

BMJ Open How and why a multifaceted intervention to improve adherence post-MI worked for some (and could work better for others): an outcome-driven qualitative process evaluation

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ABSTRACT

Objectives To explore (1) the extent to which a multicomponent intervention addressed determinants of the desired behaviours (ie, adherence to cardiac rehabilitation (CR) and cardiovascular medications), (2) the associated mechanism(s) of action and (3) how future interventions might be better designed to meet the needs of this patient population.

Design A qualitative evaluation embedded within a multicentre randomised trial, involving purposive semistructured interviews.

Setting Nine cardiac centres in Ontario, Canada.

Participants Potential participants were stratified according to the trial's primary outcomes of engagement and adherence, resulting in three groups: (1) engaged, adherence outcome positive, (2) engaged, adherence outcome negative and (3) did not engage, adherence outcome negative. Participants who did not engage but had positive adherence outcomes were excluded. Individual domains of the Theoretical Domains Framework were applied as deductive codes and findings were analysed using a framework approach.

Results Thirty-one participants were interviewed. Participants who were engaged with positive adherence outcomes attributed their success to the intervention's ability to activate determinants including behavioural regulation and knowledge, which encouraged an increase in self-monitoring behaviour and awareness of available supports, as well as reinforcement and social influences. The behaviour of those with negative adherence outcomes was driven by beliefs about consequences, emotions and identity. As currently designed, the intervention failed to target these determinants for this subset of participants, resulting in partial engagement and poor adherence outcomes.

Conclusion The intervention facilitated CR adherence through reinforcement, behavioural regulation, the provision of knowledge and social influence. To reach a broader and more diverse population, future iterations of the intervention should target aberrant beliefs about consequences, memory and decision-making and emotion.

Strengths and limitations of this study

- Outcome-driven exploration of how and why the intervention worked for patients with positive primary outcomes.
- Inclusion of patients with both positive and negative primary outcomes to provide insight into how to improve the intervention.
- Results mapped to intervention components to understand which aspect(s) of the intervention should be replicated at scale and why.
- Limited ability to understand why the overall trial led to a significant improvement in cardiac rehabilitation adherence but not medication adherence due to blinded, a priori recruitment.
- Unable to comment on the impact of intervention dose for the educational booklets as there was no way to measure engagement.

Trial registration number ClinicalTrials.gov registry; NCT02382731

INTRODUCTION

Myocardial infarctions (MI) are a leading cause of death and disability globally.¹ Survivors experience higher rates of all-cause death compared with the general population with an annual risk ranging from 6.5% to 10.0%.² Twenty per cent of patients discharged from hospital after an MI experience a subsequent cardiovascular event within the first year after the index MI,³ highlighting the importance of secondary prevention efforts.

Cardiac rehabilitation (CR) is an essential component of standard secondary-preventive care. CR content addresses the risk factor education, psychological issues, drug therapy and modified exercise with the aim of having patients resume optimal functioning and



improve health behaviour (eg, achieve recommended levels of activity and adhere to an appropriate diet).⁴⁻⁷ Exercise-based CR has been associated with lower risk of recurrent MI, cardiac mortality and all-cause mortality.^{4,8} Despite its association with improved survival and quality of life, CR completion rates range between 24% and 49%.^{9,10} People who do not complete CR are more often older, have lower socioeconomic status, tend to minimise the severity of their illness and lack the belief that they have control over the course and outcome of their illness.^{11,12} Selected cardiovascular drugs also contribute to reduced cardiovascular mortality post-MI,¹³ with increased adherence leading to reduced mortality risk.^{14,15} Unfortunately, within 1 month following an acute MI, more than one in five patients discontinued at least one cardiovascular medication, while one in eight discontinued all such medications.¹⁵

Changing health behaviour is complex, and interventions to support health behaviour change may be more effective when informed by evidence-based principles described in behaviour change theory.¹⁶ The Interventions Supporting Long-term Adherence and Decreasing cardiovascular events (ISLAND) study used the Theoretical Domains Framework (TDF) and the Health Action Process Approach (HAPA)¹⁷ to inform the development of mail outs and telephone calls to improve patient adherence to CR and to prescribed cardiovascular drug therapy.¹⁸

Descriptions of interventions often lack insight into the context within which recipients interact with (and act on) the intervention.^{19,20} When considering whether and how to scale up promising interventions, decision-makers need these insights to inform whether and how the intervention can be implemented as part of routine care. The ISLAND intervention is a complex intervention, meaning it has multiple components that are intended to have a synergistic effect, therefore traditional trial results will not be able to disentangle which intervention components led to the observed effect (or lack thereof) and how (or why). To address this gap, this study reports the findings of an embedded, theory-informed process evaluation that aimed to qualitatively explore how and why the intervention worked as observed. Informed by the UK Medical Research Council (MRC) Guidance on Process Evaluations of Complex Interventions,²¹ our objectives were to (1) explore the extent to which the intervention addressed underlying determinants of the desired behaviours (ie, adherence to CR and cardiovascular medications), (2) understand the associated mechanism(s) of action and (3) describe how future interventions might be better designed to meet the needs of this patient population.

