOBT kit should be incorporated into mail-out FOBT screening programs to increase participation. However, for interventions to have the greatest effect on participation rates, a multi-faceted approach that targets all aspects of the HAPA model is required (Glanz & Bishop, 2010). A summary of a multifaceted consumer-endorsed behaviour change strategy based on the current findings is shown in Figure 7.5.

Figure 7.5.

Summary of Consumer Endorsed Interventions that Target all Factors Within the HAPA Model to Promote FOBT Screening Participation



7.5.1. *Forming FOBT Screening Intentions*

The results of the PAMS scale indicates that multiple factors directly impact intentions to participate. These include (1) participants' belief in the positive health outcomes from completing their FOBT kit, (2) their confidence in their ability to complete the FOBT kit, and (3) their reduced negative perceptions regarding FOBT screening. Interestingly, once these factors have been taken into consideration, the participant's perception of the risks associated with bowel cancer had little to no direct impact on forming intentions to return their completed FOBT kit. The diminished direct impact that risk perception has on forming intentions to perform a health behaviour is a common finding in the application of the HAPA model (Barg et al., 2012; Hattar et al., 2016; Parschau et al., 2014). However, risk perception should still be considered as an important factor. Within the HAPA model, risk perception is thought to be a key driver in the initial formation of behavioural intentions and is thought to be vital for an individual to begin contemplating issues regarding the remaining motivational factors (i.e., positive and negative outcome expectancies and action self-efficacy; Schwarzer et al., 2011). It has also been noted that the relationship between risk perception and behaviours may change over time, and the cross-sectional nature of this study would not be able to model this effect (Weinstein & Nicolich, 1993). It is possible that for some of these participants, their previous bowel cancer screening behaviour *lowers* their level of risk perception (as they feel protected from bowel cancer due to their screening behaviour) and at the same time increases their intention to participate in the NBCSP in the future. For these, the effect of risk perception would be in the opposite direction than originally hypothesised in the HAPA model (i.e., higher levels of risk perception leads to higher screening intention) and would reduce the overall effect across all participants. Therefore, the relationship between risk perception and intentions remains unclear and interventions aiming to increase participatory intention in mail-out bowel cancer screening programs should benefit from incorporating multiple strategies that target all motivational factors of the HAPA model.

The results from the UR-MSI scale found that the highest endorsed intervention strategies to positively impact these key motivational factors were those that either (a) clearly highlighted the medical and psychological benefits of FOBT participation, (b) increased the invitee's confidence by providing clear picture-based instructions, or (c) reduced aversive perceptions of FOBT screening by giving alternative FOBT storage options and noting the low chance of follow-up testing

being required after FOBT participation. These typically involved sending messages and adding provisions to the existing kit. Interventions should also still inform invitees of the risks pertaining to bowel cancer but be aware that educating invitees of these risks will not be sufficient alone to develop strong intentions to participate (Schwarzer & Luszczynska, 2008). Of note, one of the highest endorsed example interventions overall communicated the increased risk of bowel cancer for those over the age of 50. This research found no significant relationship involving risk perception for both developing intentions and increased FOBT participation. This highlights a mismatch between what the end-user considers an important factor in FOBT participation, prima facie, and what the data indicate are more influencing factors. Indeed, when similar risk perception strategies have been used in isolation (i.e., with no other behaviour change strategies present), no significant difference in participation was found (Cole et al., 2007; King et al., 1994). Thus, increasing risk perception in isolation is unlikely to affect participation rates. Nevertheless, it can and should be used in conjunction with other strategies.

7.5.2. *Transitioning from High Intentions to FOBT Participation*

As with many health behaviours, there is an intention-behaviour gap whereby people with high intentions to perform a health behaviour often do not perform that health behaviour (Rhodes & de Bruijn, 2013). Our findings suggest that the degree to which one plans to complete and return their FOBT kit is a key mediating factor that bridges a person's intentions and their actualised behaviour of completing and returning their FOBT kit. This finding is in line with previous work that showed a substantial proportion of many invitees do indeed intend to participate in the mail-out screening program but forget or procrastinate (Goodwin et al., 2019b; Hall et al., 2015). As such, in addition to fostering strong behavioural intentions, intervention strategies are needed to facilitate the invitee's transition from the motivational phase to the volitional phase of FOBT screening. Again, this research shows a mismatch between what invitees believe will promote participation and what strategies are likely to increase FOBT participation, Despite the need for action planning interventions to bridge the intention behaviour gap, these behaviour change strategies had some of the lowest endorsement rating in the UR-MSI survey.

The highest endorsed interventions aiming to promote effective planning involved sending some form of reminder to complete the FOBT kit (e.g., a reminder text message) to the invitee. A crucial aspect of any effective action plan involves

setting reminders (Hagger & Luszczynska, 2014; Schwerdtfeger et al., 2012) and these highly endorsed interventions would make this aspect of action-planning an automatic feature of the FOBT invitation process. This contrasts with the lower endorsed planning interventions that would require the invitee to be responsible for the effective planning (e.g., using sticky note reminders or completing an action plan themselves at home). Although a lack of planning often results in those wishing to complete their FOBT kit procrastinating and ultimately forgetting to complete their kit (Chapple et al., 2008; Goodwin et al., 2019b; Hall et al., 2015), a successful strategy to promote effective planning has yet to be established. As one of the lowest endorsed interventions promoted the use of action planning, future research should investigate ways of educating invitees on the benefits that effective action planning can have in reducing procrastination and forgetfulness. If invitees are not willing to engage with planning interventions to the extent needed for them to be effective, future research should investigate if multiple reminders (possibly through multiple mediums), or interventions to personalise reminders (e.g., platforms for participants to create their own automated reminder schedules) can be a more effective strategy as these results indicate invitees are more likely to engage with reminder type interventions overall.

7.5.3. *Strengths and Limitations*

To the authors' knowledge, this is the first study to apply the HAPA model in the context of mail-out FOBT screening. This is a valuable addition to the growing body of literature finding that the HAPA model can be used to describe a wide range of health behaviours. This was also the first study to translate and test the acceptance of various BCTs via example interventions in the context of mail-out FOBT screening. The study findings are also likely to have high ecological validity in health systems similar to Australia's.

However, some limitations need to be considered. This study was a cross-sectional survey meaning follow-up research will be needed to further validate the causal relationships between the factors within the HAPA model. However, it should be stated a benefit of conducting this study cross-sectionally is that it prevents the possibility of the question behaviour effect (Wilding et al., 2016), where if this study was conducted longitudinally, the questions asked may influence the participants' behaviour biasing the result.

Additionally, while these highly endorsed UR-MSI example interventions show promise, further qualitative co-design studies (e.g., workshops or focus groups) are needed to better understand how these should be implemented and constructed. After these measures have been taken, only then through applying these interventions in a large-scale randomised control trial can the true effectiveness of these interventions be assessed. The web-based design of the survey may also limit the implications of these findings for low socioeconomic groups or those with low information technology literacy. A large proportion of the participants in the current study were female, 70.5%, and this may have biased some of the results. Future studies with a higher proportion of males will be needed to further validate these findings. Finally, it should be noted that participation in this study was completely voluntary, and as such, a self-selection bias cannot be ruled out which may reduce the generalisability of the findings.

7.5.4. *Conclusion*

To increase participation in mail-out FOBT screening programs, interventions need to be implemented to facilitate the complete process of FOBT screening. Policymakers and health researchers should analyse the messaging currently used within the invitation process and assess what motivational components already exist and add messaging such that all motivational factors are addressed. Efforts should also be made to apply strategies that facilitate the invitee's transition from high intentions into action. While it is currently unclear what an engaging and useable action planning intervention would be comprised of to aid in this transition, policymakers and health researchers should implement more reminders through multiple mediums to reduce the impact forgetfulness has on FOBT screening participation. Finally, given the autonomous nature of these screening programs, it is vital that interventions are comprised of strategies that invitees immediately perceive as being beneficial or helpful such that they engage with the intervention. Taking these measures should address all the influential factors that relate to the process of FOBT screening and thereby increase participation rates.

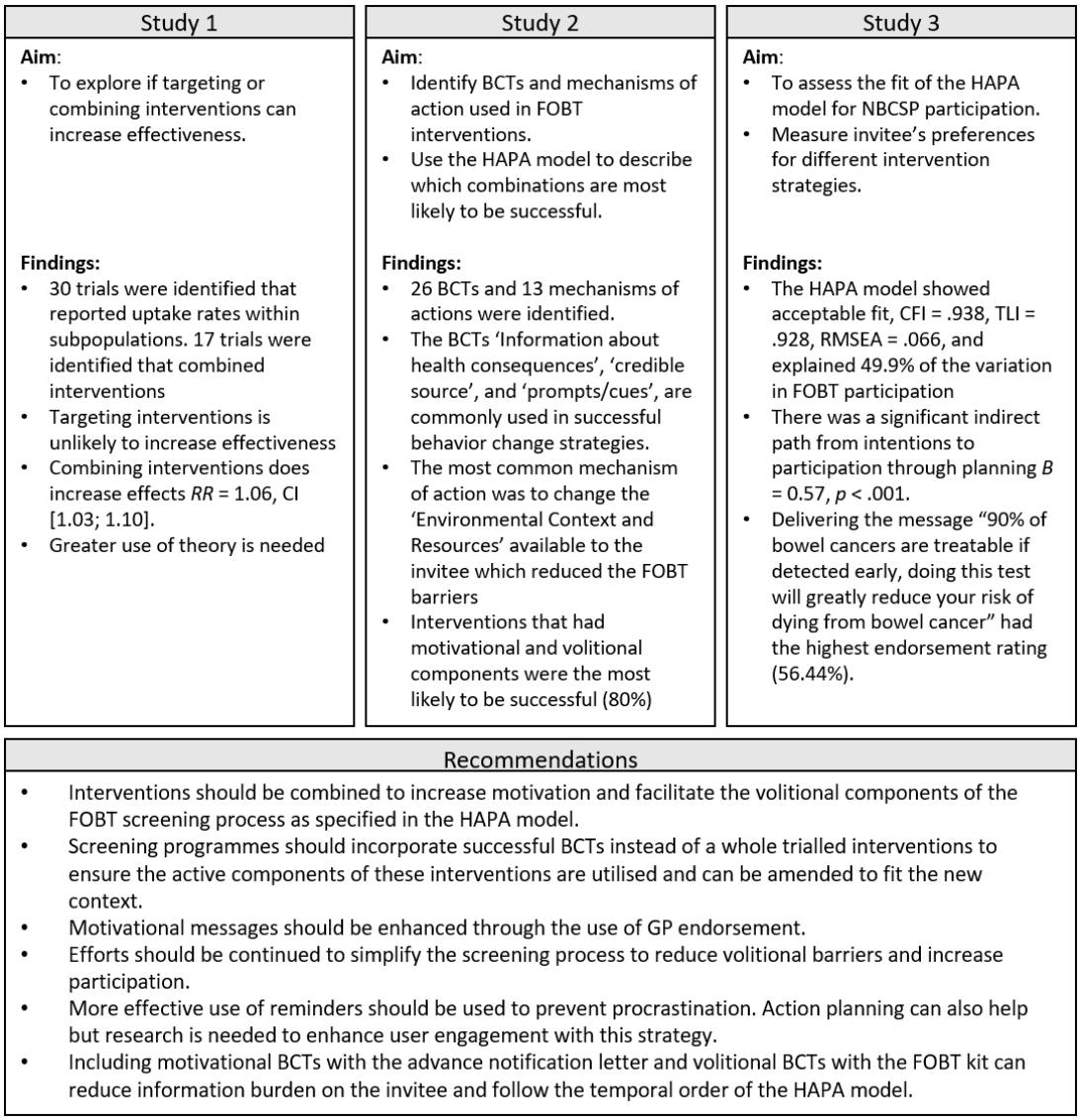
CHAPTER 8: GENERAL DISCUSSION

8.1. Overall Findings

This body of research identifies techniques that can be applied to increase participation in mail-out FOBT screening programmes. A summary of each study's findings can be found in Figure 8.1. Collectively, these indicate that for an intervention to have the highest chance of being effective they should include multiple behaviour change strategies, aim to promote motivation to participate as well as facilitate the actions of FOBT screening, encourage concrete planning, and make user-centred intervention design choices. These findings address many of the limitations within the literature regarding mail-out FOBT screening interventions. Specifically, (1) this research has shown that combining interventions can be an effective method to overcome the limited success of the one-size-fits-all approach, (2) it provides a much needed theoretical framework to guide how future multifaceted intervention should be designed, (3) it identified the specific intervention components and behavioural mechanisms that should be incorporated into screening programmes, and (4) it was the first to examine invitee's preferences for a wide range of different intervention strategies which can be used to increase invitee engagement with interventions.

