Interventions supporting cardiac rehabilitation completion: process evaluation investigating theory-based mechanisms of action

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Abstract

Objective: A randomised trial informed by the Health Action Process Approach evaluated interventions to improve cardiac rehabilitation completion. This study investigated indirect effects of the interventions on cardiac rehabilitation adherence via targeted constructs. **Methods:** In this quantitative theory-based process evaluation, participants in all three trial arms (usual care; mailouts; mailouts plus telephone support) completed a questionnaire at 12 months follow-up assessing intention, goal priority, outcome expectancies, risk perception, self-efficacy, social support, action planning, and coping planning. Consecutive sampling was used until the target sample size (167 per arm) was met. Completion of cardiac rehabilitation at the same time point was self-reported. We used multiple regression mediation models to explore indirect effects. **Results:** In total, 594 participants completed the cardiac rehabilitation questionnaire; 588 were analysed (6 excluded due to missing data). For mailouts alone, there were no significant indirect effects. There were small indirect effects of mailouts plus telephone support on intention via goal priority, outcome expectancies, and self-efficacy, with a negative effect via severity risk perception. There were also small indirect effects on cardiac rehabilitation completion via self-efficacy and action planning. **Conclusions:** Findings suggest that mailouts plus telephone support increased the likelihood of completing cardiac rehabilitation by enhancing self-efficacy and action planning, and increased intention by enhancing goal priority, self-efficacy, and outcome expectancies, with an unintended consequence of a negative effect via risk perceptions. Conducting theory-based process evaluations alongside trials of behaviour change interventions can clarify mechanisms of action, which can inform efforts to refine interventions and to replicate and generalize findings to other jurisdictions.

Keywords: cardiac rehabilitation, myocardial infarction, health action process approach, process evaluation, indirect effects

TRIAL REGISTRATION: ClinicalTrials.gov identifier: NCT02382731

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Clinical guidelines recommend that patients complete cardiac rehabilitation after hospitalization for a myocardial infarction (MI) (CACPR, 2009; NICE, 2013). Internationally, cardiac rehabilitation programs focus on health behaviour change and typically include exercise training, education about heart health, and counselling to reduce stress (Anderson & Taylor, 2014; Grace, Bennett, et al., 2014; O'Gara et al., 2013). In Ontario, Canada, the setting of this study, programs are typically delivered 2-3 times a week over 5 months (Grace, Bennett, et al., 2014; Ndegwa, 2010), within a hospital by an interprofessional team (Polyzotis et al., 2012). A Cochrane systematic review found that attending exercise-based cardiac rehabilitation significantly reduced the risk of cardiovascular mortality compared to no exercise (27 trials; risk ratio 0.74, 95% CI 0.64 to 0.86) (Anderson et al., 2016). However, existing programs are under-utilized, limiting their impact on population health. Surveys in many countries indicate that only 30% of eligible patients participate in cardiac rehabilitation (Bethell et al., 2001; Kotseva et al., 2009; Suaya et al., 2007). Fewer still complete their program and maintain exercise after completion (Daly et al., 2002; S. M. Moore et al., 2003). Barriers to participation in cardiac rehabilitation programs in Canada include perceptions of not needing programs, work or time conflicts, and healthcare system factors such as wait times (de Melo Ghisi et al., 2013). Similar barriers (such as denial of severity of illness, financial or occupational constraints, and healthcare system factors) are experienced in other countries (Clark et al., 2012; Cooper et al., 2002; Neubeck et al., 2012).

Santiago de Araújo Pio et al. (Santiago de Araújo Pio et al., 2019) synthesized the evidence on the effectiveness of interventions to increase participation. Included interventions were varied and comprised multiple components. Compared to usual care, interventions improved enrolment, adherence, and completion. However, this evidence was judged to be of low to moderate quality. The authors concluded that the heterogeneity between studies and lack of understanding of underlying

mechanisms limited the informativeness of the evidence. They recommended that further researchrigorously evaluate interventions that target patient-identified barriers, examine how interventions work, and identify 'active ingredients' (Santiago de Araújo Pio et al., 2019).