METHODS

Study design

This qualitative evaluation was embedded within a multi-centre, pragmatic, three-arm randomised trial to evaluate

interventions targeting increased adherence to CR and cardiovascular medications following an MI.¹⁸ Participants from nine cardiac centres in Ontario, Canada were randomised post-MI to usual care or one of two intervention arms. Patients in the first intervention arm received mail-outs with content designed to address determinants of treatment adherence. Patients in the second (full) intervention arm received these mail-outs plus automated interactive voice response system (IVRS) phone calls. If the IVRS call identified challenges with adherence, a trained lay health worker (LHW) phoned the patient to try to address concerns or barriers. The trial was registered on ClinicalTrials.gov; trial results are published separately.

Intervention

As described previously,¹⁸ interventions were delivered through a single organisation in Ontario, on behalf of patients' cardiologists, timed to correspond with the anticipated need for prescription refills at approximately 4, 8, 20, 32 and 44 weeks post-MI. Both intervention components incorporate behaviour change techniques selected to address factors within the TDF and HAPA identified as determinants of the targeted patient behaviours.^{22,23} Wherever possible, BCTs (Behaviour Change Technique) were selected when there was existing evidence demonstrating their effectiveness for changing health behaviour.²³

Educational and self-regulatory content

A series of booklets were mailed to participants to encourage participation in CR and long-term adherence to secondary prevention medications. Booklets were designed with people who had had an MI using methods of user-centred design.²³ Booklet content addressed predictors of intention to follow recommended treatments and predictors of behaviour previously identified,¹⁷ including the future likelihood of cardiovascular events and potential concerns with medications and adherence self-efficacy (refer to [table 1](#)). Patients were prompted to develop action and coping plans in their booklet, focusing on: (1) discussing treatment concerns with providers, (2) obtaining refills, (3) adhering to daily medication regimes and (4) participating in CR. The first two mail-outs also included a letter for the patient to bring to their family physician, providing evidence supporting recommended treatments and a prefilled referral form for the CR programme closest to the patient's residence.

IVRS and LHW calls

In addition to the mail-outs, patients in the third trial arm received automated IVRS phone calls 1–2 weeks after each educational booklet had been mailed. The cover letter for the booklets primed these patients to expect the call and the IVRS encouraged patients to follow the action and coping plans emphasised in the booklets. The IVRS provided advice regarding next steps needed to achieve adherence based on a structured algorithm. When the IVRS calls identified suboptimal adherence

Table 1 Active intervention content in educational booklets

TDF domain	Behaviour change technique ²⁰
Beliefs about capabilities	<ol style="list-style-type: none"> 1. Persuasion about capability 2. Vicarious consequences 3. Instruction on how to perform the behaviour
Beliefs about consequences	<ol style="list-style-type: none"> 1. Information about health consequences 2. Information about social and environmental consequences 3. Comparative imagining of future outcomes
Intention	<ol style="list-style-type: none"> 1. Goal setting (outcome)
Memory, attention, decision-making	<ol style="list-style-type: none"> 1. Prompts/cues
Social influences	<ol style="list-style-type: none"> 1. Social support 2. Credible source
Behavioural regulation	<ol style="list-style-type: none"> 1. Action planning 2. Problem-solving 3. Self-monitoring of behaviour 4. Adding objects to the environment

TDF, Theoretical Domains Framework.

or a lack of recent contact with their family physician, a trained LHW called the patient. The LHWs sought to develop rapport, help patients identify options to overcome barriers (ie, further coping planning/problem-solving) and encourage the patient to discuss concerns or barriers with their healthcare team (ie, further action planning and practical social support).

Patient and public involvement

The study team for the overall trial included a patient partner who was involved in the design of the intervention and associated educational content. Patients were the target population and this study specifically sought to understand their experiences with the intervention. Patient participants were not involved in plans to disseminate the results.

Recruitment

Participants allocated to the full intervention arm were recruited from one academic and one community centre participating in trial. Recruitment was restricted to participants in the full intervention arm to allow for exploration of both the educational content and calls as distinct intervention components, in addition to the potential interaction between them.

Potentially eligible participants consented during the outcome assessment of the trial and were subsequently contacted by phone by a member of the research team for this qualitative process evaluation. A purposive sampling

strategy was used to ensure variation in sex, age, socioeconomic status, marital status and ethnicity. Potential participants were stratified according to their engagement and adherence outcomes: (1) engaged with intervention, adherence outcome positive, (2) engaged with intervention, adherence outcome negative and (3) did not engage with intervention, adherence outcome negative. Participants who were not engaged but had positive adherence outcomes were not included as they did not participate in the study. Engagement was defined as completion of all five IVRS calls. A positive adherence outcome was defined as either self-reported completion of CR or self-reported adherence to the recommended cardiovascular medication regimen at the time of trial outcome assessment 1 year post-MI. Interviews were completed by phone by two research coordinators (MS and KR) who had no relationship with the participants. Questions were informed by HAPA and the TDF to facilitate the ability to link participant responses to the pre-existing determinants of behaviour as well as individual intervention components (refer to online supplementary appendix 1). Interviews were audio-recorded and explored participant experiences post-MI and with the individual intervention components. All interviews were conducted once the participants had completed the 1 year of intervention period, but prior to the end of the trial.