Figure 8.1.

Summary of Thesis Findings and Recommendations



The utility of several frameworks that should be used in the design process for FOBT screening interventions have been demonstrated through the methods and findings of this research. Firstly, this thesis found strong evidence that the HAPA model is an appropriate framework for the context of mail-out FOBT screening and will assist in evidence-based intervention design. The first obstacle in creating a theory-based intervention is choosing an appropriate theory. There are numerous theories of health behaviour that are often very adept at predicting health behaviours, but when used to create health interventions their effects tend to be much more limited (Prestwich et al., 2015). When basing an intervention design on a specific health behaviour theory it is vital that the theory reflects the specific properties of the health behaviour attempted to be modified (Prestwich et al., 2015). While generally

applications of the HAPA model relate to enduring health behaviours, such as dieting and increasing levels of physical activity, this research found that the HAPA model maybe even more effective for one-off health behaviours as the amount of variance the HAPA model could explain in this context (i.e., 49%) was substantially larger than the average amount reported in the meta-analysis conducted by Zhang et al. (2019; i.e., 17.5%). Intervention designers should use this theoretical model to construct new multifaceted intervention strategies as the HAPA model was found to accurately describe the important factors and processes related to FOBT screening and previous interventions which contained strategies with motivational and volitional components were the most likely to be successful at increasing participation rates.

Secondly, the BCT-Taxonomy v1 (Michie et al., 2013) and theory and techniques tool kit (Johnston et al., 2020) are effective methods to standardise the description of intervention strategies, identify the effective (and ineffective) intervention components used throughout the literature, and can act as a base from which new behaviour change strategies can be created. It is considered best practice to develop multifaceted interventions that systematically use available evidence (Craig et al., 2008; Dobrow et al., 2004). However, it is often difficult to adapt previously trialled behaviour change intervention strategies into practice; with the design of new interventions to promote FOBT screening being no exception (Dobrow et al., 2004; Michie et al., 2017; Moore & Evans, 2017). This is of particular importance for mail-out FOBT screening programmes as they exist across many different cultures, languages, and vary in their implementation. This means adaptations need to be made to previously trialled interventions to fit the new contexts in which they will be implemented. By describing behaviour change strategies in terms of their BCTs and mechanisms of action, successful behaviour change strategies can be adapted to the cultural and environmental context of any national screening program without compromising the effective components. For example, GP endorsement interventions have been successful as they act as a credible source from which health information can be delivered (e.g., Hewitson et al., 2011). However, some cultures, such as indigenous Australians, do not have strong continued relationships with GPs meaning this strategy may be less effective for them (Christou et al., 2010). Instead, sending FOBT endorsement messaging from

more culturally relevant organisations, such as Aboriginal Medical Services, may be an effective adaptation of this behaviour change strategy for this subpopulation.

Finally, this research demonstrates consumer preferences for different behaviour change strategies to be considered in future intervention design. For example, it was found that despite the important role planning has in FOBT kit completion (Goodwin et al., 2021), interventions that promoted FOBT action planning were among the lowest invitee endorsed interventions. For other health behaviours, action planning interventions have consistent medium-to-large positive effects (Carraro & Gaudreau, 2013). However, action planning interventions to promote mail-out FOBT screening have had little to no effect (Lo et al., 2014; Neter et al., 2014). A possible reason for these conflicting findings could be that invitees do not foresee the benefit of action planning in the context of bowel cancer screening. When the invitees receive unsolicited instructions to facilitate the planning of stool collection, engagement may be low, and effectiveness reduced. This knowledge that invitees do not immediately perceive the benefit of completing action plans can direct future research to investigate the right action planning intervention that focuses on maximising invitee engagement. These factors of engagement and perceived utility would be relevant to other behaviour change strategies as well and should be considered in future intervention development and evaluation research.

8.2. Recommendations for Population Bowel Cancer Screening

Most national mail-out screening programmes already incorporate effective behaviour change strategies (e.g., Moss et al., 2016). However, there are many opportunities for components to be added or amended to increase participation rates. These are discussed below with the Australian NBCSP used as an exemplar, however, many of these recommendations could and should be applied in other national mail-out bowel cancer screening programmes.

8.2.1. *Messaging*

The messages (i.e., information sent to the invitee that appears on packaging and in letters associated with the kit) currently included in the NBCSP invitation materials cover many aspects of motivation as described in the HAPA model. The messaging provides the invitee with information regarding their increased risk of developing bowel cancer (i.e., risk perception), the increased chance of surviving bowel cancer through FOBT screening participation (i.e., positive outcome expectancies), notes that not all positive tests are indicative of bowel cancer (i.e.,

reducing negative outcome expectancies), and includes simple and clear picture-based instructions (i.e., action self-efficacy). However, based on the low participation rates (AIHW, 2020), it is possible that invitees do not read or engage with these messages to the extent required to motivate them to use the kit or the messages are not presented in a way that conveys the correct meaning. The current research found that NBCSP invitees highly endorsed a message regarding the positive emotional consequences of completing the FOBT kit (i.e., having a sense of relief or having peace of mind). Previous interventions have successfully used positive and negative emotional messaging to improve a range of health behaviours such as smoking cessation, increasing physical activity, and improved dietary behaviour (Carfora et al., 2019; Devi et al., 2014; Sims et al., 2016). However, emotional messaging is not currently in the NBCSP invitation materials and could be an effective strategy to increase engagement with the motivational components of the invitation messaging.

8.2.2. *Planning*

Based on the finding that people with high levels of concrete planning are also more likely to complete and return their FOBT kit, NBCSP invitation materials should include strategies that promote effective planning. This type of intervention should aim to promote and facilitate the invitee to engage in planning to prevent procrastination and forgetting; a phenomenon frequently reported by non-responders of FOBT programmes both here in Australia and in international programmes (Chapple et al., 2008; Goodwin et al., 2019b; Van Rijn et al., 2008). However, in this study, interventions designed to facilitate planning, such as encouraging the invitee to set specific FOBT screening behavioural goals, had low endorsement by participants. Further research needs to be conducted to identify the ways in which interventions that promote planning can be successfully implemented such that the invitee will engage with the planning intervention. Upon reviewing planning interventions, Hagger and Luszczynska (2014) recommend that for planning interventions to have the highest chance of success they should use *if-then* prompts, such as "*If* you already have the kit, *then* take advantage and use it!", which was used by Neter et al. (2014) to successfully increase mailed FOBT screening rates. Hagger and Luszczynska (2014) also suggest gathering pilot data to identify relevant cues that can be used to prompt the wanted behaviour and setting reminders to prevent forgetting. These guidelines reported by Hagger and Luszczynska (2014) could be

used in the context of mail-out FOBT screening to guide future action planning intervention research.

8.2.3. *Reminders*

Another strategy that was highly endorsed by NBCSP invitees in this research was sending reminders to participate. Currently, one reminder letter is mailed to non-respondent NBCSP invitees 8-weeks after the FOBT invitation (Department of Health, *n.d.*). It may be beneficial to increase the number of reminders sent to the non-responsive invitee and to do so using multiple modalities (e.g., telephone calls and text messages). This multimodal approach has been shown to increase a range of screening behaviours including mail-FOBT screening (Coronado et al., 2018), mammography screening (Feldstein et al., 2009), and cervical cancer screening (Peitzmeier et al., 2016). One option, that also incorporates planning is to encourage invitees to set reminders for themselves, such as leaving visual cues around the house or placing the kit in the bathroom or toilet. Hagger and Luszczynska (2014) argue that plans to perform a health behaviour are far more likely to be enacted upon when there are salient and accessible cues throughout the persons' environment, particularly when they are relevant to the target behaviour (e.g., setting a cue to complete the kit near the toilet). However, these types of interventions were found to have low endorsement from NBCSP invitees in the current research and therefore may be unlikely to be used. Future research should use a user-centred approach to inform the design of a self-reminder intervention that maximises invitee engagement.

8.2.4. *GP Endorsement*

The current NBCSP invitation materials include a health message from the Chief Medical Officer (Department of Health, *n.d.*). While this could be considered as an endorsement from a credible source, a very effective behaviour change strategy in this context, the current findings indicated that the most successful way to implement this behaviour change strategy is by using the invitee's personal GP as the credible source. In many national bowel cancer screening programmes, including Australia, the United Kingdom, and the Netherlands, the invitee's personal GP is only involved after the invitee has decided to participate in the program, completed and returned their FOBT kit, and received a positive test (Bertels et al., 2019; Dawson et al., 2017; Morris et al., 2012). Involving GPs in the initial invitation process in Australia, specifically implementing routine GP endorsement of

participation in FOBT screening programmes, will very likely lead to greater participation rates (Goodwin et al., 2019a).

8.2.5. *Advance Notification*

In the Australian NBCSP invitation and screening process, invitees receive an advance notification letter two weeks prior to the FOBT kit arrival. Advance notification letters like these have consistently been shown to increase FOBT participation rates (Goodwin et al., 2019a), however, not all screening programmes implement them in their invitation process. For instance, the Scottish bowel cancer screening program does not currently send advance notification letters prior to the FOBT kit arrival (NHS Scotland, 2017). Greater use of advance notification letters in the process of bowel cancer screening programmes is a cost-effective way to increase participation and should be incorporated in more national screening programmes (Cronin et al., 2013).

The use of advance notification letters in the NBCSP also allows for the delivery of behaviour change interventions to follow the temporal order of the HAPA model. For instance, the advance notification letter could focus on delivering messages that motivate invitees to participate. The intervening time between the advance notification letter and the arrival of the FOBT kit would allow the invitee time to elaborate on the meaning of the motivational messages making them more likely to be effective. Then, when the invitation that contains the FOBT kit arrives, the accompanying messages could focus on telling the invitee about the risk of procrastination leading to forgetting and encourage specific action planning by the invitee to prevent this. This spreading out of intervention materials would reduce the information burden that could occur if all these interventions were delivered to the invitee at once.

8.2.6. *Stool Collection Processes*

The FOBT kit used in the NBCSP is immunochemical based and as such, there is no requirement for the invitee to undergo any dietary restriction, and only needs two samples to be collected (Department of Health, *n.d.*). All of these procedures are effective at promoting participation and should continue in the future. There is some evidence to suggest that only requiring one FIT sample to be collected can increase participation rates without reducing the number of cancers detected through the program (Schreuders et al., 2019). This research was conducted in the

Netherlands and future research should investigate if the same positive effects of one-sample FIT collection can be replicated in other countries.