We conducted a multicentre, pragmatic, three-arm randomised controlled trial to evaluate two interventions to improve cardiac rehabilitation completion post-MI (Interventions Supporting Long-term Adherence aNd Decreasing cardiovascular events: ISLAND) (N. M. Ivers et al., in press, 2017). The trial took place in nine cardiac care centres and all eligible patients were enrolled. Participants were randomized to: i) usual care (no standardized follow up interventions; herein referred to as the usual care arm); ii) usual care plus a series of mailouts designed to target factors influencing adherence, including a letter and pre-filled cardiac rehabilitation referral form for the patient to bring to their family physician (herein referred to as the mailouts only arm); or iii) usual care plus the series of mailouts, plus automated reminder telephone calls to identify those at risk of nonadherence, followed by additional support and navigation via trained lay health worker calls for such participants (herein referred to as the mailouts+calls arm). The trial had two co-primary outcomes – adherence to cardiac medications, and cardiac rehabilitation completion – both measures of adherence to guideline-recommended treatments (CACPR, 2009; NICE, 2013; O'Gara et al., 2013).

While randomised trials are essential for evaluating whether behaviour change interventions work or not (causal description), further work is typically required to establish the 'how' and 'why' of intervention effectiveness (causal explanation). A process evaluation is a type of study which "aims to understand the functioning of an intervention, by examining implementation, mechanisms of impact, and contextual factors" (G. F. Moore et al., 2015). We conducted a theory-based process evaluation alongside the trial to investigate the mechanisms of action of the interventions.

The Health Action Process Approach (HAPA) (Schwarzer, 2008; Schwarzer et al., 2011) informed intervention design. HAPA proposes that health behaviour is influenced by a series of determinants in

two phases. In the motivational phase, an individual forms an intention to engage in the behaviour, which is influenced by: i) their perceptions of their risk of experiencing health events related to the behaviour (risk perception); ii) what they expect the outcomes of enacting the behaviour might be (outcome expectancies); iii) their confidence in their ability to enact the behaviour (self-efficacy); and iv) specific barriers and resources, such as social support (Schwarzer, 2008; Schwarzer et al., 2011). In the volitional phase, an individual's enactment of the behaviour is influenced by: i) their intention; ii) their self-efficacy; and iii) specific barriers and resources. The theory proposes that the influence of intention on behaviour is mediated (i.e. translated into action) via the individual's development of plans specifying when, where, and how they will enact the behaviour (action planning); and how they will overcome barriers they may face (coping planning) (Schwarzer, 2008; Schwarzer et al., 2011). Action control (the processes by which an individual evaluates their enactment of the behaviour as compared to a standard) is also important for continuous or repeated enactment (Schwarzer, 2008; Schwarzer et al., 2011).

In our preparatory work, we found that HAPA constructs predicted medication adherence in this population (another behaviour of focus in the trial) (Presseau et al., 2017). Wider literature shows that HAPA constructs also predict adherence with cardiac rehabilitation exercise (Schwarzer et al., 2008; Sniehotta et al., 2005, 2010). HAPA constructs were therefore targeted as intervention mechanisms of action in the ISLAND trial. In addition, there have been calls in the behaviour change literature to move away from focusing on only one behaviour at a time and towards incorporating a multiple behaviour approach, which may achieve greater impact since health outcomes tend to be influenced by multiple health behaviours (Nigg et al., 2002; Presseau et al., 2015). This is especially important given that cardiac rehabilitation exercise must be incorporated into everyday life, in which participants are already engaging in multiple health behaviours which either facilitate or conflict with rehabilitation-related goals (Presseau et al., 2015). We incorporated this perspective by investigating the impact of the interventions on the prioritization of cardiac rehabilitation exercises relative to participants' other everyday life

behaviours (goal priority). The aim of this process evaluation was to investigate indirect effects of the interventions on cardiac rehabilitation adherence via theory-based constructs targeted. In line with the phases of the HAPA and the addition of goal priority previously outlined, we hypothesised that compared to usual care, both interventions would

i) increase participants' intention to participate in cardiac rehabilitation exercises by increasing their risk perceptions, positive outcome expectancies, self-efficacy, social support, and the priority of participating compared to other activities; and

ii) increase participants' likelihood of completing cardiac rehabilitation by increasing intention, self-efficacy, social support, action planning, and coping planning.

Methods

Design

Theory-based quantitative process evaluation alongside a randomized controlled trial.

