

BMJ Open Design and rationale of the MyHeartMate study: a randomised controlled trial of a game-based app to promote behaviour change in patients with cardiovascular disease

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ABSTRACT

Introduction Recurrence of cardiac events is common after a first event, leading to hospitalisations and increased health burden. Patients have difficulties achieving the lifestyle changes required for secondary prevention and access to secondary prevention programs is limited. This study aims to evaluate the impact of a game-based mobile app, MyHeartMate, which is designed to motivate engagement in secondary prevention behaviours for cardiovascular risk factors.

Methods and analysis The MyHeartMate study is a randomised controlled trial with 6-month follow-up and blinded assessment of the primary outcome. Participants (n=394) with coronary heart disease will be recruited from hospitals in metropolitan Sydney and randomly allocated to standard care or the MyHeartMate app intervention. The intervention group will receive the app, which uses game techniques to promote engagement and lifestyle behaviour change for secondary prevention. The primary outcome is difference between the groups in physical activity (metabolic equivalent of task minutes/week) at 6 months. Secondary outcomes include change in low-density lipoprotein cholesterol, systolic blood pressure, medication adherence, body mass index, waist circumference, mood and dietary changes at 6 months. Data on app engagement, and patient perspectives of usability and acceptability, will also be analysed.

Ethics and dissemination The study has received ethics approval from Northern Sydney Local Health District Human Research Ethics Committee. The study findings will be disseminated via peer-reviewed publications and presentation at international scientific meetings/conferences.

Trial registration number ACTRN12617000869370; Pre-results.

INTRODUCTION

Globally, coronary heart disease (CHD) is a leading cause of death.¹ Recurrent events are common, leading to hospitalisations and an increased burden on the individual and the

Strengths and limitations of this study

- The study evaluates a novel game-based mobile app strategy of accessing secondary prevention support for reducing cardiovascular disease (CVD) risk factors in patients at high risk of further CVD events.
- A standalone freely available mobile app on iPhone Operating System and Android platforms is being tested on coronary heart disease (CHD) patients.
- This study will be the first to provide rigorous data on effectiveness of a gamification approach through a randomised controlled trial in CHD patients.
- This initial study is being conducted in a single city (Sydney, Australia) and in English, which may limit potential generalisability to other countries and languages. Contamination of the control group is possible as participants may choose to use the app. Blinding of the primary outcome is enabled by automatic upload of activity data; however, other assessments are non-blinded.

health system.² Secondary prevention has a key role in limiting recurrence; however, patients have difficulty achieving the lifestyle changes required, including increasing levels of physical activity, and medication adherence.³ Data from registries indicate that 6 months post myocardial infarction (MI) only 68% of patients are taking all cardioprotective medications prescribed,⁴ and <60% are engaging in sufficient exercise.⁵ When patients do engage in secondary prevention, with the support of effective programmes they can reduce cardiovascular mortality and hospital admission.^{6,7} Despite these benefits, patients often do not participate in these programmes; only one-third of MI patients attend cardiac rehabilitation (CR).⁸ The limited times and location of conventional

CR mean that many patients cannot attend due to travel requirements, conflict with work and carer demands and group-based delivery not being a personal preference.^{6,8} Therefore, new strategies are needed to enable access to secondary prevention support.

Advances in technology, particularly through the growth of smartphone use, provide an opportunity to overcome barriers to secondary prevention access. The adoption of smartphones has been widespread in developed countries, and adoption by seniors shows the fastest increase.⁹ A recent study of 285 cardiac patients reported that 70.9% used mobile phones, and 54.6% were using technology for health purposes.¹⁰ Furthermore, 68% of cardiac patients were interested in receiving CR support via their mobile phone.¹¹ Mobile technology offers immediate access to information, and the potential to personalise secondary prevention support and incentivise behaviour change. In line with the increased availability and affordability of smartphones, there has been huge expansion in availability of mobile health apps.

Mobile apps show promise for improving CHD risk factor and lifestyle behaviours, although the evidence is still accumulating for CHD-specific apps.¹² A recent systematic review identified 10 standalone apps for adults who had evidence supporting their use in CHD.¹³ Benefits were demonstrated for risk factors including blood pressure, body mass index (BMI), cholesterol and exercise capacity, as well as reduction in hospitalisation rates.¹³ The reviewers noted that sustained engagement with the app was crucial for benefits to be achieved, and also reported app features participants preferred. Goal setting, recognition of achievements, challenges, data entry, team-based competition and other game-related design techniques were identified as elements most preferred by app users.