8.2.7. *Key Recommendations*

In summary, the findings from this research highlight key areas for improving mail-out bowel cancer screening recruitment processes to increase participation. Motivational messaging in the initial invitation needs to be enhanced. This could potentially be done by leveraging the positive emotional consequences of participating in FOBT screening. The inclusion of GPs in the invitation process, through GP endorsement letters, should be implemented as it is very likely to increase participation rates. Further actions need to be taken to prevent invitees with high screening intentions from procrastinating and forgetting to participate. Issuing more frequent reminders may help prevent address this issue, though having invitees engage in action planning and setting their own reminders may also be effective strategies. Finally, interventions should be implemented following the temporal order of the HAPA model where strategies that increase FOBT screening motivations should be delivered first, followed by interventions that aid the volitional aspects of FOBT screening such as planning and setting reminders. These additions to FOBT screening programmes should increase participation rates while not altering the program recruitment components that are already in place that are effective at promoting participation.

8.3. Strengths and Limitations

This research was the first to systematically investigate the aspects of behaviour change interventions that are crucial for increasing participation in mail-out screening programmes. Given the small and heterogeneous effects of previous interventions and the variation in the way similar interventions are implemented within this literature (Goodwin et al., 2019a), this innovative research was needed to discern the elements that made certain strategies more effective than others and to identify the key components that should be incorporated into national mail-out screening programmes.

There have been recent advances in health psychology regarding the use of psychological theory for behaviour change and the translation of research findings into practice. Specifically, ‘realist review’ methods allow researchers to go beyond the question of what interventions work to addressing higher-level questions such as how interventions bring about behaviour change and under what circumstances

should they be applied (Pawson et al., 2005). Further, work by Michie et al. (2013) in developing the BCT-Taxonomy v1 has begun to establish a standardised language for describing effective components of interventions along with the mechanism of action framework to identify how these components bring about change (Carey et al., 2018; Connell et al., 2018). This program of research has been the first to adopt these new research tools to apply them in the context of mail-out FOBT screening programmes. These efforts are vital for policymakers and health care professionals that wish to translate research findings into their practice.

The research also provides two psychometrically sound measurement instruments developed using the principles outlined by Zamanzadeh et al. (2015). The PAMS scale was the first application of the HAPA model in the context of FOBT screening and the PAMS scale was the first to translate BCTs to behaviour change interventions that could be used to increase participation in mail-out FOBT screening. These scales can be used in future research to assess the fit of the HAPA model in mail-out screening programmes in other countries and measure the preferences for intervention strategies in other populations.

However, there were limitations within this body of research that need to be acknowledged. All studies within this thesis focussed on a specific type of FOBT screening where the FOBT kit is mailed to the invitee's home without request. While this is a common mail-out procedure, these invitation methods can be different in other national bowel cancer screening programmes and may limit the generalisability of these finding to those screening programmes. For example, other FOBT screening programmes exist where the invitee needs to request an FOBT kit to be mailed to them (e.g., France and some parts of USA; Jager et al., 2019; Le Bonniec et al., 2020). These programs tend to have much lower population level participation rates and the psychological and behavioural processes may differ from those described in the current research. While this research showed the utility of the HAPA model in this context, it is possible that other theoretical frameworks, such as the theory of planned behaviour (Ajzen, 1991) or the transtheoretical model (Prochaska & Velicer, 1997), could be equally or even more applicable. If one of these alternative theoretical models were more applicable, the intervention recommendations of this research would need to change to better reflect the models uniquely specified psychosocial and behavioural factors and processes.

Finally, all individuals from which data was collected in this research were Australian residents, recruited by convenience sampling, and sampled cross-sectionally. As such, a self-selection bias cannot be excluded and the generalisability of these findings to other countries may be limited. It is possible that the FOBT screening related views and experiences of those that chose not to participate in this research were systematically different to those who did choose to participate in this research (Eysenbach & Wyatt, 2002) and caution should be applied in generalising findings to the entire Australian population. Additionally, due to the cross-sectional nature of the data, it is not yet clear if the current account of past screening behaviour using the HAPA model will generalise to accurately predicting future NBCSP screening behaviour and this research cannot draw definitive conclusions about causation. Past participation in the NBCSP is one of the key indicators of future participation (AIHW, 2020), however, longitudinal studies should be conducted to formally address these issues.

8.4. Directions for Future Research

These current findings provide an evidence base on which new intervention strategies can be designed. However, as these recommendations have yet to be applied in a large scale RCT, their effectiveness in promoting FOBT screening participation cannot be for certain. Future research will be needed to test if these strategies do indeed promote FOBT screening participation and which of the options stated within this thesis will be the most effective.

8.4.1. *Testing Behavioural Mechanisms*

To enhance the use of theory in intervention design and ensure that behaviour change strategies are working through their intended behaviour change mechanism, the process of developing future interventions should incorporate and report on the theoretical mechanism by which the BCT is expected to bring about behaviour change (Michie & Abraham, 2004). In the context of FOBT screening interventions, this would mean that future trials should not necessarily evaluate the effectiveness of individual BCTs solely on the basis of if they ultimately lead to increased participation rates, rather, more efforts should be made to evaluate BCTs by understanding if it positively influenced a pre-specified determinate of the health behaviour. As an example, interventions with the sole aim of informing invitees of the positive health outcomes of FOBT screening, should be evaluated as effective or ineffective based on its ability to promote positive outcome expectancies in an

individual as well as its overall effect on uptake. In order to do this, a measure of positive outcome expectancies should be captured during intervention trials. Currently, the majority of research focuses on *whether* an intervention can increase FOBT screening participation without consideration for the mediating factors that explain the cause of these increased participation rates. Establishing whether the behaviour change strategy has influenced its intended mechanism will enable designers of multifaceted interventions to accurately target and change all determinants of participation in mail-out FOBT screening programmes. These efforts will result in intervention design and evaluation that makes greater use of psychological theory and ultimately be more successful and widely applicable in different contexts (Michie et al., 2017).

8.4.2. *Testing Variation of the HAPA Model*

While the current findings suggest that the HAPA model is appropriate for describing the social-cognitive factors and process of mail-out FOBT screening in the general population, future research should investigate if this holds equally for all subpopulations as this can guide the appropriate targeting of future interventions. Participation rates are lower within certain demographics, such as males, younger invitees, and invitees in low SES areas, and needs to be further understood and remedied (AIHW, 2020). It is possible that these subpopulations vary systematically in the degree to which they experience the social-cognitive factors relating to FOBT screening (such as having lower levels of positive outcome expectancies or planning) and/or the degree to which these factors relate to participation could be attenuated (e.g., the relationship between planning and action could be weaker in these groups). Potential variation in the behaviour change processes underlying mail-out FOBT screening across these subpopulations are currently unknown and should be explored. This information could inform how interventions can be targeted at specific social-cognitive factors of the HAPA model to reduce screening disparity in these demographic groups. The finding that a targeting approach would unlikely increase intervention effects may be due to the fact that the interventions trialled thus far did not take this theory-driven approach to design.

8.5. Conclusion

Participation rates in population mail-out FOBT screening programmes are poor, and the global burden of bowel cancer could be greatly reduced through effective interventions to increase these rates (Issaka et al., 2019). Collectively, these

research findings provide a useful and prescriptive theoretical framework from which new interventions can be designed. Based on this framework and the associated evidence, interventions to increase participation in population bowel cancer screening should take a multifaceted approach implementing behaviour change strategies that facilitate each behavioural and psychological process that plays an influential role in FOBT screening. Specifically, messaging should be used with the invitation process that relates to promoting action self-efficacy, positive outcome expectancies, and risk perception, while also reducing negative outcome expectancies. Crucially, interventions should be implemented that facilitate the invitee's transition from the motivation stage to the volition stage of behaviour change by simplifying the testing procedure where possible, encouraging participants to engage in planning, and sending multiple reminders to prevent procrastination and forgetfulness. Collecting more information from screening invitees on how these strategies should be implemented will be key for intervention engagement and success. Following the recommendations presented here should ensure that future interventions are theory-driven, evidence-based, multifaceted and, most importantly, effective at increasing participation in screening and aid in the early detection of bowel cancer.

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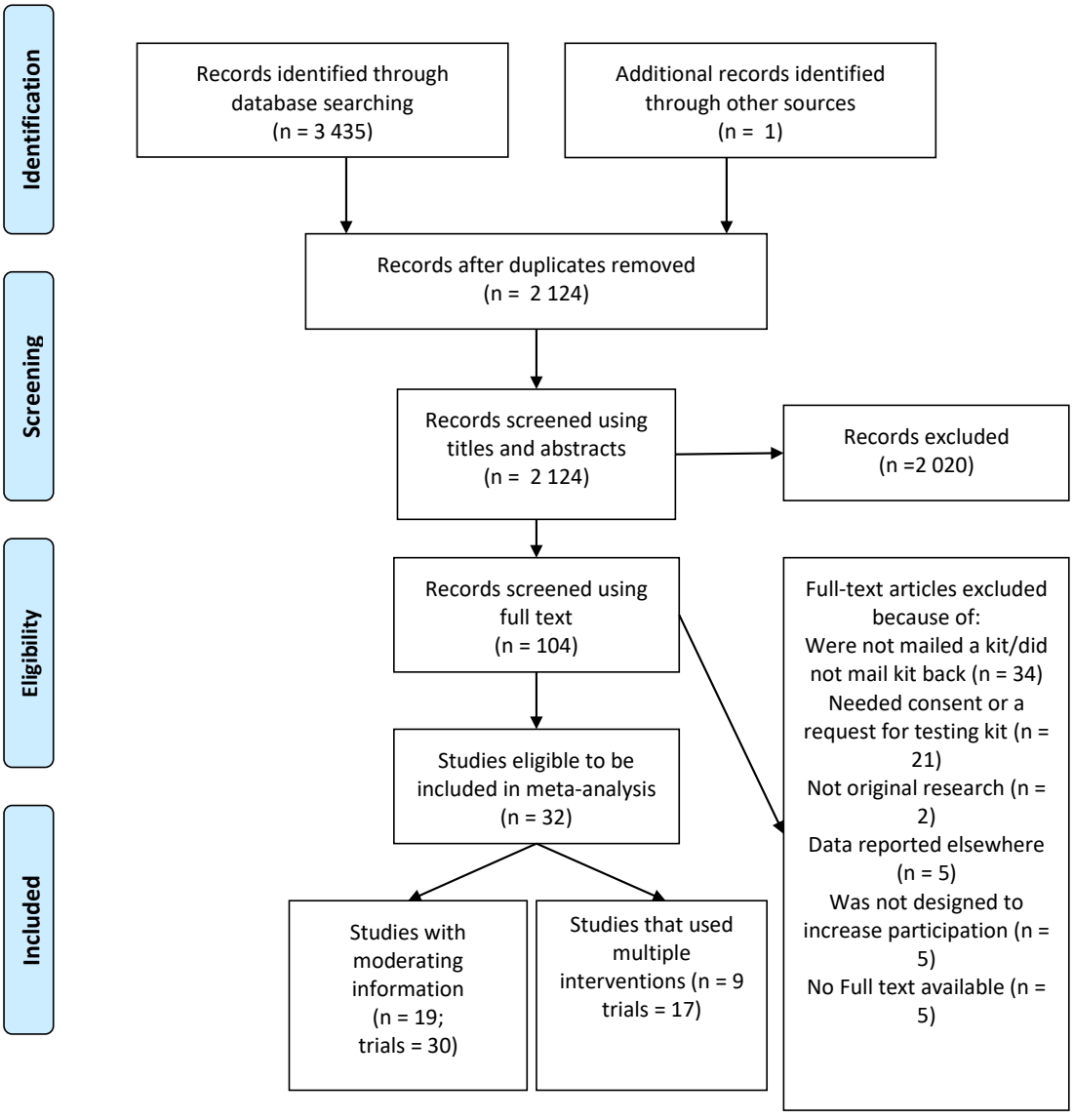
10. APPENDICES