Ethical approvals

Ethical approval for the trial was provided by the nine cardiac centers involved (Hamilton General Hospital, Kingston General Hospital, London Health Sciences Centre, Peterborough Regional Health Care, St Catharines General Hospital, Sunnybrook Health Sciences Centre, Trillium Health Partners, University Health Network, and William Osler Health Centre). Given the low-risk nature of the intervention, research ethics boards approved a waiver of consent for patients enrolled in the trial with provision of multiple opportunities to opt out and a debrief at the time of outcome assessment. Ethics approval for the analyses reported here was granted by the Women's College Hospital Research Ethics Board (#2017-0135-E), and the Ottawa Health Science Network Research Ethics Board (#20170832-01H).

Interventions

Full details of the intervention development process have been published (Witteman et al., 2017), including the embedded Behaviour Change Techniques (BCTs) (Michie et al., 2013) mapped to the theoretical constructs targeted, and the final series of mailouts used. Table 1 lists the underlying constructs assessed as mechanisms of change in this process evaluation, the BCTs used to target those constructs, and examples of how these BCTs were operationalized.

TABLE 1 HERE

Participants

When outcome data for the trial were gathered at 12 months follow-up over the telephone, participants were invited to take part in the process evaluation. Participants were asked if they would be willing to answer a few more questions relating to their views about participating in exercise and / or taking heart pills. As there were two co-primary outcomes in this trial, there were two process evaluation questionnaires. We recognised that completing all questionnaires may have been burdensome for participants, and may also have impacted the accuracy and completeness of the responses received. Therefore, participants were initially invited to complete one of the process evaluation questionnaires (randomly assigned), and then once completed, were asked if they would be willing to complete a second questionnaire.

The target sample size was 500 participants for each co-primary outcome, calculated based on testing the effect of a continuous mediator in a logistic regression model (Vittinghoff et al., 2009). We assumed that the overall prevalence of cardiac rehabilitation completion at the end of the study would be 0.4; we also assumed a partial correlation between the mediator and each treatment indicator of 0.5 and a standard deviation for the mediator of 1. With these assumptions, 500 participants achieve 80% power at a two-sided 5% significance level to detect an Odds Ratio for the mediator of 1.34, i.e., a relative increase of 34% in the odds of completing cardiac rehabilitation per 1-unit change in the

mediator. Participants were consecutively invited to take part in the process evaluation until the target sample size had been met. Participants were offered entry into a raffle to win one of five $20 gift cards.

Data collection

Completion of cardiac rehabilitation in the past year was assessed via self-report at 12 months and categorized as a binary outcome. Questions were validated in a previous study in Ontario which found almost perfect agreement between self-reported and site-verified use of cardiac rehabilitation services (Kayaniyil et al., 2009). Participants in our study were first asked if they had attended even one session of cardiac rehabilitation in the past year; if they reported that they had, they were then asked whether they fully participated in the program, including the final re-assessment of heart health at the end of the program; if participants reported not completing the program, they were asked to estimate the proportion of total scheduled sessions attended. In line with consensus-derived data definitions (Grace, Poirier, et al., 2014), those reporting multiple visits and re-assessment were considered to have completed cardiac rehabilitation.

Process evaluation questionnaires were also administered over the telephone at 12 months. The questionnaire included items assessing the HAPA constructs, based on previously validated scales. A new item was included to assess goal priority. Exercise is the key focus of cardiac rehabilitation, and participants could have been at various stages of program completion when responding (with some potentially having not attended any sessions). For participants who had attended at least one rehabilitation session, questions were phrased in relation to participating in cardiac rehabilitation exercises. For participants who had not attended at least one session, questions were phrased in relation to participating in exercise to stay fit. Details of the constructs assessed are presented in Table 2. All questions (those used in the outcome evaluation and process evaluation) are included in the Online Supplemental Materials.

Participant socio-demographic and clinical characteristics were gathered for the trial from administrative sources. A provincial cardiac registry, hosted by CorHealth Ontario (previously Cardiac Care Network), with data collected by each cardiac centre, along with patient-reported data were linked to the population-level health administrative databases held at ICES (an Ontario-based health informatics research institute). Demographic data collected via administrative sources comprised age, sex, smoking status, education, ethnicity, rurality, and socioeconomic status (neighbourhood income quintile estimate) (Statistics Canada, Government of Canada, 2017). Additional demographic data collected as part of the outcome assessment questionnaire for the main trial comprised immigration status, marital status, prior cardiac event or procedure, and whether the participant had diabetes.