Data analysis

Qualitative analysis was completed prior to analysing trial results to avoid bias. The interview transcripts were transcribed by a third party and independently coded by two members of the research team (MS and KR) to generate a codebook. Individual TDF domains were applied using a directed content analysis, with domains mapped to the individual components of the intervention wherever possible. Inductive coding was used to capture contextual characteristics that were not described by the TDF. All interviews were analysed by a third researcher (LD) with expertise in qualitative methods and behaviour change theory for coding verification. Discrepancies were discussed until agreement was reached.

Using a framework approach,^{24 25} resulting codes were analysed according to participant groups (eg, engaged with intervention, adherence outcome positive) to articulate individual determinants and contextual factors that served as underlying mechanisms of intervention engagement and adherence to treatment. Following analysis of the trial results in 2019, the qualitative themes were triangulated with the primary outcome data to address the study objectives.

RESULTS

Trial results revealed a significant intervention effect in the full intervention arm (educational booklets+LHW calls) compared with usual care for participation in CR but not medication adherence (see online supplementary appendix 2). The full trial report is published separately.²⁶

Participants

A total of 90 potential participants consented to be contacted for an interview. Of these, 37 either declined participation or had a telephone number that was out of service and 22 did not return the researcher coordinator's call after they left a message. The remaining 31 participants consented to an interview (34% response rate).

Interviews were conducted by phone over a 4-month period from February to May 2017. The average duration of the interviews was 35 min (ranging from 13 min to 63 min). Thematic saturation was reached after interviewing 28 participants and performing member checking with a small group of interviewed participants (n=8). A total of 66 participants were approached for an interview. Of those individuals who declined, lack of time and/or interest in participating were the reasons for refusal. The resulting sample was well balanced for gender (17 man and 13 woman) and captured variation in age (mean 63±10 years), level of education, ethnicity (n=23 white participants and n=8 non-white participants) and marital status (table 2). The majority of participants was born in Canada (n=23), while those who immigrated had been living in Canada for an average of 49±18 years.

HOW DID THE INTERVENTION PROMOTE INCREASED OUTCOME ADHERENCE?

All participants who demonstrated positive adherence outcomes (participant group 'engaged with intervention, adherence outcome positive') described strong *beliefs in their capabilities* and *beliefs about the consequences* of non-adherence to recommended behaviour changes. For most of these individuals, experiencing an MI established their *intention* to adjust their lifestyle, which supported them in remaining adherent to an exercise programme and their medications. The presence of these behavioural determinants facilitated engagement with the intervention, as it is aligned with participants' intentions to better manage their health and therefore supported individuals who were already somewhat motivated to change (refer to table 3 for supporting quotations and the online supplementary appendix 3 for definitions of TDF domains).

Pre-existing beliefs and available support facilitated intervention engagement and positive outcomes

Beliefs about capabilities were often described against the backdrop of a lifelong approach to managing change with participants commenting on their perceived discipline or following instructions 'to a T'. The idea of being disciplined often translated into participating in an exercise programme, managing medications and maintaining healthy eating habits. This disciplined lifestyle was an enduring trait for those who had established the habit of a physically active lifestyle prior to experiencing a cardiac event.

Participants unanimously acknowledged the belief that non-adherence to certain recommendations may lead to a shortened life (beliefs about consequences). One

participant described a deliberate decision to participate in the intervention and his recovery plan because he simply would 'like to stay around for a few more years' (P004). For others, the desire to live a life in a perceived state of health was a strong motivating factor, which would be threatened by the prospect of adverse consequences such as declining health and additional medical challenges.

For many participants with positive outcomes, sources of support (*social influences*) were easily identified and regularly referenced as a facilitator of exercise adherence. These sources included family and healthcare providers who were readily available and were seen as providing emotional, informational and instrumental types of support. Receiving verbal encouragement to exercise or having their support network model a physically active lifestyle was a form of instrumental support that reinforced a commitment to physical activity. Other participants described more generic support that helped sustain individual commitment to maintaining health.

Although the pre-existing determinants were referenced as facilitating engagement more broadly, beliefs about consequences were highlighted as a key determinant of engaging in a healthy lifestyle.

The intervention components provided knowledge and strategies to promote adherence

Several participants attributed their positive adherence outcomes to different components of the intervention that activated key behavioural determinants, including behavioural regulation, knowledge, reinforcement and social influences. Individual narratives outlined that behavioural regulation and knowledge encouraged an increase in self-monitoring behaviour and awareness of available supports.

Educational and self-regulatory booklets

Being prompted to self-monitor was a key feature of the educational booklets that activated behavioural regulation. Participants recognised this overt strategy and appreciated its inclusion, acknowledging that it often cued them to think about how to improve on what they were currently doing. The educational booklets also included practical knowledge about completing tasks of interest, including both procedural knowledge and knowledge of available supports. Participants described the educational booklets as a source of credible information from which they gained procedural knowledge to support optimal recovery from a cardiac event. Receiving the booklets reassured participants that somebody was interested in their recovery following their cardiac event and was available if needed.