10.1. Study One Appendices

10.1.1 *Appendix A: PRISMA Flow Diagram*



10.1.2. *Appendix B: Search Strings Used for Systematic Search*

Pubmed (n= 1296; 31/10/2018)

((("fecal occult blood"[Title/Abstract] OR "faecal occult blood"[Title/Abstract] OR FOBT[Title/Abstract] OR "fecal immunochemical test" OR "faecal immunochemical test" [Title/Abstract])) AND (participat*[Title/Abstract] OR adher*[Title/Abstract] OR uptake[Title/Abstract] OR return [Title/Abstract] OR complian* [Title/Abstract]))

Scopus (n=1568; 31/10/2018)

TITLE-ABS-KEY ("fecal occult blood" OR "faecal occult blood" OR fobt OR "fecal immunochemical test" OR "faecal immunochemical test") AND TITLE-ABS-KEY (participat* OR adher* OR uptake OR return OR complian*))

PsycInfo (n= 37; 31/10/2018)

TI ("fecal occult blood" OR "faecal occult blood" OR FOBT OR "fecal immunochemical test" OR "faecal immunochemical test") OR AB ("fecal occult blood" OR "faecal occult blood" OR fobt OR "fecal immunochemical test" OR "faecal immunochemical test") AND TITLE-ABS-KEY (participat* OR adher* OR uptake OR return OR complian*)) AND TI (participat* OR adher* OR uptake OR return OR complian*) AND AB (participat* OR adher* OR uptake OR return OR complian*)

CINAHL (n= 421; 31/10/2018)

TI ("fecal occult blood" OR "faecal occult blood" OR FOBT OR "fecal immunochemical test" OR "faecal immunochemical test") OR AB ("fecal occult blood" OR "faecal occult blood" OR fobt OR "fecal immunochemical test" OR "faecal immunochemical test") AND TITLE-ABS-KEY (participat* OR adher* OR uptake OR return OR complian*)) AND TI (participat* OR adher* OR uptake OR return OR complian*) AND AB (participat* OR adher* OR uptake OR return OR complian*)

Google Scholar (n= 54; 31/10/2018)

allintitle: "fecal occult blood" OR "feacal occult blood" OR FOBT OR "fecal immunochemical test" OR "faecal immunochemical test" AND participate OR participation OR uptake OR return OR adhere OR adherence OR compliance OR compliant

Proquest Theses and Dissertations (n= 59; 31/10/2018)

ti("faecal occult blood" OR "fecal occult blood" OR fobs OR "fecal immunochemical test" OR "faecal immunochemical test") AND ti(participat* OR uptake OR return OR complian* OR adher*) OR ab("faecal occult blood" OR "fecal occult blood" OR fobs OR "fecal immunochemical test" OR "faecal immunochemical test") AND ab(participat* OR uptake OR return OR complian* OR adher*)

10.1.3. *Appendix C: Data Extraction Tables*

Data Extraction for Intervention Effects Across Demographic Groups

Author	Intervention	Participants	Available data	Risk of Bias
		Advance notification letters		
Cole et al. (2007)	Advance notification letter sent 2 weeks prior to the FOBT kit arrival.	Community members in Adelaide selected from the Australian electoral commission, aged between 50-74 years. Intervention n = 600, control n = 600.	Gendered data was available for males and females. Age data was available with a <65 & ≥65 year cut-off. SES data was available with a two least deprived quintile & three most deprived quintile cut-off.	Low (ROB-2)
Libby et al. (2011)	Advance notification letter sent 2 weeks prior to the FOBT kit arrival.	Invitees to the Scottish national bowel cancer screening program, aged between 50-74 years. Intervention n = 19 975, control n = 19 987.	Gendered data was available for males and females. Age data was available with a <65 & ≥65 year cut-off. SES data was available with a two least deprived quintile & three most deprived quintile cut-off.	Low (ROB-2)
		GP endorsement letter		
Benton et al. (2017)	GP endorsement letter.	Invitees of the English Bowel cancer screening program, Southern hubs. Aged 60 – 74 years. Intervention n = 12 878, control n = 11 858.	Gendered data was available for males and females. Age data was available with a ≤ 65 & 66+ year cut-off. SES data was available with a two least deprived quintile & three most deprived quintile cut-off.	Serious (ROBINS-I)
Cole et al. (2002)	GP endorsement letter – by the GP practice.	Residents of South Australia aged over 50 years. Persons from patient lists of two primary care practices and people randomly selected from the electoral role. Intervention n = 600, control n = 600.	Gendered data was available for males and females. Age data was available with a < 60 & ≥ 60 year cut-off.	Low (ROB-2)

Cole et al. (2002)	GP endorsement letter.	Residents of South Australia aged over 50 years. Persons from patient lists of two primary care practices and people randomly selected from the electoral role. Intervention n = 600, control n = 600.	Gendered data was available for males and females. Age data was available with a < 60 & ≥ 60 year cut-off.	Low (ROB-2)
Hewitson et al. (2011)	GP endorsement letter.	Invitees of the English national bowel cancer screening program, aged 60 – 75 years. Participants were also seeing GPs in the Southern Program Hub. Intervention n = 322, control n = 322.	Gendered data was available for males and females.	Low (ROB-2)
Hirst et al. (2017)	GP endorsement SMS.	Invitees to the English national bowel cancer screening program, in the London area. Participants were aged between 60 – 74 years. Intervention n = 4 135, control n = 4 135.	Gendered data was available for males and females. Age data was available with a < 65 & ≥ 65 year cut-off. SES data was available with a two least deprived quintile & three most deprived quintile cut-off.	Low (ROB-2)
Wardle et al. (2016)	GP endorsement letter.	Invitees to the English national bowel cancer screening program, aged 60 – 74 years. Intervention n = 131 423, control n = 134 011	Gendered data was available for males and females. Age data was available with a < 65 & ≥ 65 year cut-off. SES data was available with a two least deprived quintile & three most deprived quintile cut-off.	Low (ROB-2)
Simplified Testing Procedure				
Cole et al. (2003)	Flexsure FIT over standard gFOBT.	Residents of South Australia randomly selected from the electoral role aged between 50 – 69 years.	Gendered data was available for males and females. Age data was available with a < 60 & ≥ 60 year cut-off. SES data was available with a SEIFA ≤ 997.6 & > 997.6 cut-off.	Some (ROB -2)

		Intervention n = 606, control n = 606.		
Cole et al. (2003)	InSure FIT over standard gFOBT.	Residents of South Australia randomly selected from the electoral role aged between 50 – 69 years. Intervention n = 606, control n = 606.	Gendered data was available for males and females. Age data was available with a < 60 & ≥ 60 year cut-off. SES data was available with a SEIFA ≤ 997.6 & > 997.6 cut-off.	Some (ROB -2)
Digby et al. (2013)	FIT over standard gFOBT.	Invitees of the Scottish national bowel cancer screening program, aged between 50 – 74 years. Total sample 65 909.	Gendered data was available for males and females. Age data was available with a < 65 & ≥ 65 year cut-off. SES data was available with a two least deprived quintile & three most deprived quintile cut-off.	Serious (ROBINS-I)
Moss et al. (2016)	OC-sensor FIT over the standard gFOBT	Invitees of the English national bowel cancer screening program aged between 59 – 75 years. Intervention n = 40 930, control n = 1 126 087.	Gendered data was available for males and females. Age data was available with a < 65 & ≥ 65 year cut-off. SES data was available with a two least deprived quintile & three most deprived quintile cut-off.	Low (ROB-2)
Santare et al. (2015)	OC-sensor & FOB Gold FITs over the standard gFOBT	Randomly selected residents of Latvia, aged between 50 – 74 years. Intervention n = 10 000, control n = 5 000.	Gendered data was available for males and females. Age data was available with a < 65 & ≥ 65 year cut-off.	Low (ROB-2)
van Rossum et al. (2008)	OC-sensor FIT over the standard gFOBT	Random selection of Dutch residents aged between 50- 75 years. Intervention n = 10 322, control n = 10 301.	Gendered data was available for males and females. Age data was available with a < 60 & ≥ 60 year cut-off.	Low (ROB-2)

Blom et al. (2018)	OC-sensor FIT over the standard gFOBT	Invitees to the colorectal cancer screening program of Stockholm-Gotland, Sweden, aged between 60 – 69 years. Intervention n = 87 269, control n = 127 030.	Gendered data was available for males and females. Age data was available with a < 65 & ≥ 65 year cut-off.	Moderate (ROBINS-I)
Added Print Materials				
Cole et al. (2007)	Added information about CRC risk	Community members in Adelaide selected from the Australian electoral commission, aged between 50-74 years. Intervention n = 600, control n = 600.	Gendered data was available for males and females. Age data was available with a <65 & ≥65 year cut-off. SES data was available with a two least deprived quintile & three most deprived quintile cut-off.	Low (ROB-2)
Cole et al. (2007)	Advocacy from peers	Community members in Adelaide selected from the Australian electoral commission, aged between 50-74 years. Intervention n = 600, control n = 600.	Gendered data was available for males and females. Age data was available with a <65 & ≥65 year cut-off. SES data was available with a two least deprived quintile & three most deprived quintile cut-off.	Low (ROB-2)
Hewitson et al. (2011)	Enhanced procedural leaflet	Invitees of the English national bowel cancer screening program, aged 60 – 75 years. Participants were also seeing GPs in the Southern Program Hub. Intervention n = 322, control n = 322.	Gendered data was available for males and females.	Low (ROB-2)
Libby et al. (2011)	Added information about CRC risk	Invitees to the Scottish national bowel cancer screening program, aged between 50-74 years.	Gendered data was available for males and females. Age data was available with a <65 & ≥65 year cut-off. SES data was available with a two least deprived quintile & three most deprived quintile cut-off.	Low (ROB-2)

		Intervention n = 19 991, control n = 19 987.		
O'Carroll et al. (2015)	Added Health Locus of Control questionnaire with invitation.	Invitees to the Scottish national bowel cancer screening program, aged between 50 – 74 years. Intervention n = 20 040, control n = 19 797.	Gendered data was available for males and females. Age data was available with a ≤65 & >65 year cut-off. SES data was available with a two least deprived quintile & three most deprived quintile cut-off.	Low (ROB-2)
O'Carroll et al. (2015)	Added Health Locus of Control and anticipated regret questionnaire with invitation.	Invitees to the Scottish national bowel cancer screening program, aged between 50 – 74 years. Intervention n = 20 163, control n = 19 797.	Gendered data was available for males and females. Age data was available with a ≤65 & >65 year cut-off. SES data was available with a two least deprived quintile & three most deprived quintile cut-off.	Low (ROB-2)
Wardle et al. (2016)	Adding GIST leaflet for simpler explanation.	Invitees to the English national bowel cancer screening program, aged 60 – 74 years. Intervention n = 84 421, control n = 79 104	Gendered data was available for males and females. Age data was available with a < 65 & ≥ 65 year cut-off. SES data was available with a two least deprived quintile & three most deprived quintile cut-off.	Low (ROB-2)
Wardle et al. (2016)	Advocacy from peers.	Invitees to the English national bowel cancer screening program, aged 60 – 74 years. Intervention n = 73 722, control n = 76 695	Gendered data was available for males and females. Age data was available with a < 65 & ≥ 65 year cut-off. SES data was available with a two least deprived quintile & three most deprived quintile cut-off.	Low (ROB-2)
Wardle et al. (2016)	Adding an enhanced reminder.	Invitees to the English national bowel cancer screening program, aged 60 – 74 years. Intervention n = 78 067, control n = 90 413	Gendered data was available for males and females. Age data was available with a < 65 & ≥ 65 year cut-off. SES data was available with a two least deprived quintile & three most deprived quintile cut-off.	Low (ROB-2)