Data processing and analysis

Participants were excluded from analyses if they did not have a value for at least 50% of the items for 50% (4/8) of the constructs. For the theoretical constructs assessed using multiple items, we assessed internal consistency using Cronbach's alpha (Table 2). If internal consistency was <0.7, we explored whether consistency could be improved by omitting individual items. We calculated the mean of the items measuring each construct to create a summary score. Mean scores for constructs were calculated using the data available, and analyses were conducted using pairwise deletion. Differences between trial arms were assessed using one-way ANOVA with post-hoc Tukey tests to further investigate any observed differences.

TABLE 2 HERE

We investigated indirect associations between the interventions and completion via the constructs assessed. Models were built using Hayes' SPSS PROCESS macro (Hayes, 2013), using the bootstrapping procedure with 5000 resamples. Consistent with HAPA's two phases, we built one model to investigate indirect effects of the interventions on intention via motivational constructs, and a second model to investigate effects on rehabilitation completion via volitional constructs. All analyses were

conducted using IBM SPSS Statistics 25. All analyses were conducted, and subsequent interpretations made, before knowledge of the final trial results was obtained.

Results

Summary of the ISLAND trial results

Compared to usual care, mailouts+calls resulted in a significantly greater proportion of patients completing cardiac rehabilitation (N. M. Ivers et al., in press). There was no significant difference between usual care and mailouts only in cardiac rehabilitation completion (N. M. Ivers et al., in press).

Process evaluation response rates and participant characteristics

Participant flow through the process evaluation is summarized in Figure 1. In total, 2742 patients were enrolled in the trial; 2632 were included in trial analyses. Of these, 1566 were invited to the process evaluation; 1162 (74%) consented. Details of participants' reasons for declining to participate were not gathered. Of the 1162, 594 responded to the cardiac rehabilitation completion questionnaire (589 responded to the medication adherence questionnaire not included in this manuscript, with 21 responding to both); 588 (99%) were included in our analyses (6 were excluded due to the volume of missing data); 214 (36%) in the usual care arm, 187 (32%) in the mailouts only arm, and 187 (32%) in the mailouts+calls arm. This fulfilled our target sample size of 167 participants per arm.

FIGURE 1 HERE

Participant characteristics are summarized in Table 3. On average, participants in each arm were 63-64 years old, and most were male (74-75%). Within each arm, there was spread across categories of socioeconomic status and extent of education.

TABLE 3 HERE

Intervention effects on constructs

Results of internal consistency analyses are included in Table 2. The threshold of 0.7 was not met for risk perception or social support. The two items assessing risk perception were analysed as

separate items. The Cronbach's alpha value could not be improved for social support by omitting any of the three items: therefore, all items were included but interpreted with due caution.

Mean scores, and differences between arms, are shown in Table 4. Between-group differences were found for severity risk perception, self-efficacy, action planning, and coping planning. Post-hoc Tukey tests indicated that: i) untreated coronary health problems were viewed as less severe in the mailouts+calls arm than the usual care arm (p=.001), and in the mailouts+calls arm than the mailouts only arm (p<.001); ii) self-efficacy for exercise participation despite potential barriers was higher in the mailouts+calls arm than the usual care arm (p=.006); iii) action planning for participation in exercises was greater in the mailouts+calls arm than the usual care arm (p=.020); and iv) coping planning for participation in exercises was greater in the mailouts+calls arm than the usual care arm (p<.001).

TABLE 4 HERE

Indirect effects of interventions on intention to participate in cardiac rehabilitation exercises

We identified significant positive indirect effects of the mailouts+calls intervention on intention to participate in cardiac rehabilitation exercises via increased priority, positive outcome expectancies, and self-efficacy (Figure 2). Controlling for all other variables: relative to the control group, the intention scores of those who received the mailouts+calls were on average 0.06 units higher (95%CI 0.01 to 0.12) due to the impact of this intervention on priority; 0.04 units higher (95%CI 0.01 to 0.09) due to the impact of this intervention on positive outcome expectancies; and 0.10 units higher (95%CI 0.04 to 0.18) due to the impact of this intervention on self-efficacy.

However, this was mitigated by a negative indirect effect via severity risk perception (i.e. reduced severity with which untreated coronary health problems were viewed). Controlling for all other variables: relative to the control group, the intention scores of those who received the mailouts+calls were on average 0.02 units lower (95%CI -0.06 to -0.01) due to the impact of this intervention on severity risk perception. There were no significant indirect effects of mailouts only (Figure 2).