Interestingly, several individuals did not directly link the intervention content to their actions or adherence outcomes. Instead, some participants explained using the educational materials to communicate adverse consequences to individuals outside the intervention who needed additional support and information.

Table 2 Participant characteristics

Study ID	Sex	Age range (years)	CR adherence (Y/N)	Med adherence (Y/N)	Highest level of education*	Marital status
Engaged, adherence outcomes positive						
01	F	61–70	Y	Y	PS	Married
04	M	61–70	Y	Y	PS	Married
06	M	61–70	Y	Y	PS	Married
07	M	51–60	Y	Y	PS	Married
14	F	61–70	Y	Y	PS	Married
15	M	61–70	Y	Y	HS	Common law
21	M	71–80	Y	Y	PS	Married
Engaged, adherence outcome(s) negative						
10	F	71–80	N	Y	HS	Married
16	M	61–70	N	Y	PS	Married
17	M	71–80	N	N	PS	Married
18	F	61–70	N	Y	PS	Widow
20	M	61–70	N	Y	PS	Married
22	F	>80	N	Y	PS	Widow
25	M	51–60	N	Y	HS	Divorced
30	M	61–70	N	Y	PS	Married
Not engaged, adherence outcome(s) negative						
02	F	61–70	N	Y	PS	Married
03	M	<40	Y	N	PS	Married
05	M	51–60	N	Y	HS	Separated
08	M	41–50	N	Y	PS	Married
09	M	51–60	N	Y	PS	Single
11	M	61–70	N	Y	PS	Married
12	M	61–70	N	Y	PS	Divorced
13	F	71–80	N	Y	HS	Single
19	F	51–60	N	Y	HS	Widow
23	M	71–80	N	Y	HS	Divorced
24	F	51–60	N	Y	PS	Married
26	F	41–50	N	N	PS	Married
27	M	61–70	N	Y	PS	Married
28	F	41–50	N	Y	PS	Common law
29	F	41–50	N	Y	PS	Married
31	F	71–80	N	Y	PS	Divorced

*Education reflects enrolment and does not necessarily indicate graduation.

CR, cardiac rehabilitation; F, female; HS, high school; M, male; PS, postsecondary education.

IVRS calls

Similar to the educational booklets, the IVRS calls also facilitated behavioural regulation by prompting participants to self-monitor their adherence to recommended treatment. The consistency of the calls was particularly useful in helping participants stay ‘*on top of things*’. The calls also served as reinforcement of physician recommendations, whereby participants viewed a dependent

relationship between receiving the call and their progression from non-adherent to adherent behaviour.

For some participants, the automated calls served as a reminder that access to additional supports were available if required. This knowledge of available supports was made more salient by the automated call and was often valued more than the educational booklets because of this perception.

Table 3 Supporting quotations for qualitative themes**Subtheme (TDF domain) Supporting quotations****Theme 1: Pre-existing beliefs and available support facilitated intervention engagement and positive outcomes**

Beliefs about capabilities	'I'm very good at, you know, if I have a program that I start with I'm very good at sticking to it...I've lost a considerable amount of weight. I'm getting more exercise than I ever did in the past, things like that. So, yeah, diet and exercise mainly, and staying on the meds that have been prescribed, following that to a T'. (P006) 'I have been exercising vigorously and very dedicated for 40 years. I go to the gym four or five times a week and when I go to the gym I work hard...I'm a very disciplined person, a very disciplined person. No, they didn't have to tell me to exercise, they didn't have to change my diet, they didn't need to tell me to lose weight, I'm disciplined'. (P015)
Beliefs about consequences	'It wasn't hard for me to make the changes, because my thinking is that I want to live. And, I want my health while I'm living. To be healthy. I'd rather make those changes than to run into a more difficult situation'. (P014) 'I wanted to get back to the gym as fast as I can so I asked the doctor. This was probably a week after I had the angioplasty. He said well, give it about 10 days, and then go back so I went back to the gym. I took it easy for the first day, and then I went back to exactly what I was doing before'. (P021)
Social influences	'The coaching at the rehab, the physiotherapists that were there, they really encourage you, they really tell you you're doing great. You're better, but just give it another five min, just try a little harder, I bet you can do it, you know, that's very helpful for me. And it was helpful to the point where now when I'm at home working out myself, and, like you said, you get to that point where your knees are just aching, your ankle's hurting. You're like, ah, this is stupid, I've got to take a break. Then you've got to tell yourself, no, you can't. And I think, basically, I'm kind of reflecting back on them telling me that, that's still helping me, and you get through it'. (P006)

Theme 2: The intervention components provided knowledge and strategies to promote adherence