Watson et al. (2013)	Questionnaire sent with the FOBT kit.	Invitees to the English national bowel cancer screening program, aged between 60 -74 years. Intervention n = 5 857, control n = 5 722.	Gendered data was available for males and females. Age data was available with a < 65 & ≥ 65 year cut-off. SES data was available with a two least deprived quintile & three most deprived quintile cut-off.	High (ROB-2)
Watson et al. (2013)	Questionnaire sent 2-weeks after the FOBT kit.	Invitees to the English national bowel cancer screening program, aged between 60 -74 years. Intervention n = 11 954, control n = 24 241	Gendered data was available for males and females. Age data was available with a < 65 & ≥ 65 year cut-off. SES data was available with a two least deprived quintile & three most deprived quintile cut-off.	High (ROB-2)
Neter et al. (2014)	Use of implementation intentions questions.	Israeli HMO-insured members, aged between 50 – 74 years. Intervention n = 13 713, control n = 13 920.	Gendered data was available for males and females. Age data was available with a ≤ 65 & > 65 year cut-off. SES data was available with a least deprived tertile & two most deprived tertile cut-off.	Low (ROB-2)
Singularly Trailed Interventions				
Denters et al. (2003)	Collection paper to aid with sampling.	Invitees to the second pilot round for the national bowel cancer screening program in the Netherlands, aged between 50 – 74 years. Intervention n = 5 129, control n = 5 136.	Gendered data was available for males and females. Age data was available with a < 65 & ≥ 65 year cut-off.	Low (ROB-2)
Gupta et al. (2016)	$5 - $10 financial incentives.	Patients of the John Peter Smith Health Network, Texas, aged between 50 – 64 years. Intervention n = 2 000, control n = 6 565.	Gendered data was available for males and females. SES data was available with a neighbourhood poverty level of <20% & ≥ 20% cut-off.	Low (ROB-2)

Sandiford et al. (2018)	Community laboratory drop off as an added alternative return method.	Invitees to the New Zealand national bowel cancer screening program, aged 50 – 74 years. Intervention n = 29 257, control n = 52 831	Gendered data was available for males and females. Age data was available with a < 65 & ≥ 65 year cut-off.	Moderate (ROBINS-I)

Data Extraction For Combined Interventions

Study	Participants and Risk of Bias	Comparison	Results
Coronado et al. (2018)	Patients of the Sea Mar Community Health Centres, aged between 50-74 years. This study was conducted in the USA. Low risk of bias (ROB-2).	(1) Reminder letter VS reminder letter + live phone call	62 out of 262 people returned a kit in the comparison group, and 73 out of 266 retuned a kit in the combined intervention group. This resulted in a non-significant difference in uptake, RR = 1.16, 95%CI [0.87, 1.55].
		(2) Automated phone call VS automated phone call + live phone call	72 out of 309 people returned a kit in the comparison group, and 83 out of 287 retuned a kit in the combined intervention group. This resulted in a non-significant difference in uptake, RR = 1.24, 95%CI [0.95, 1.63].
		(3) Text message VS Text message + live phone call	52 out of 307 people returned a kit in the comparison group, and 81 out of 299 retuned a kit in the combined intervention group. This resulted in

			a significant increase in uptake, RR = 1.60, 95%CI [1.17, 2.18].
Hewitson et al. (2011)	Invitees to the English national bowel cancer screening program aged between 60 – 75 years. Low risk of bias (ROB-2).	(1) GP endorsement letter VS GP endorsement letter + leaflet	177 out of 322 people returned a kit in the comparison group, and 197 out of 322 retuned a kit in the combined intervention group. This resulted in a non-significant difference in uptake, RR = 1.11, 95%CI [0.98, 1.27].
		(2) Leaflet VS Leaflet + GP endorsement letter	178 out of 322 people returned a kit in the comparison group, and 197 out of 322 retuned a kit in the combined intervention group. This resulted in a non-significant difference in uptake, RR = 1.11, 95%CI [0.97, 1.26].
King et al. (1992)	Patients from three different GP practices in South Sydney, Australia. They were aged between 45 and 75. Some risk of bias (ROB-2).	(1) GP Endorsement letter VS GP letter endorsement letter + no dietary restrictions	95 out of 199 people returned a kit in the comparison group, and 104 out of 190 retuned a kit in the combined intervention group. This resulted in a non-significant difference in uptake, RR = 1.15, 95%CI [0.94, 1.39].
		(2) GP endorsement letter + no dietary restrictions VS GP endorsement letter +no dietary restrictions + brochure	104 out of 190 people returned a kit in the comparison group, and 93 out of 204 retuned a kit in the combined

			intervention group. This resulted in a non-significant difference in uptake, RR = 0.83, 95%CI [0.68, 1.02].
Libby et al. (2011)	Invitees to the Scottish national bowel cancer screening program, aged between 50-74 years. Low risk of bias (ROB-2).	Advance notification letter VS advance notification letter + booklet	11 780 out of 19 975 people returned a kit in the comparison group, and 11 695 out of 19 991 retuned a kit in the combined intervention group. This resulted in a non-significant difference in uptake, RR = 0.99, 95%CI [0.98, 1.01].
Myers et al. (1991)	Members of the U.S. Healthcare, INC. These were residents of the U.S.A. and were aged between 50 – 74 years. Some risk of bias (ROB-2).	(1) Reminder call VS Reminder call + self-held screening booklet	167 out of 450 people returned a kit in the comparison group, and 168 out of 450 retuned a kit in the combined intervention group. This resulted in a non-significant difference in uptake, RR = 1.01, 95%CI [0.85, 1.19].
		(2) Reminder call + self-held screening booklet VS reminder call + self-held screening booklet + instructions call	168 out of 450 people returned a kit in the comparison group, and 337 out of 700 retuned a kit in the combined intervention group. This resulted in a significant increase in uptake, RR = 1.29, 95%CI [1.12, 1.49].

O'Carroll et al. (2015)	Invitees to the Scottish national bowel cancer screening program, aged between 50 – 74 years. Low risk of bias (ROB-2).	Health locus of control and ICK questions VS health locus of control and ICK questions+ Anticipated regret questions	11 280 out of 19 828 people returned a kit in the comparison group, and 11 450 out of 19 934 retuned a kit in the combined intervention group. This resulted in a non-significant difference in uptake, RR = 1.01, 95%CI [0.99, 1.03].
Santare et al. (2015)	Randomly selected residents of Latvia, aged between 50 – 74 years. Low risk of bias (ROB-2).	(1) FIT test VS FIT + Advance notification	2 230 out of 5 006 people returned a kit in the comparison group, and 2 226 out of 4 994 retuned a kit in the combined intervention group. This resulted in a non-significant difference in uptake, RR = 1.02, 95%CI [0.98, 1.06].
Verne et al. (1993)	Patients of a large general practice in Oxfordshire, England, aged between 40 – 74 years. Some risk of bias (ROB-2).	(1) Early detector pads (paper that can be analysed at home) VS Early detector pads + no dietary restrictions.	50.1% of 307 people complied with the testing using the early detector pads with no dietary restrictions. While 54% of 302 people complied with the test using the early detector pads with dietary restrictions. This was a non-significant difference in uptake rates, RR = 0.93, CI[0.80; 1.08].
		(2) Coloscreen Self-test (pads that can be placed in toilet water so results can	53.4% of 283 people complied with the testing using the Coloscreen Self-test with no dietary restrictions.

		be analysed at home) VS Coloscreen Self-test + no dietary restrictions.	While 48.1% of 316 people complied with the test using the Coloscreen Self-test with dietary restrictions. This was a non-significant difference in uptake rates, RR = 1.11, CI[0.95; 1.30].
White et al. (2015)	Invitees to the English national bowel cancer screening program, aged between 60 – 74 years. Critical risk of bias (ROBINS-I)	(1) CRUK endorsement flyer only VS CRUK endorsement flyer + kit enhancement pack	4 206 out of 10 286 people returned a kit in the comparison group, and 3 921 out of 9 096 retuned a kit in the combined intervention group. This resulted in a significant increase in uptake, RR = 1.05, 95%CI [1.02, 1.09].
		(2) CRUK endorsement flyer only VS CRUK endorsement flyer + advertising campaign	4 206 out of 10 286 people returned a kit in the comparison group, and 2 179 out of 5 121 retuned a kit in the combined intervention group. This resulted in a non-significant difference in uptake, RR = 1.04, 95%CI [1.00, 1.08].
		(3) CRUK endorsement flyer + kit enhancement pack VS CRUK endorsement flyer + plus kit enhancement pack + advertising campaign	3 921 out of 9 096 people returned a kit in the comparison group, and 2 537 out of 5 297 retuned a kit in the combined intervention group. This resulted in a significant increase in uptake, RR = 1.11, 95%CI [1.07, 1.15].

	(4) Endorsement flyer + advertising campaign VS CRUK endorsement flyer + plus kit enhancement pack + advertising campaign	2 179 out of 5 121 people returned a kit in the comparison group, and 2 537 out of 5 297 retuned a kit in the combined intervention group. This resulted in a significant increase in uptake, RR = 1.13, 95%CI [1.08, 1.17].

10.2. Appendices for Study Two

10.2.1 *Appendix D: RAMESES II Checklist*

RAMESES II reporting standards for realist evaluations checklist		
		Page(s) in document
TITLE		
1	In the title, identify the document as a realist evaluation	1
SUMMARY OR ABSTRACT		
2	Journal articles will usually require an abstract, while reports and other forms of publication will usually benefit from a short summary. The abstract or summary should include brief details on: the policy, program or initiative under evaluation; program setting; purpose of the evaluation; evaluation question(s) and/or objective(s); evaluation strategy; data collection, documentation and analysis methods; key findings and conclusions Where journals require it and the nature of the study is appropriate, brief details of respondents to the evaluation and recruitment and sampling processes may also be included Sufficient detail should be provided to identify that a realist approach was used and that realist program theory was developed and/or refined	2
INTRODUCTION		
3 Rationale for evaluation	Explain the purpose of the evaluation and the implications for its focus and design	3 – 4
4 Program theory	Describe the initial program theory (or theories) that underpin the program, policy or initiative	4
5 Evaluation questions, objectives and focus	State the evaluation question(s) and specify the objectives for the evaluation. Describe whether and how the program theory was used to define the scope and focus of the evaluation	4
6 Ethical approval	State whether the realist evaluation required and has gained ethical approval from the relevant authorities, providing details as appropriate. If ethical approval was deemed unnecessary, explain why	n/a
METHODS		
7 Rationale for using realist evaluation	Explain why a realist evaluation approach was chosen and (if relevant) adapted	4 – 5
8 Environment surrounding the evaluation	Describe the environment in which the evaluation took place	n/a