FIGURE 2 HERE

Indirect effects of interventions on exercise-based cardiac rehabilitation completion

Cardiac rehabilitation completion was defined as participating in the full program, including the final re-assessment of heart health at the end of the program. Self-reported rehabilitation completion rates for process evaluation participants were as follows: 34.1% (73/214) in the usual care arm; 40.1% (75/187) in the mailouts only arm; and 41.7% (78/187) in the mailouts+calls arm. Pearson Chi-squared tests indicated that among the 1,773 individuals with a non-missing response for cardiac rehabilitation completion, those whose data were analysed as part of either process evaluation (n=1,152) were more likely to complete rehabilitation than those who did not take part in the process evaluation (those not asked to participate, as well as those asked but who declined) (n = 621) in the usual care arm ($X^2(1)=19.6$, $p<.001$), mailouts only arm ($X^2(1)=30.9$ $p<.001$), and the mailouts+calls arm ($X^2(1)=13.0$, $p<.001$).

We identified significant positive indirect effects of the mailouts+calls on cardiac rehabilitation completion via increased self-efficacy and action planning (Figure 3). Controlling for all other variables: relative to the control group, the odds of completing rehabilitation in those who received the mailouts+calls were on average 1.13 times greater (95%CI 1.04 to 1.30) due to the impact of this intervention on self-efficacy, and 1.08 times greater (95%CI 1.02 to 1.20) due to the impact of this intervention on action planning. There were no significant indirect effects of mailouts only (Figure 3).

FIGURE 3 HERE

Discussion

Embedded within a randomized trial, we conducted a theory-based quantitative process evaluation to investigate the mechanisms of action of two interventions designed to support completion of exercise-based cardiac rehabilitation. Compared to usual care, the intervention comprising a series of mailouts alone had no indirect effect on either intention to participate in exercises, or completion of

cardiac rehabilitation (assessed via self-report) via proposed mechanisms (goal priority, outcome expectancies, risk perception, self-efficacy, social support, action planning, coping planning). However, the intervention comprising the mailouts plus additional telephone support had indirect effects on intention via increased priority of participating in exercise compared to other activities; increased positive outcome expectancies related to participating; and increased self-efficacy in participating in exercise despite potential barriers. Of note, this intervention also had an unintended negative effect in that it reduced the severity with which untreated coronary health problems were viewed (risk perceptions). This intervention also had indirect effects on self-reported cardiac rehabilitation completion via increased self-efficacy and increased action-planning (development of a detailed plan specifying when, where, and how they would participate in exercise).

Implications for interpreting intervention effectiveness

Although effect sizes are small and we cannot infer causality, our findings suggest that the mailouts+calls intervention improved cardiac rehabilitation completion by enhancing participants' self-efficacy and action-planning. Five interventions included in the recent Cochrane review of interventions to increase participation in cardiac rehabilitation (Santiago de Araújo Pio et al., 2019) were explicitly based on Social Cognitive Theory or exercise self-efficacy (D. L. Carroll et al., 2007; Dolansky et al., 2011; Focht et al., 2004; Pfaeffli Dale et al., 2015; Price, 2012). In two further studies which considered self-efficacy, interventions were designed to support maintenance of exercise following a rehabilitation program (Izawa et al., 2005; S. M. Moore et al., 2006). Six of these seven interventions improved rehabilitation utilization or exercise maintenance (D. L. Carroll et al., 2007; Dolansky et al., 2011; Focht et al., 2004; Izawa et al., 2005; S. M. Moore et al., 2006; Price, 2012), indicating the potential of these interventions. Self-efficacy was measured in four of the six studies (Dolansky et al., 2011; Izawa et al., 2005; S. M. Moore et al., 2006; Price, 2012): a significant increase in self-efficacy was found in only one (Izawa et al., 2005). Previous studies did not involve exploration of indirect effects. Our results advance

the understanding of effective intervention components by highlighting self-efficacy as a potential mechanism of effect.