Behavioural regulation	Educational booklets '(There were) small things I would pick up. Again, the reminders, and although I can't think of anything specific, but there were little things that (the booklets) said to do. I'd say 'oh, I'm not doing that much so maybe I'd better pick up on that one a bit' or something. They talk I guess quite a bit about missing medicines and stuff'. (P021)
Reinforcement	'(The automated phone call) sort of reinforces what you should do, even if you're not doing what you're supposed to do, and you get the phone call. Just by them asking you these questions, it would be like, oh, I should have been doing that, I forgot about that, or I missed that. To me, that aspect, it helped'. (P007)
Knowledge	'I think the (automated) calls were more helpful than the literature. I think it was just a way of keeping me on track and realizing there was ... even though it was automated and all that, that you could access something if you really needed help'. (P001)
Social influence	'With (LHW calls), they ask you questions you wouldn't think about. That would help you in the end because if it's somebody who has been doing, asking these questions, they will think about things which you ... well, I wouldn't think of, some of the things. But just by them asking you, then it gets your mind going on it'. (P007)

Theme 3: Failure to address aberrant beliefs, emotion and identity contributed to non-adherence

Beliefs about consequences	'I'm just kind of leery of that exercise and stuff. I have known people that went for them and died doing them...I even worked with a fellow. He'd come in and he said, I just dropped my aunt off and I worked in the office. Ten minutes later he got a call she dropped dead on one of the treadmills'. (P010) 'I started doing laundry, but when they're dry I bend and stretch to take out each piece individually, so I'm bending and stretching. That's it. If I'm going for a walk I like a destination. If I'm doing bending and stretching, I want to accomplish something. And if I'm doing the laundry all the time, I'm getting that exercise'. (P022)
Emotion	'I think I was surprised that shortly after the heart attack, maybe within a month or two, I was a little bit more emotional. It affected me more psychologically'. (P020) 'I was paranoid. I cried a lot. I would have nightmares about going for a walk to the garage and I would fall over... I was even thinking about suicide about three or four months ago. I would just sit here and cry'. (P016)
Identity	'I felt like I could do it on my own and go the holistic route, which did work until I decided to change my mind again'. (P008)
Memory, attention and decision-making	'It's a thing I've got to learn to deal. I can't rely on people all the time to remind me every time I'm supposed to take my meds. It's something I have to get into a routine'. (P026) 'If you get tied up in something a little different, you're going to go out and do something, it's easy to just forget that it is something you have to take'. (P017)

TDF, Theoretical Domains Framework.

LHW calls

LHW calls were an extension of the IVRS calls, acting as a social influence among those who opted out of IVRS calls or those for whom a flag was identified. Engaging with the LHW influenced the thought patterns of participants, prompting thinking around problem-solving for self-management and overcoming potential barriers to adherence (coping planning).

WHAT COULD BE IMPROVED TO BETTER MEET POPULATION NEEDS?

Failure to address aberrant beliefs, emotion and identity contributed to non-adherence

Participants in this group (engaged, adherence outcomes negative) failed to complete CR, did not enrol or indicated missing medications within the preceding week (in relation to when they were contacted at the end of the study). Several TDF domains were consistently identified in reference to participants' non-adherent behaviour, including beliefs about consequences, emotions and identity. Less prominent were the memory, attention and decision-making and beliefs about capabilities domains. The intervention components failed to effectively target these determinants for this subset of participants, resulting in partial engagement and poor adherence outcomes.

Beliefs about consequences

Aberrant beliefs about the consequences of activity acted as a barrier to participating in CR. For some individuals, strong beliefs about the perceived risk of exercise were sensational in description, while for others, inaccurate beliefs stemmed from their understanding of their physical limitations or what constitutes exercise.

Some participants rationalised a lack of lifestyle changes by identifying the cardiac event as genetic (and therefore beyond their control) or by stating that previous engagement in exercise did not prevent their cardiac event. These individuals often emphasised the importance of medication versus physical activity, as they did not believe previous lifestyle choices influenced their health.

Emotion

Participants in this group detailed the emotional toll of having a heart attack, which often resulted in an exacerbation of depressive symptoms or new, unexpected emotions. Participants described feeling down, crying and having paranoid thoughts about the risk of future cardiac events. Some were distraught over the fact that their heart attack affected their ability to return to work, which they identified as being a significant component of their identity. In most cases, individuals did not seek mental health treatment, but instead responded by 'sitting around for a few months' or lacking motivation to re-engage in healthy behaviours. For these participants, emotions surrounding their MI experience were determinants of non-adherent behaviour that the intervention did not target.

Identity

Participants who chose not to attend CR were unable to reconcile their social and professional identities with their perception of CR. Some individuals considered themselves to be different than the other CR participants and therefore opted to engage in physical activity independently. Among those who declined rehab, some were unable to follow through in maintaining an active lifestyle.

For others, the inability to transport themselves to CR presented a barrier as they wanted to avoid the perceived identity of being a burden to their family.

Memory, attention and decision-making

A few participants expressed difficulties remembering components of the intervention (ie, content of the educational booklets) or taking prescribed medication. These participants also demonstrated emotional issues (as outlined above), which may have influenced their ability to attend to intervention content. Although the intervention facilitated behavioural regulation in the first group, it failed to encourage habit formation in this group of participants.