9 Describe the program policy, initiative or product evaluated	Provide relevant details on the program, policy or initiative evaluated	3 – 4
10 Describe and justify the evaluation design	A description and justification of the evaluation design (i.e. the account of what was planned, done and why) should be included, at least in summary form or as an appendix, in the document which presents the main findings. If this is not done, the omission should be justified and a reference or link to the evaluation design given. It may also be useful to publish or make freely available (e.g. online on a website) any original evaluation design document or protocol, where they exist	5 – 6
11 Data collection methods	Describe and justify the data collection methods – which ones were used, why and how they fed into developing, supporting, refuting or refining program theory Provide details of the steps taken to enhance the trustworthiness of data collection and documentation	5 – 6
12 Recruitment process and sampling strategy	Describe how respondents to the evaluation were recruited or engaged and how the sample contributed to the development, support, refutation or refinement of program theory	n/a
13 Data analysis	Describe in detail how data were analysed. This section should include information on the constructs that were identified, the process of analysis, how the program theory was further developed, supported, refuted and refined, and (where relevant) how analysis changed as the evaluation unfolded	5 – 6
RESULTS		
14 Details of studies	Report (if applicable) who took part in the evaluation, the details of the data they provided and how the data was used to develop, support, refute or refine program theory	6 – 7
15 Main findings	Present the key findings, linking them to contexts, mechanisms and outcome configurations. Show how they were used to further develop, test or refine the program theory	7 – 10
DISCUSSION		
16 Summary of findings	Summarise the main findings with attention to the evaluation questions, purpose of the evaluation, program theory and intended audience	10 – 11

17 Strengths, limitations and future directions	Discuss both the strengths of the evaluation and its limitations. These should include (but need not be limited to): (1) consideration of all the steps in the evaluation processes; and (2) comment on the adequacy, trustworthiness and value of the explanatory insights which emerged In many evaluations, there will be an expectation to provide guidance on future directions for the program, policy or initiative, its implementation and/or design. The particular implications arising from the realist nature of the findings should be reflected in these discussions	11
18 Comparison with existing literature	Where appropriate, compare and contrast the evaluation's findings with the existing literature on similar programmes, policies or initiatives	10 – 11
19 Conclusion and recommendations	List the main conclusions that are justified by the analyses of the data. If appropriate, offer recommendations consistent with a realist approach	12
20 Funding and conflict of interest	State the funding source (if any) for the evaluation, the role played by the funder (if any) and any conflicts of interests of the evaluators	12

10.2.2. *Appendix D: Search Terms*

Pubmed
((("fecal occult blood"[Title/Abstract] OR "faecal occult blood"[Title/Abstract] OR FOBT[Title/Abstract] OR "fecal immunochemical test" OR "faecal immunochemical test" [Title/Abstract])) AND (participat*[Title/Abstract] OR adher*[Title/Abstract] OR uptake[Title/Abstract] OR return [Title/Abstract] OR complian* [Title/Abstract]))

Scopus
TITLE-ABS-KEY ("fecal occult blood" OR "faecal occult blood" OR fobt OR "fecal immunochemical test" OR "faecal immunochemical test") AND TITLE-ABS-KEY (participat* OR adher* OR uptake OR return OR complian*))

PsycInfo
TI ("fecal occult blood" OR "faecal occult blood" OR FOBT OR "fecal immunochemical test" OR "faecal immunochemical test") OR AB ("fecal occult blood" OR "faecal occult blood" OR fobt OR "fecal immunochemical test" OR "faecal immunochemical test") AND TITLE-ABS-KEY (participat* OR adher* OR uptake OR return OR complian*)) AND TI (participat* OR adher* OR uptake OR return OR complian*) AND AB (participat* OR adher* OR uptake OR return OR complian*)

CINAHL
TI ("fecal occult blood" OR "faecal occult blood" OR FOBT OR "fecal immunochemical test" OR "faecal immunochemical test") OR AB ("fecal occult blood" OR "faecal occult blood" OR fobt OR "fecal immunochemical test" OR "faecal immunochemical test") AND TITLE-ABS-KEY (participat* OR adher* OR uptake OR return OR complian*)) AND TI (participat* OR adher* OR uptake OR return OR complian*) AND AB (participat* OR adher* OR uptake OR return OR complian*)

Google Scholar
allintitle: "fecal occult blood" OR "feacal occult blood" OR FOBT OR "fecal immunochemical test" OR "faecal immunochemical test" AND participate OR participation OR uptake OR return OR adhere OR adherence OR compliance OR compliant

Proquest Theses and Dissertations
ti("faecal occult blood" OR "fecal occult blood" OR fobs OR "fecal immunochemical test" OR "faecal immunochemical test") AND ti(participat* OR uptake OR return OR complian* OR adher*) OR ab("faecal occult blood" OR "fecal occult blood" OR fobs OR "fecal immunochemical test" OR "faecal immunochemical test") AND ab(participat* OR uptake OR return OR complian* OR adher*)

10.2.3. *Appendix F: Data Extraction Table*

Study	Trial Arm and Effect	Materials Available	BCT	Behavioural Mechanism	HAPA Stage
Benton et al. (2017)	Reminder letter endorsed by personal GP. Significant increase in participation.	Yes	Prompts/cues Credible source Information about health consequences Social comparison Feedback on behaviour Information about health consequences	Behavioural cueing Attitude towards the behaviour Perceived susceptibility Social norms Feedback process Beliefs about consequences	Volition Motivation Motivation Motivation Volition Motivation
Blom et al. (2018)	Using FIT with not dietary restrictions. Significant increase in participation.	No	Remove punishment	Environmental context & resources	Volition
Cole et al. (2002a)	GP endorsement letter by personal GP. Significant increase in participation.	No	Credible source	Attitude towards the behaviour	Motivation
Cole et al. (2002b)	GP endorsement letter by GP practice. Significant increase in participation.	No	Credible source	Attitude towards the behaviour	Motivation
Cole et al. (2003a)	Use of FlexSure FIT – removal of dietary restrictions. Significant increase in participation.	No	Remove punishment	Environmental context & resources	Volition
Cole et al. (2003b)	Use of InSure FIT – removal of dietary restrictions and fewer samples needed. Significant increase in participation.	No	Remove punishment Remove aversive stimulus	Environmental context & resources Environmental context & resources	Volition Volition
Cole et al. (2007a)	Additional message about risk of CRC. No significant difference in participation	Yes	Information about health consequences Information about health consequences	Perceived susceptibility Beliefs about consequences	Motivation Motivation
Cole et al. (2007b)	Advocacy for screening from previous screening program participants. No significant difference in participation.	Yes	Information about others' approval Vicarious consequences	Social norms Beliefs about consequences	Motivation Motivation
Cole et al. (2007c)	Advance notification letter. Significant increase in participation.	Yes	Credible source Advance notification	Attitude towards the behaviour Intentions	Motivation Volition
Coronado et al. (2018a)	Two automated phone calls reminders. No significant difference in participation.	Yes	Credible source Prompts/cues	Attitude towards the behaviour Behavioural cueing	Motivation Volition
Coronado et al. (2018b)	Two text messages reminders. Significant decrease in participation.	Yes	Credible source Prompts/cues	Attitude towards the behaviour Behavioural cueing	Motivation Volition
Coronado et al. (2018c)	A live phone call reminder. Significant increase in participation.	Yes	Social support (unspecified) Social support (practical) Feedback on behaviour Prompts/cues Credible source Commitment	Social influence Environmental context &resources Feedback process Behavioural cueing Attitude towards the behaviour Intentions	Motivation Volition Volition Volition Motivation Volition
Coronado et al. (2018d)	A reminder letter and a live phone call. Significant increase in participation.	Yes	Information about health consequences Social support (unspecified)	Beliefs about consequences Social influence	Motivation Motivation

			Social support (practical) Feedback on behaviour Prompts/cues Credible source Commitment	Environmental context &resources Feedback process Behavioural cueing Attitude towards the behaviour Intentions	Volition Volition Volition Motivation Volition
Coronado et al. (2018e)	Two automated phone calls and a live phone call reminder. Significant increase in participation.	Yes	Social support (unspecified) Social support (practical) Credible source Feedback on behaviour Prompts/cues Commitment	Social influence Environmental context & resources Attitude towards the behaviour Feedback process Behavioural cueing Intentions	Motivation Volition Motivation Volition Volition Volition
Coronado et al. (2018f)	Text message and live phone call reminder. Significant increase in participation.	Yes	Prompts/cues Credible source Social support (unspecified) Social support (practical) Feedback on behaviour Commitment	Behavioural cueing Attitude towards the behaviour Social influence Environmental context & resources Feedback process Intentions	Volition Motivation Motivation Volition Volition Volition
Coronado et al. (2019a)	Advance notification text message. No significant difference in participation.	Yes	Advance notification	Intention	Volition
Coronado et al. (2019b)	Three live phone call reminders. Significant increase in participation.	Yes	Social support (unspecified) Social support (practical) Feedback on behaviour Problem solving	Social influence Environmental context & resources Feedback process Beliefs about capabilities	Motivation Volition Volition Volition
Denters et al. (2013)	Faeces collection paper to aid in sampling. No significant difference in participation.	No	Adding objects to the environment Demonstration of the behaviour	Environmental context &resources Beliefs about capabilities	Volition Volition
Deutekom et al. (2010)	Use of FIT with fewer samples needed to be taken. Significant increase in participation.	No	Remove aversive stimulus	Environmental context & resources	Volition
Digby et al. (2013)	Use of FIT with fewer samples needed to be taken. Significant increase in participation	No	Remove aversive stimulus	Environmental context & resources	Volition
Durkin et al. (2019a)	High intensity media campaign (Queensland trial). Significant increase in participation.	Yes	Information about health consequences Vicarious consequences Prompts/cues Information about health consequences	Perceived susceptibility Beliefs about consequences Behavioural cueing Beliefs about consequences	Motivation Motivation Volition Motivation
Durkin et al. (2019b)	Low intensity media campaign (Western Australia trail). No significant difference in participation.		Information about health consequences Vicarious consequences Prompts/cues Information about health consequences	Perceived susceptibility Beliefs about consequences Behavioural cueing Beliefs about consequences	Motivation Motivation Volition Motivation
Gupta et al. (2016a)	$5 incentive conditional on kit return. No significant difference in participation.	Yes	Material incentive (behaviour)	Reinforcement	Motivation
Gupta et al. (2016b)	$10 incentive conditional on kit return. No significant difference in participation.	Yes	Material incentive (behaviour)	Reinforcement	Motivation
Hewitson et al. (2011a)		Yes	Information about health consequences	Beliefs about consequences	Motivation

	GP endorsement letter by personal GP. Significant increase in participation.		Credible source Information about health consequences	Attitude towards the behaviour Perceived susceptibility	Motivation Motivation
Hewitson et al. (2011b)	Leaflet giving more explicit information on how to carry out and return the FOBT along with more CRC risk information. Significant increase in participation.	Yes	Information about health consequences Instruction on how to perform the behaviour Information about health consequences	Beliefs about consequences Beliefs about capabilities Perceived susceptibility	Motivation Volition Motivation
Hewitson et al. (2011c)	Both interventions strategies of the other trials combined. Significant increase in participation.	Yes	Information about health consequences Instruction on how to perform the behaviour Information about health consequences Credible source	Beliefs about consequences Beliefs about capabilities Perceived susceptibility Attitude towards the behaviour	Motivation Volition Motivation Motivation
Hirst et al. (2017)	A text-message reminder from GP. No significant difference in participation.	Yes	Credible source Prompts/cues	Attitude towards the behaviour Behavioural cueing	Motivation Volition
Hughes et al. (2005)	Use of FIT that does not require dietary restriction and uses fewer samples. Significant increase in participation.	No	Remove aversive stimulus Remove punishment	Environmental context & resources Environmental context & resources	Volition Volition
King et al. (1992a)	GP endorsement letter. Significant increase in participation.	No	Information about health consequences Credible source	Beliefs about consequences Attitude towards the behaviour	Motivation Motivation
King et al. (1992b)	GP endorsement letter with no dietary restriction given with the kit. Significant increase in participation.	No	Information about health consequences Credible source Remove punishment	Beliefs about consequences Attitude towards the behaviour Environmental context & resources	Motivation Motivation Volition
King et al. (1992c)	GP endorsement letter, no dietary restriction given with the kit, and CRC information brochure. Significant increase in participation.	No	Information about health consequences Credible source Remove punishment Information about health consequences	Beliefs about consequences Attitude towards the behaviour Environmental context & resources Perceived susceptibility	Motivation Motivation Volition Motivation
King et al. (1994)	Educational brochure. No significant difference in participation.	No	Information about health consequences Information about health consequences	Perceived susceptibility Beliefs about consequences	Motivation Motivation
Libby et al. (2011a)	Advance notification letter. Significant increase in participation.	Yes	Advance notification	Intentions	Volition
Libby et al. (2011b)	Sending the CRC information pack with advance notification. Instead of with FOBT. Significant increase in participation.	Yes	Advance notification	Intentions	Volition
Lo et al. (2014)	Sending implementation intention questions with prefilled with responses. No significant increase in participation.	Yes	Instruction on how to perform the behaviour Self-talk Action planning Reduce negative emotions	Beliefs about capabilities Motivation Intentions Behavioural regulation	Volition Volition Volition Volition
Mehta et al. (2019a)	Unconditional $10 incentive included with the mailing. No significant difference in participation.	No	Unconditional material incentive	Social influence	Motivation
Mehta et al. (2019b)	$10 incentive conditional on FIT completion. No significant difference in participation.	No	Material incentive (behaviour)	Reinforcement	Motivation