The importance of planning in this population has been highlighted. Sniehotta et al. (Sniehotta et al., 2006) found that although action planning alone had no significant effect, it led to higher levels of physical activity in combination with coping planning. Sniehotta et al. (Sniehotta et al., 2006) suggested that action planning may have been less effective than combined planning because participants may have already formed action plans prior to the intervention. Following this line of reasoning, participants in our study may not have already formed action plans and therefore benefitted from reminders and support to do so. However, it is important to highlight the small effect size and to note that mean scores for action planning and coping planning were still relatively low in this group (2.74 and 2.72 respectively). A narrative synthesis conducted within a systematic review of coping planning interventions suggested that these interventions work better when planning is supported by someone (Kwasnicka et al., 2013). Participants in our study may have benefitted from more support to develop both their action and coping plans. Combined with previous literature (Schwarzer et al., 2008; Sniehotta et al., 2010), our results highlight the potential impact of these relatively straightforward, personalized, scalable interventions.

The mailouts+calls also impacted participants' motivation. A novel finding was that this intervention increased the priority of these exercises relative to other behaviours of everyday life. Previous work in non-clinical populations indicated that increasing the priority of physical activity strengthens the influence of intention on physical activity behaviour (Conner et al., 2016). Ours is the first study to indicate the value of considering goal priority for intervention development with clinical populations, thereby reinforcing the importance of taking a multiple behaviour perspective when developing behaviour change interventions (Nigg et al., 2002; Presseau et al., 2015).

However, there was also a negative effect on severity risk perceptions. During intervention development, patients reviewing mail-out materials noted that the included health risk information was potentially frightening (Witteman et al., 2017). The team acknowledged that this was worrisome, but agreed that they had an ethical imperative to convey this information (Witteman et al., 2017). Although this does not seem to have been an issue for the group receiving the mailouts only, the likelihood of participants being frightened may have been increased for the group receiving the calls, which were aimed at individuals at risk of non-adherence and frequently emphasized that adhering to treatments could reduce the risk of a further heart attack. This may have elicited defensive reactions, resulting in the perceptions of reduced seriousness of untreated coronary health problems (Ditto et al., 1988). Alternatively, the reassurance and support provided in the calls may have reduced some concerns about risks in general, which may have contributed to the lower scores for this item in this group. In any case, risk perception is conceptualized as a distal predictor of behaviour (Schwarzer, 2008; Schwarzer et al., 2011) and therefore according to the underlying theory, this negative effect is unlikely to have had a great deal of impact on cardiac rehabilitation completion in the trial. That said, this finding highlights a general strength of conducting mechanistic process evaluations, in that this has enabled us to identify unintended consequences of the intervention that we may not have discovered otherwise. This can inform subsequent iterations of intervention content.

Although both interventions were developed to include the same active ingredients (i.e. the same BCTs), they differentially effected the proposed mechanisms, and neither influenced all proposed mechanisms. There are several potential explanations for this. First, the differences could be related to BCT operationalization. BCTs can be operationalized in various ways; there are no standardized methods. It may be that in the intervention comprising mailouts alone, which did not influence underlying mechanisms, the chosen BCTs were not operationalized in the most appropriate way for targeting the proposed mechanisms. A related but separate possibility is that the differences are related

to differences in dose or intensity of BCT delivery (the amount of the specific active component included in the overall intervention (Hoffmann et al., 2014)). Given that the same BCTs were repeated, the mailouts+calls contained a higher dose (repetition) of the same BCTs as those included in the mailouts only. A third potential explanation relates to mode of delivery: discussions over the phone with another person may have been more powerful than paper format only. Finally, the additional phone calls may have enhanced intervention fidelity (the degree to which an intervention is applied as intended (C. Carroll et al., 2007))by encouraging or reminding participants to read and use the mailouts.

Strengths and limitations

This study demonstrates the value of applying contemporary behaviour change theory to develop and evaluate interventions alongside randomized trials in health care. Validated measures were used to assess theoretical constructs where available. We identified potential mechanisms of effect of one intervention, and proposed multiple possible explanations for the lack of effects of the other intervention. The response rate to the overall process evaluation study was reasonable (74%), and exclusions from analyses were kept to a minimum: only six participants were excluded from all analyses, and the lowest number of participants in an analysis was 548 of a possible 594 (92%).