Game-design techniques (gamification) harness innate human desires for competition and social connection and incorporate multiple behaviour change techniques.¹⁴ Game techniques include undertaking challenges/quests that are increasingly difficult, and incorporating rewards and the opportunity for comparison with other players at each level.¹⁵ These game strategies are congruent with social cognitive theory-based techniques for the development of self-efficacy.¹⁶ Game attributes, both alone and in combination, are evident in many well-established health behaviour change interventions, regardless of whether they have that label.^{17,18} Despite identifying 64 health behaviour apps in the Apple and Google Play stores in a comprehensive systematic review, the reviewers concluded that few use game techniques.¹⁸ Standalone game-based mobile apps designed specifically for CHD patients are even rarer.

Game strategies accessed through mobile tablets offer insights. Two games, one for heart failure patients, *Heart Health*,¹⁹ and another for CHD patients and their families, *The Heart Game*, have pilot studies which report high levels of engagement²⁰ and benefits for self-care behaviours. Interest and enjoyment are critical to the feasibility of game-based apps, and 67% of older cardiac patients are

reported to be interested in game-based CR (67%).¹¹ Both studies reported stronger interest in younger patients.^{19,20} To date, there is very limited research testing of game-based apps for CHD patients; therefore, the primary objective of this study is to determine the impact of a game-based app on physical activity. EUROASPIRE IV demonstrated that having little or no physical activity was the most prevalent modifiable risk factor in CHD patients.²¹ Given the well-established dose–response benefits for mortality by increasing the volume and intensity of habitual physical activity in CHD patients a focus on physical activity outcomes is justified.²² The secondary objective is to determine the impact of the app on CHD risk factors, lifestyle-based risk factor behaviours and psychological status. An additional objective is to determine level of engagement, acceptability of the app in practice and identification of game strategies participants find useful.

METHODS AND ANALYSIS

Study design

The *MyHeartMate* study is a parallel group, two-arm, superiority randomised controlled trial with 1:1 allocation ratio and 6-month follow-up. The study will be conducted in three university teaching hospitals in Sydney, Australia serving ethnically, culturally and socio-economically diverse populations. Participants with CHD will be randomly allocated to either the control group for standard care or to the intervention group, who will be provided the *MyHeartMate* app to engage with to receive support for secondary prevention behaviours (figure 1). Outcomes will be assessed using objective measures at 6 months in-person at the hospital site. Recruitment to the study began in December 2017 and will be concluded in December 2019.

Randomisation

Participants will be randomly allocated to either the control group or intervention group (1:1) via a computerised randomisation schedule (www.randomization.com). After enrolment, recruiting research staff will call the study coordinator who will first provide the allocation, and then register the participant. Participants will be asked not to discuss their group allocation or the study app with any other heart patients except with immediate family during the study to avoid contamination. The intervention is self-delivered and the primary outcome data automatically uploaded from the Fitbit tracker to the database. However, staff undertaking all other outcome assessments are not blinded.

Study population

Eligible patients will be those presenting to hospital for management of CHD. Patients will be eligible if they have (1) presented with acute coronary syndrome and/or have documented CHD on angiography (>50% stenosis in at least one epicardial vessel), (2) own a smartphone and