Mehta et al. (2019c)	Conditional lottery with a 1-in-10 chance of winning $100 after FIT completion. No significant difference in participation.	No	Material incentive (behaviour)	Reinforcement	Motivation
Moss et al. (2016)	Use of FIT with no dietary restriction and fewer samples. Significant increase in participation.	No	Remove aversive stimuli Remove punishment	Environmental context & resources Environmental context & resources	Volition Volition
Myers et al. (1991a)	Live telephone reminder call. Significant increase in participation.	No	Instruction on how to perform the behaviour Prompts/cues Problem solving Commitment	Beliefs about capabilities Behavioural cueing Beliefs about capabilities Intention	Volition Volition Volition Volition
Myers et al. (1991b)	Live telephone reminder with CRC screening and information pack. Significant increase in participation.	No	Information about health consequences Information about health consequences Instruction on how to perform the behaviour Prompts/cues Problem solving Commitment	Perceived susceptibility Beliefs about consequences Beliefs about capabilities Behavioural cueing Beliefs about capabilities Intention	Motivation Motivation Volition Volition Volition Volition
Myers et al. (1991c)	Live telephone instruction and reminder call with CRC screening and information pack. Significant increase in participation	No	Information about health consequences Information about health consequences Instruction on how to perform the behaviour Prompts/cues Problem solving Commitment	Perceived susceptibility Beliefs about consequences Beliefs about capabilities Behavioural cueing Beliefs about capabilities Intention	Motivation Motivation Volition Volition Volition Volition
Neter et al. (2014)	Sending implementation intention questions with invitation. Significant increase in participation.	Yes	Action planning	Intention	Volition
O'Carroll et al. (2015a)	Health locus of control questions with invitation. No significant difference participation.	Yes	Framing/reframing	Attitude towards the behaviour	Motivation
O'Carroll et al. (2015b)	Health locus of control and anticipated regret questions with invitation. No significant difference participation.	Yes	Framing/reframing Anticipated regret	Attitude towards the behaviour Beliefs about consequences	Motivation Motivation
Ore et al. (2001)	Added information about risks of CRC. No significant difference in participation.	No	Information about health consequences	Perceived susceptibility	Motivation
Robinson et al. (1994a)	Removing dietary restrictions. Significant increase in participation.	No	Remove punishment	Environmental context & resources	Volition
Robinson et al. (1994b)	Requesting fewer samples to be taken. No significant difference in participation.	No	Remove aversive stimulus	Environmental context & resources	Volition
Sandiford et al. (2017)	Offering alternative community drop off locations for samples. Significant increase in participation.	Yes	Adding objects to the environment Restructuring the physical environment	Environmental context & resources Environmental context & resources	Volition Volition
Santare et al. (2015a)	Using OC-Sensor (FIT) kit. Significant increase in participation.	No	Remove punishment Remove aversive stimulus	Environmental context & resources Environmental context & resources	Volition Volition
Santare et al. (2015b)	Using FOB Gold (FIT) kit. Significant increase in participation.	No	Remove punishment Remove aversive stimulus	Environmental context & resources Environmental context & resources	Volition Volition

Santare et al. (2015c)	Sending advance notification letters. Significant increase in participation.	No	Advance notification Information about health consequences Information about health consequences	Intention Perceived susceptibility Beliefs about consequences	Volition Motivation Motivation
Schreuders et al. (2019)	Requiring one instead of two samples. Significant increase in participation.	No	Remove aversive stimulus	Environmental context & resources	Volition
Van Roon et al. (2011)	Sending advance notification letters. Significant increase in participation.	No	Advance notification Information about health consequences Information about health consequences	Intention Perceived susceptibility Beliefs about consequences	Volition Motivation Motivation
Verne et al. (1993a)	Using Early Detector Pads for testing. Significant increase in participation.	No	Adding objects to the environment	Environmental context & resources	Volition
Verne et al. (1993b)	Using *Early Detector Pads* for testing and not requesting dietary restrictions. No significant difference in participation.	No	Adding objects to the environment Remove punishment	Environmental context & resources Environmental context & resources	Volition Volition
Verne et al. (1993c)	Using *Colscreen Self-Test* for testing. Significant increase in participation.	No	Adding objects to the environment Remove aversive stimulus	Environmental context & resources Environmental context & resources	Volition Volition
Verne et al. (1993d)	Using *Colscreen Self-Test* for testing and not requesting dietary restrictions. No significant difference in participation.	No	Adding objects to the environment Remove aversive stimulus Remove punishment	Environmental context & resources Environmental context & resources Environmental context & resources	Volition Volition Volition
Wardle et al. (2016a)	Gist leaflet giving additional simplified information. No significant difference in participation	Yes	Instruction on how to perform the behaviour Information about health consequences Information about health consequences	Beliefs about capabilities Perceived susceptibility Beliefs about consequences	Volition Motivation Motivation
Wardle et al. (2016b)	Narratives of positive experiences of FOBT screening from peers. No significant difference in participation.	Yes	Information about health consequences Information about emotional consequences Vicarious consequences Information about others' approval	Beliefs about consequences Beliefs about consequences Beliefs about consequences Social Norms	Motivation Motivation Motivation Motivation
Wardle et al. (2016b)	GP endorsement letter with FOBT invitation. Significant increase in participation.	Yes	Credible source	Attitudes towards the behaviour	Motivation
Wardle et al. (2016d)	Enhanced reminder. Significant increase in Participation.	Yes	Information about health consequences Prompts/cues	Beliefs about consequences Behavioural cueing	Motivation Volition
Watson et al. (2013)	Sending research questionnaire with FOBT kit. Significant decrease in participation.	No	Adding objects to the environment	Environmental context & resources	Motivation
White et al. (2015a)	CRC informational flyers from Cancer Research UK (CRUK). No significant difference in participation.	Yes	Information about health consequences Credible source Social comparison	Beliefs about consequences Attitude towards the behaviour Social norms	Motivation Motivation Motivation
White et al. (2015b)	CRC informational flyers from CRUK and sending sample collection aids. Significant increase in participation.	Yes	Adding objects to the environment Information about health consequences Credible source Social comparison Instruction on how to perform the behaviour Demonstration of the behaviour Prompts/cues	Environmental context & resources Beliefs about consequences Attitude towards the behaviour Social norms Beliefs about capabilities Beliefs about capabilities Behavioural cueing	Volition Motivation Motivation Motivation Volition Volition Volition

White et al. (2015c)	CRC informational flyers from CRUK and advertising campaign. Significant increase in participation.	Yes	Information about health consequences Credible source Social comparison Prompts/cues	Beliefs about consequences Attitude towards the behaviour Social norms Behavioural cueing	Motivation Motivation Motivation Volition
White et al. (2015d)	CRC informational flyers from CRUK, sending sample collection aids, and advertising campaign. Significant increase in participation.	Yes	Adding objects to the environment Information about health consequences Credible source Social comparison Instruction on how to perform the behaviour Demonstration of the behaviour Prompts/cues	Environmental context & resources Beliefs about consequences Attitude towards the behaviour Social norms Beliefs about capabilities Beliefs about capabilities Behavioural cueing	Volition Motivation Motivation Motivation Volition Volition Volition