DISCUSSION

The results of this process evaluation identified determinants of patient behaviour that influenced varying degrees of adherence to recommended treatment following a cardiac event. Components of the intervention successfully promoted completion of CR when combined with participant-reported pre-existing positive beliefs and available social support. Failure to address aberrant beliefs about consequences among a subset of individuals resulted in suboptimal adherence outcomes. Taken together, these findings help to understand not only how individual components of the intervention facilitated success for some participants but also how to modify the intervention to address a broader range of behavioural determinants. Specifically, the intervention supported 'inclined abstainers'—those who were motivated and intended to make changes but experienced challenges with the intention-behaviour gap. For those 'disinclined abstainers', the intervention did not contain a sufficient amount of motivational content to support the formation of new behavioural intentions.

Success of the ISLAND intervention in improving adherence to CR was explained by an overall alignment with behavioural determinants and a combination of components that supported existing attitudes and beliefs. Specifically, the intervention moved beyond simply motivating participants to include a self-regulatory element of support around self-monitoring, including problem-solving and coping planning. Intervention success relies on its acceptability to recipients,²⁷ which is dependent on individual attitudes towards treatment options and perceived suitability of the intervention with the individual's lifestyle,²⁸ underscoring the importance of 'fit'.



Beliefs about capabilities, beliefs about consequences and intentions were pre-existing, positive determinants of behaviour whose reinforcement contributed to treatment adherence—simply put, the intervention worked well for participants who already intended to change their behaviour by providing assistance in following through on their motivations (ie, bridging the intention-behaviour gap). Additionally, evidence shows that interventions targeting coping planning are most effective when they are supported by someone (in this case the LHW) instead of simply being prompted without support.²⁹ These findings align with previous work on participation in CR^{30–32} and the tenets of the HAPA, which outlines self-efficacy, outcome expectations, risk perception as predictors of intention and coping planning and social support as predictors of health behaviour.³³ Taken together, this evidence highlights the importance of multifaceted interventions targeting multiple determinants of behaviour in order to successfully promote adherence.

Beliefs about consequences and individual *identity* were key explanatory factors underlying the difference between those with positive and negative adherence outcomes. Previous research supports this assertion that the concept of ‘balanced beliefs’, including an appreciation of potential consequences while recognising that the condition is manageable, increases the likelihood of adherence.³² Positive, balanced beliefs characterised the individuals with positive outcomes, while individuals with poor adherence outcomes associated undue risk with recommended treatment and did not perceive the same degree of control over the future impact of their condition. People who did not complete CR were more likely to exhibit misconceptions regarding overexertion and are generally less aware of the nature and benefits of CR.³⁴ Individual beliefs inform how patients choose to cope,^{35 36} suggesting that modifications to the current intervention are likely needed to successfully target the broader range of existing patient beliefs that influence adherence. Identity and emotion were key behavioural determinants identified by participants who did not adhere to CR and prescribed medication, suggesting that future iterations of the intervention could target these determinants to appeal to a broader population. Beliefs about consequences, memory/attention/decision-making processes, social influences and behavioural regulation are modifiable factors that promote medication adherence¹⁷ that were addressed in the current intervention but may not have been included at a ‘dose’ that was sufficient to activate motivation among those participants who ‘disinclined abstainers’ (ie, not already motivated to change behaviour). Further work is required to determine how best to operationalise components of the existing intervention in order to target these determinants to meet the needs of individuals who experience lower levels of motivation. Using reliable measures to characterise patient beliefs³⁴ may provide an opportunity to screen for misconceptions and facilitate a more tailored approach. Specifically, the presence of aberrant beliefs signalled an external locus of control (the belief

that fate or chance determines health status). Given this belief negatively impacts medication adherence,³⁷ direct messaging around self-efficacy and individual capability may increase an individual’s internal locus of control (a sense that control over their health is directly related to their own actions), which may positively influence medication adherence.

The emotional sequelae of a cardiac event was another key experience among a subset of non-adherers who was not addressed through the intervention. One-third of patients exhibit mild-to-moderate depressive symptoms following an MI, with one in five patients experiencing major depression.³⁸ Patients are greater than three times more likely to experience post-traumatic stress disorder (PTSD) compared with healthy peers following an incident MI.³⁹ Screening for PTSD, using a brief questionnaire such as the primary care PTSD screen,⁴⁰ could be incorporated into the automated IVRS call component of the intervention in order to assess an individual’s psychosocial/emotional status. If a flag is identified, the intervention could consider the inclusion of a PTSD assessment, telephone-based counselling and/or referral to local mental health resources.^{41 42} The LHW may then offer telephone-based counselling and/or offer information on nearby mental health resources. Identifying and targeting emotional distress early in the patient’s experience could thereby meet the needs of a broader range of individuals, further expanding the reach of the intervention.