However, there are some key limitations to note. The behavioural outcome (cardiac rehabilitation completion) was self-reported, which may lead to inaccuracies in reporting or increase the likelihood of socially desirable responding. However, there was not uniform reporting of high adherence as may be expected. In addition, the items we used were validated in a previous study in our province which indicated that self-reported rates of cardiac rehabilitation participation are concordant with program-reported rates (Kayaniyil et al., 2009). Our approach to handling missing data was not based on a precedent in the literature but reflected our aim to use as much of the gathered data as possible in our analyses. The theoretical constructs and outcome were assessed at the same time, which limits the interpretation of causality in the analyses of indirect effects. Given this design, we cannot rule out the

possibility that attending cardiac rehabilitation contributed to the increase in mean scores for constructs seen in the mailouts+calls intervention group. However, while rehabilitation completion rates were similar for both intervention groups, only the mailouts+calls group showed indirect effects via self-efficacy which suggests that this intervention likely had an effect on self-efficacy over-and-above cardiac rehabilitation attendance per se. While the pragmatic nature of this trial precluded this option, future research should aim to decouple and sequence mediator and outcome assessment over time where possible. In addition, the wording of theoretical construct questions varied for participants who had not attended a session of cardiac rehabilitation (focussing on conducting exercise in general as opposed to conducting exercises learned at rehabilitation). We were unable to control for this in our analyses due to questionnaire wording being directly linked to the outcome (cardiac rehabilitation completion). This constitutes a risk of bias in our findings. However, there were no significant differences across groups in the proportion of participants who completed the two different versions of the questionnaire ($X^2(2)=1.570$, $p=.456$). Although this makes it less likely that questionnaire wording would account for the differences in indirect effects observed between the groups, it does not eliminate this risk of bias. Future research should avoid this risk, for example by using wording referring to exercise in general for all participants.

There was an imbalance of sex in our participant group, with most participants being male. However, the majority of individuals diagnosed with MI in the general population are male (Albrektsen et al., 2016; Public Health Agency of Canada, 2018). Trial results demonstrated that intervention effects on cardiac rehabilitation completion did not differ depending on any sociodemographic characteristics, including sex (N. M. Ivers et al., in press). The analyses reported here were not powered to include moderator effects. Effect modification on constructs hypothesised as underlying mechanisms of change, and the impact of tailoring interventions based on sociodemographic characteristics such as sex, could be explored in further research. Although the effect sizes found for the mailouts+calls are small, such

effects were achieved in the context of a pragmatic trial introducing a feasible, minimally-invasive intervention delivered at scale as part of routine care, indicating the potential for scalability and impact at a population level. We found differences in cardiac rehabilitation completion in the sub-set of participants who took part in the process evaluation compared to those in the trial who did not, which may call into question the generalisability of our findings. However, differences were found in both intervention arms as well as the control arm, indicating that some trial participants were less likely to adhere to cardiac rehabilitation whether or not they received one of the interventions. It is likely that this group of participants faced challenges with cardiac rehabilitation completion different to those addressed by the interventions evaluated in this study, and therefore require different types of additional supports.

Suggestions for future development and evaluation of interventions

Our results indicate that those developing interventions to facilitate cardiac rehabilitation completion should consider targeting goal priority, outcome expectancies, self-efficacy, and action planning, while mitigating negative effects on risk perceptions. Since the mailouts+calls improved cardiac rehabilitation completion in the overall trial, the pragmatic nature of the project would suggest that scale and spread of this intervention are key next steps. Our findings indicate that the positive effects of this intervention may be optimized if it is refined beforehand, for example, by re-visiting the content targeting risk perceptions, and reinforcing the content targeting action planning. In addition, future work should evaluate impacts using objective reports of program completion where possible and feasible. Although we proposed several reasons why mailouts only did not influence theoretical constructs, we cannot definitively say why this occurred: future research could explore the effects of different BCT operationalizations, methods of delivery, dose/intensity, and assessments of fidelity.

Conclusions

Our theory-based process evaluation conducted alongside a pragmatic randomised trial indicates that an intervention comprising a series of theory-informed mailouts plus additional telephone support increased the likelihood of completing cardiac rehabilitation (assessed via self-report) by increasing participants' confidence in participating in exercise despite potential barriers (self-efficacy), and by encouraging participants to develop a detailed plan specifying when, where, and how they would participate in exercise (action-planning). An intervention comprising the mailouts alone did not influence hypothesised mechanisms of action. Our findings, coupled with the clear delineation of the specific behaviour change techniques included in the interventions in previous publications, may serve as a roadmap for researchers and practitioners wishing to translate this work into other settings.

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