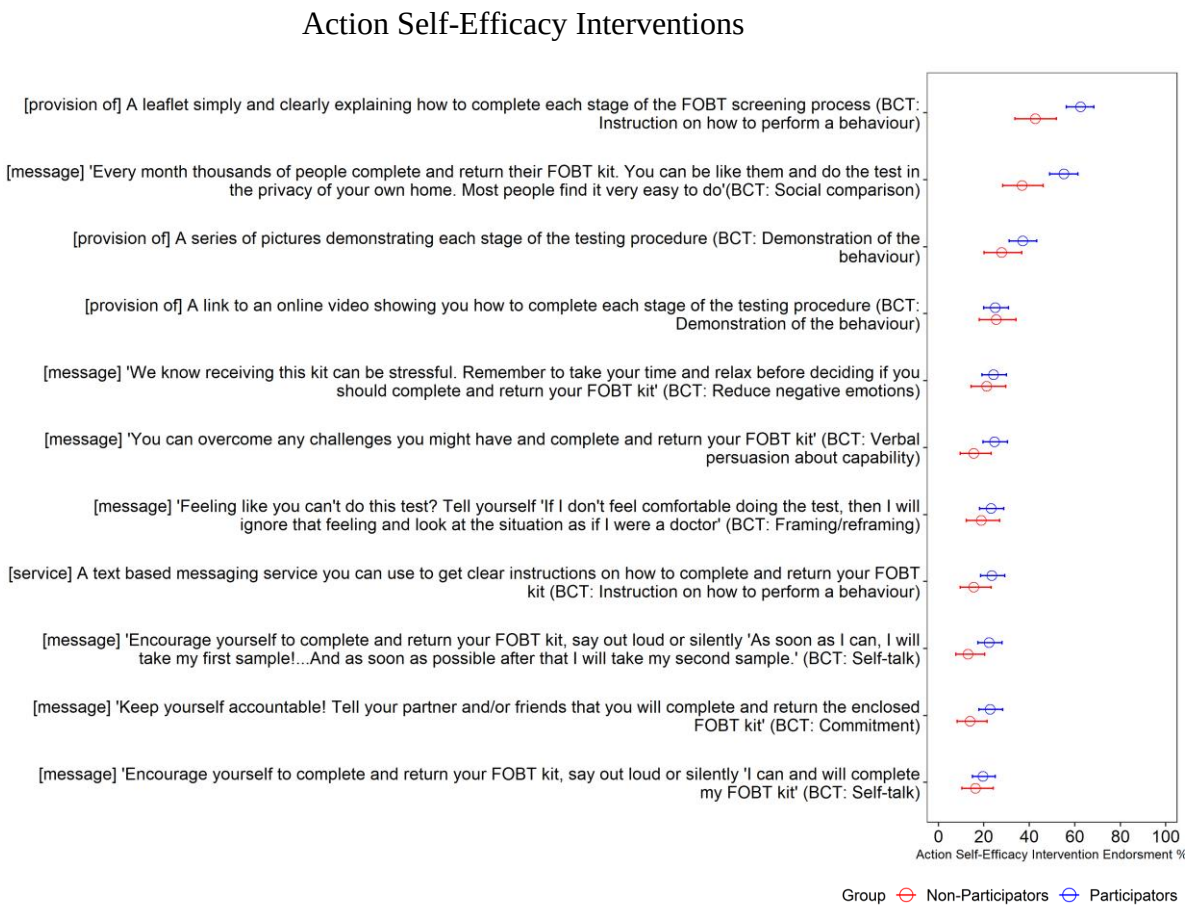
10.3. Appendices for Study Three

10.3.1. *Appendix G: Items Used in the PAMS Scale*

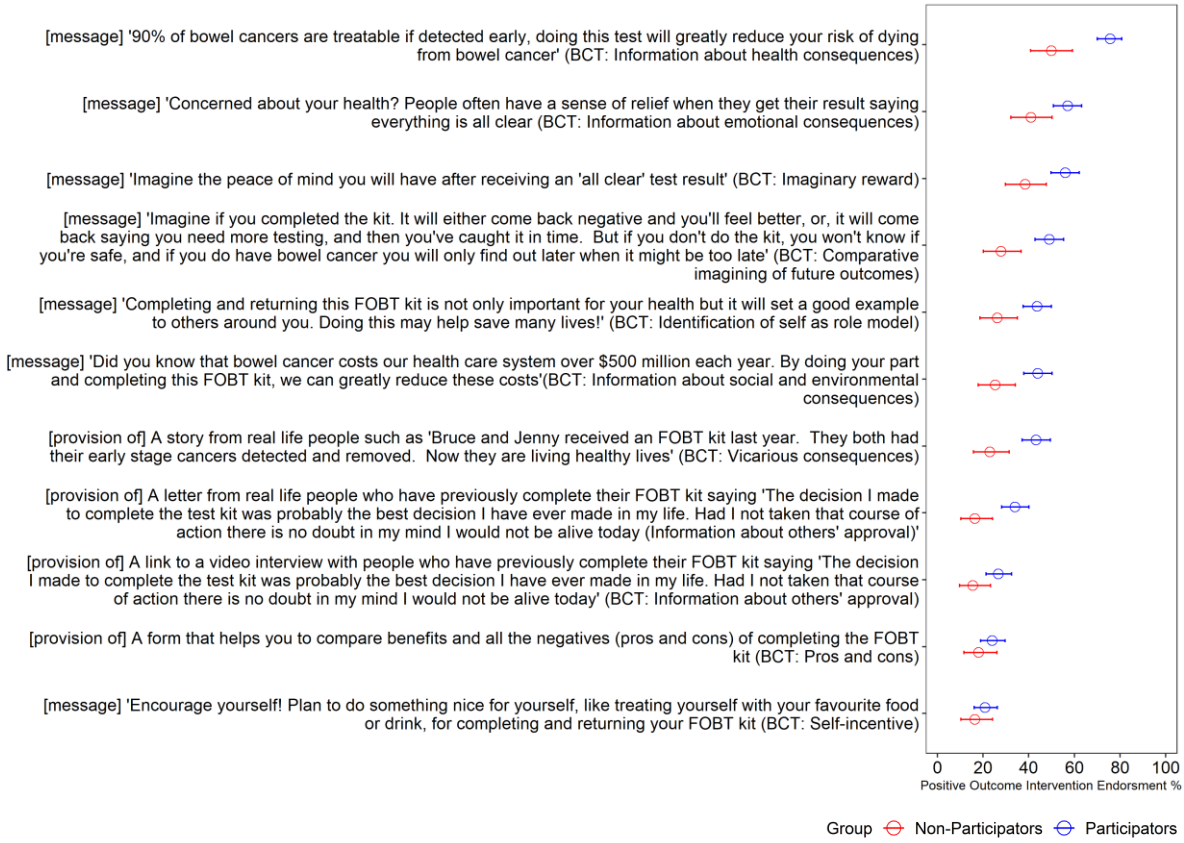
PAMS Factor	Question
Risk perception	Question stem: The following statements and questions relate to participating in the National Bowel Cancer Screening Program and bowel cancer generally. Please read each question or statement carefully and respond as accurately as possible using the responses provided. 1. How do you estimate the likelihood that you will ever suffer from bowel cancer? 2. If I compare myself with an average person of my sex and age, then my risk of suffering from bowel cancer is ... 3. The threat of bowel cancer to your health is ...
Positive outcome expectancies	Question stem: Please indicate how much you agree or disagree with the following statements that relate to participating in the National Bowel Cancer Screening Program. 1. If I complete an FOBT kit, it will increase the chance of finding bowel cancer early 2. If I complete an FOBT kit, this will decrease the chance of me dying from bowel cancer 3. If I complete an FOBT kit, I will have peace of mind knowing whether or not I have bowel cancer. 4. If I have bowel cancer and I complete an FOBT kit, the bowel cancer would be found early before it becomes fatal.
Negative outcome expectancies	Question stem: Please indicate how much you agree or disagree with the following statements that relate to participating in the National Bowel Cancer Screening Program. 1. If I complete my FOBT kit, I am concerned I will feel disgusted while collecting the stool sample. 2. If I complete my FOBT kit, I am concerned I may accidently touch my own stool. 3. If I complete my FOBT kit, I would be embarrassed to send my stool sample in the mail. 4. If I complete my FOBT kit, I am concerned I would feel disgusted reaching into the toilet to collect a stool sample. 5. If I complete my FOBT kit, I would not like to store my stool sample in the fridge.
Action self-efficacy	Question stem: Please indicate how truthful the following statements that relate to participating in the National Bowel Cancer Screening Program are for you. 1. I would be able to complete the FOBT kit even if I had to make a detailed plan describing when and how to complete it. 2. I would be able to complete the FOBT kit even if I had to overcome any negative feelings that I may have towards FOBT screening.

	3. I would be able to complete the FOBT kit even if I found it embarrassing to send a stool sample to another person for testing. 4. I would be able to complete the FOBT kit even if I had to stop myself from procrastinating. 5. I would be able to complete the FOBT kit even if I had to overcome some of the disgust that might arise from collecting stool samples.
Planning	Question stem: Please indicate how truthful the following statements that relate to participating in the National Bowel Cancer Screening Program are for you. 1. The last time I received an FOBT kit I had a plan for where I was going to keep the kit. 2. The last time I received an FOBT kit I had a plan for when I was going to complete the kit. 3. The last time I received an FOBT kit I had a plan for when I was going to return the kit by. 4. The last time I received an FOBT kit I had a plan for how I was going to return the kit. 5. The last time I received an FOBT kit I had a plan to keep me from forgetting to complete the kit.
Intention	When you first received your last FOBT kit in the mail did you intend to complete and return it?
Participation	Last time you received an FOBT kit did you complete and return it?

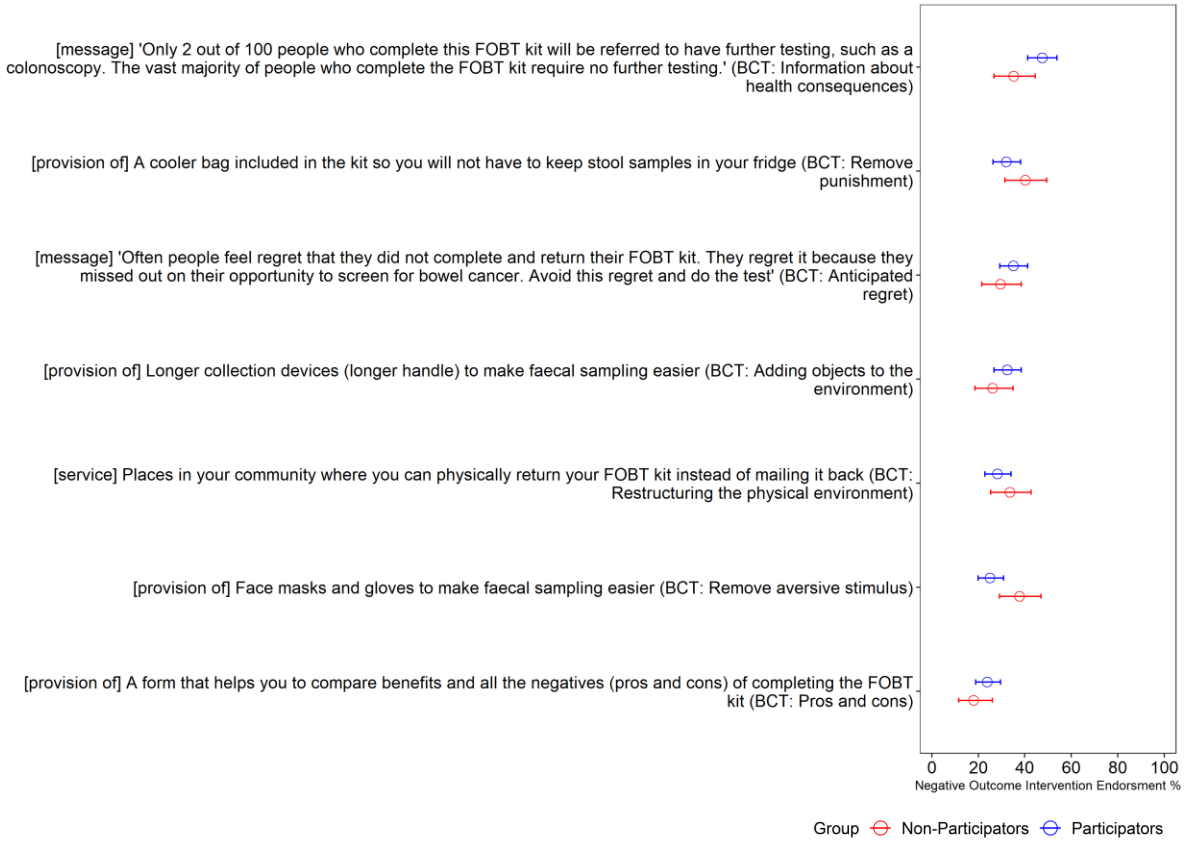
10.3.2. *Appendix H: UR-MSI Items*



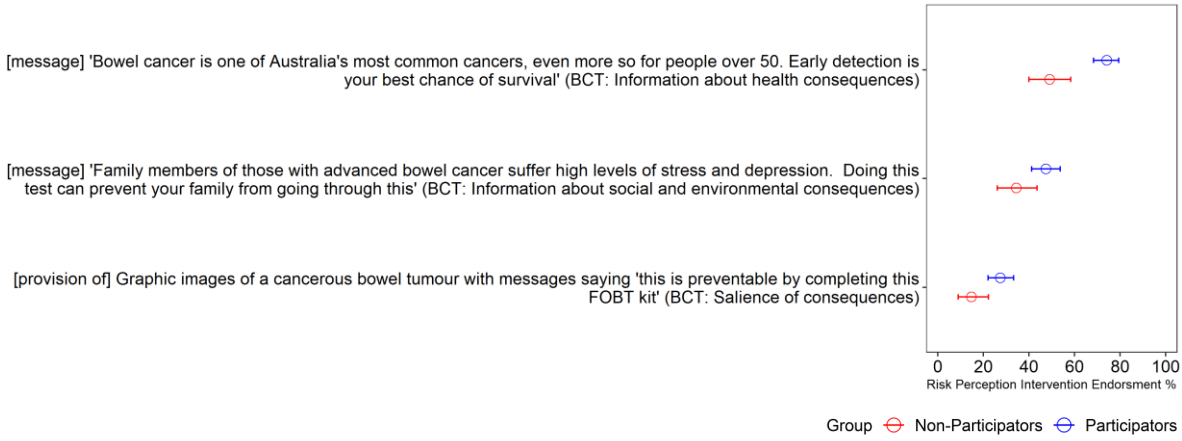
Positive Outcome Expectancy Interventions



Negative Outcome Expectancy Intervention



Risk Perception Interventions



Planning Interventions