LIMITATIONS

Interview participation was voluntary that introduces the potential of volunteer bias. To mitigate this, purposive sampling was used to capture the perspectives of participants that had both positive and negative adherence outcomes, in addition to those who did not engage with the intervention. Inclusion of participants from only two recruitment sites in a confined geographical area limited generalisability beyond this population. We did not engage with physicians and other healthcare providers to understand whether and how the intervention supported these interactions or was viewed as useful by the healthcare team. Finally, our study design has several limitations. We are limited in our ability to understand why the intervention led to a significant improvement in CR adherence but not medication adherence as only three participants in the current study had a negative adherence outcome for medications. This is a limitation of conducting an embedded, a priori process evaluation of an intervention targeting multiple behaviours and evaluating two copriary outcomes, which precluded our ability to purposively target recruitment for a given group. Despite this, insights from this study provide an understanding of how to modify the existing intervention to reach a broader population. The nature of patient self-report is often inaccurate; however, this was a necessary reality of conducting the larger pragmatic trial at a system-wide scale. Finally,

without a preassessment of individual patient beliefs prior to intervention exposure, our qualitative study lacks a true behavioural control. Future work would benefit from establishing baseline behavioural determinants prior to engagement with intervention.

CONCLUSION

An individual's beliefs about consequences, beliefs about capabilities (self-efficacy), intentions, social influences and emotions influenced adherence to recommended treatment following a cardiac event. A multicomponent intervention including educational material and telephone reminders facilitated CR adherence through reinforcement, behavioural regulation, the provision of knowledge and social influence. Knowledge of these factors can help to identify patients who may be at risk for non-adherence or to tailor interventions to promote adherence in this population. Modifications to target aberrant beliefs about consequences, memory, attention and decision-making and emotion would broaden the scope of the current intervention to target the needs of a more diverse group of individuals.

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REFERENCES

- 1 Johansson S, Rosengren A, Young K, *et al*. Mortality and morbidity trends after the first year in survivors of acute myocardial infarction: a systematic review. *BMC Cardiovasc Disord* 2017;17:53.
- 2 Rapsomaniki E, Thuresson M, Yang E, *et al*. Using big data from health records from four countries to evaluate chronic disease outcomes: a study in 114 364 survivors of myocardial infarction. *Eur Heart J Qual Care Clin Outcomes* 2016;2:172–83.
- 3 Jernberg T, Hasvold P, Henriksson M, *et al*. Cardiovascular risk in post-myocardial infarction patients: nationwide real world data demonstrate the importance of a long-term perspective. *Eur Heart J* 2015;36:1163–70.
- 4 Taylor RS, Brown A, Ebrahim S, *et al*. Exercise-based rehabilitation for patients with coronary heart disease: systematic review and meta-analysis of randomized controlled trials. *Am J Med* 2004;116:682–92.
- 5 Leon AS, Franklin BA, Costa F, *et al*. Cardiac rehabilitation and secondary prevention of coronary heart disease: an American heart association scientific statement from the Council on clinical cardiology (Subcommittee on exercise, cardiac rehabilitation, and prevention) and the Council on nutrition, physical activity, and metabolism (Subcommittee on physical activity), in collaboration with the American association of cardiovascular and pulmonary rehabilitation. *Circulation* 2005;111:369–76.
- 6 Perk J, De Backer G, Gohlke H, *et al*. European guidelines on cardiovascular disease prevention in clinical practice (version 2012): the fifth joint task force of the European society of cardiology and other societies on cardiovascular disease prevention in clinical practice (constituted by representatives of nine societies and by invited experts). *Int J Behav Med* 2012;19:403–88.
- 7 Stone JA, Arthur HM, Canadian Association of Cardiac Rehabilitation Guidelines Writing Group. Canadian guidelines for cardiac rehabilitation and cardiovascular disease prevention, second edition, 2004: Executive summary. *Can J Cardiol* 2005;21 Suppl D:3D–19.
- 8 Lawler PR, Fillion KB, Eisenberg MJ. Efficacy of exercise-based cardiac rehabilitation post-myocardial infarction: a systematic review and meta-analysis of randomized controlled trials. *Am Heart J* 2011;162:571–84.
- 9 Martin B-J, Hauer T, Arena R, *et al*. Cardiac rehabilitation attendance and outcomes in coronary artery disease patients. *Circulation* 2012;126:677–87.
- 10 Sundararajan V, Bunker SJ, Begg S, *et al*. Attendance rates and outcomes of cardiac rehabilitation in Victoria, 1998. *Med J Aust* 2004;180:268–71.
- 11 Cooper A, Lloyd G, Weinman J, *et al*. Why patients do not attend cardiac rehabilitation: role of intentions and illness beliefs. *Heart* 1999;82:234–6.
- 12 Cooper AF, Jackson G, Weinman J, *et al*. Factors associated with cardiac rehabilitation attendance: a systematic review of the literature. *Clin Rehabil* 2002;16:541–52.
- 13 LaRosa JC, He J, Vupputuri S. Effect of statins on risk of coronary disease: a meta-analysis of randomized controlled trials. *JAMA* 1999;282:2340–6.
- 14 Rasmussen JN, Chong A, Alter DA. Relationship between adherence to evidence-based pharmacotherapy and long-term mortality after acute myocardial infarction. *JAMA* 2007;297:177–86.
- 15 Ho PM, Spertus JA, Masoudi FA, *et al*. Impact of medication therapy discontinuation on mortality after myocardial infarction. *Arch Intern Med* 2006;166:1842–7.
- 16 Abraham C, Kelly MP, West R, *et al*. The UK National Institute for health and clinical excellence public health guidance on behaviour change: a brief introduction. *Psychol Health Med* 2009;14:1–8.



- 17 Presseau J, Schwalm JD, Grimshaw JM, *et al.* Identifying determinants of medication adherence following myocardial infarction using the theoretical domains framework and the health action process approach. *Psychol Health* 2017;32:1176–94.
- 18 Ivers N, Schwalm J-D, Wittman HO, *et al.* Interventions supporting long-term adherence and decreasing cardiovascular events (island): pragmatic randomized trial protocol. *Am Heart J* 2017;190:64–75.
- 19 Glasziou P, Meats E, Heneghan C, *et al.* What is missing from descriptions of treatment in trials and reviews? *BMJ* 2008;336:1472–4.
- 20 Hoffmann TC, Glasziou PP, Boutron I, *et al.* Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *BMJ* 2014;348:g1687.
- 21 Moore GF, Audrey S, Barker M, *et al.* Process evaluation of complex interventions: medical Research Council guidance. *BMJ* 2015;350:h1258.
- 22 Michie S, Richardson M, Johnston M, *et al.* The behavior change technique taxonomy (V1) of 93 hierarchically clustered techniques: building an international consensus for the reporting of behavior change interventions. *Ann Behav Med* 2013;46:81–95.
- 23 Wittman HO, Presseau J, Nicholas Angl E, *et al.* Negotiating tensions between theory and design in the development of Mailings for people recovering from acute coronary syndrome. *JMIR Hum Factors* 2017;4:e6.
- 24 Gale NK, Heath G, Cameron E, *et al.* Using the framework method for the analysis of qualitative data in multi-disciplinary health research. *BMC Med Res Methodol* 2013;13:117.
- 25 Smith J, Firth J. Qualitative data analysis: the framework approach. *Nurse Res* 2011;18:52–62.
- 26 Ivers NM, Schwalm J-D, Bouck Z, *et al.* Interventions supporting long term adherence and decreasing cardiovascular events after myocardial infarction (island): pragmatic randomised controlled trial. *BMJ* 2020;369:m1731.
- 27 Sekhon M, Cartwright M, Francis JJ. Acceptability of healthcare interventions: an overview of reviews and development of a theoretical framework. *BMC Health Serv Res* 2017;17:88.
- 28 Sidani S, Epstein DR, Bootzin RR, *et al.* Assessment of preferences for treatment: validation of a measure. *Res Nurs Health* 2009;32:419–31.
- 29 Kwasnicka D, Presseau J, White M, *et al.* Does planning how to cope with anticipated barriers facilitate health-related behaviour change? A systematic review. *Health Psychol Rev* 2013;7:129–45.
- 30 Jackson L, Leclerc J, Erskine Y, *et al.* Getting the most out of cardiac rehabilitation: a review of referral and adherence predictors. *Heart* 2005;91:10–14.
- 31 Robertson D, Keller C. Relationships among health beliefs, self-efficacy, and exercise adherence in patients with coronary artery disease. *Heart Lung* 1992;21:56–63.
- 32 French DP, Cooper A, Weinman J. Illness perceptions predict attendance at cardiac rehabilitation following acute myocardial infarction: a systematic review with meta-analysis. *J Psychosom Res* 2006;61:757–67.
- 33 Schwarzer R, Lippke S, Luszczynska A. Mechanisms of health behavior change in persons with chronic illness or disability: the health action process approach (HAPA). *Rehabil Psychol* 2011;56:161–70.
- 34 Cooper AF, Weinman J, Hankins M, *et al.* Assessing patients' beliefs about cardiac rehabilitation as a basis for predicting attendance after acute myocardial infarction. *Heart* 2007;93:53–8.
- 35 Petrie K, Weinman J. *Perceptions of health and illness: current research and applications*. Amsterdam: Harwood Academic, 1997.
- 36 Cameron L, Leventhal H. *The self-regulation of health and illness behaviour*. London: Routledge, 2003.
- 37 Náfrádi L, Nakamoto K, Schulz PJ. Is patient empowerment the key to promote adherence? A systematic review of the relationship between self-efficacy, health locus of control and medication adherence. *PLoS One* 2017;12:e0186458.
- 38 Thombs BD, Bass EB, Ford DE, *et al.* Prevalence of depression in survivors of acute myocardial infarction. *J Gen Intern Med* 2006;21:30–8.
- 39 Pedersen SS, Middel B, Larsen ML. Posttraumatic stress disorder in first-time myocardial infarction patients. *Heart Lung* 2003;32:300–7.
- 40 Cameron R, Gusman D. The primary care PTSD screen (PC-PTSD): development and operating characteristics. *Primary Care Psychiatry* 2003;9:9–14.
- 41 Tulloch H, Greenman PS, Tassé V. Post-Traumatic stress disorder among cardiac patients: prevalence, risk factors, and considerations for assessment and treatment. *Behav Sci* 2014;5:27–40.
- 42 Bambauer KZ, Aupont O, Stone PH, *et al.* The effect of a telephone counseling intervention on self-rated health of cardiac patients. *Psychosom Med* 2005;67:539–45.