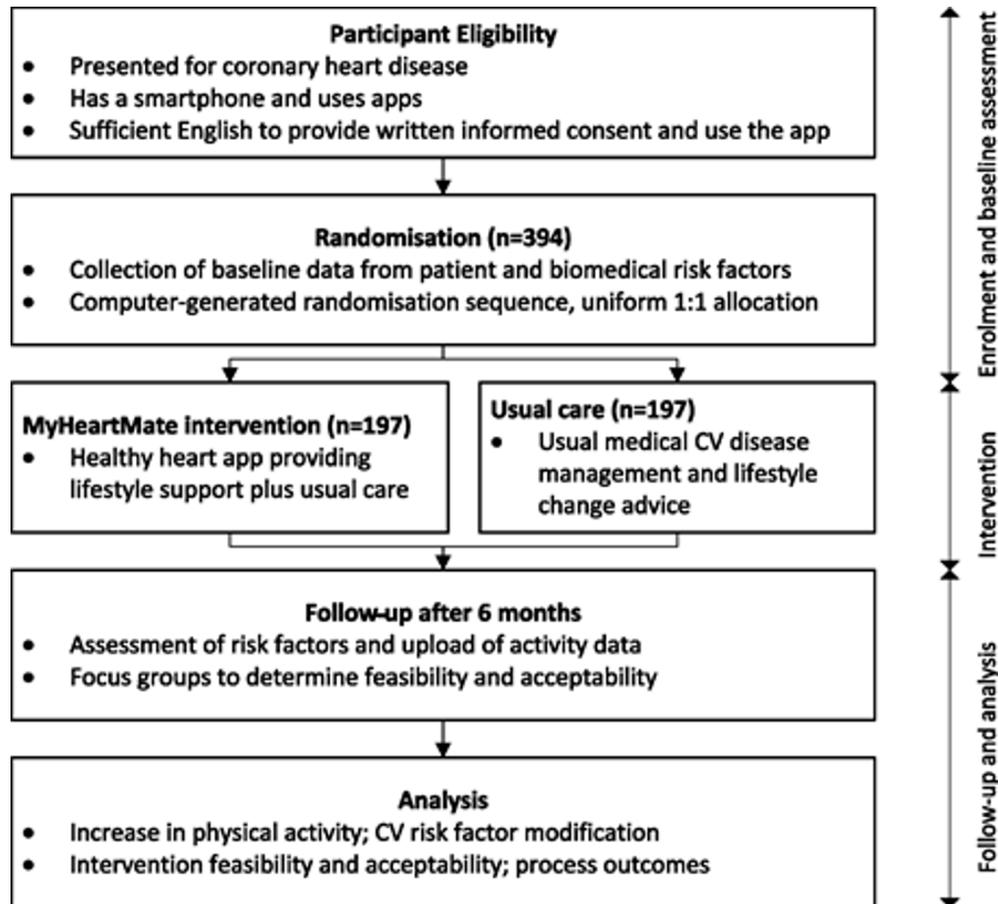


Figure 1 Study design and participant flow through study. CV, cardiovascular.

self-report using apps most days of the week, (3) provide informed consent and (4) have sufficient English proficiency to adequately/successfully interact with the app. Exclusions will apply to candidates who have visual, fine motor or diagnosed neurocognitive disorder which limits engagement with the app. Research staff will approach, screen and recruit patients at each study site. A screening log will be used to identify ineligible patients or those who refuse and include age, gender and reasons for refusal.

Interventions

The control group will receive standard care for CHD, which will include medication prescription and risk factor reduction advice according to their medical provider's determination and the Heart Foundation, *Managing My Heart Health* information booklet. Control group participants are requested to not access the app during the study, but may do so at study end. The *MyHeartMate* group (intervention) will receive standard care, plus access to the *MyHeartMate* app, a brief (5 min) in-person information provision for participants to upload and log in to the app for the first time and location of the freely available brief instructional video on the app goals and optimal use of the app functions. The *MyHeartMate* group will be encouraged to use the app at least twice weekly within the 6-month follow-up, but may choose how they do this, including returning to use the app after a period of not

using it. Multiple methods are used within the app design to promote participant's engagement with the app and with secondary prevention behaviours (online supplementary table 1). The app has a focus on promoting regular physical activity but also encourages participants to take their medications as prescribed and engage with their treating doctors, eat a healthy diet, manage their weight and lipid levels, manage stress and quit smoking if applicable.

All participants will be provided with the research staff contact details and will be contacted once by these staff by phone during the follow-up period to check contact details and book the follow-up appointment. If the *MyHeartMate* backend log indicates that a participant has not engaged with the app in the 2 days following recruitment a single phone call will be made to the participant for troubleshooting. Participants may withdraw at any time by contacting the researchers.

MyHeartMate app intervention development

The *MyHeartMate* smartphone app is designed to engage CHD patients in secondary prevention behaviours identified in national guidelines.²³ The app is built on an award-winning behaviour change platform (*Habitat the Game*) developed by Elevator Entertainment and has been developed through an iterative process involving experts and patients. The central feature is a heart avatar,

which requires the same care as the CHD patient, namely healthy food, exercise, mental health/stress-reduction time and cardiac-relevant medications. Multiple game strategies are incorporated that are known to harness innate goal-driven, competition and playful human motivations to promote engagement in healthy behaviours (online supplementary table 1).¹⁵ Specifically, feedback and monitoring, comparison of behaviour, reward and threat, associations, self-belief and goals and planning are incorporated as classified in Michie *et al* behaviour change taxonomy.¹⁷ Improving participant's self-efficacy for lifestyle change is a key goal so specific techniques derived from social cognitive theory proven to be effective are central and include mastery of graded behaviours such as exercise, understanding responses to behaviours and persuasion.²⁴

The user earns virtual coins to purchase care items for their heart avatar by completing short-term and long-term health-related challenges. These are real-world secondary prevention tasks including healthy eating, physical activity, achieving a healthy weight, activities to reduce blood pressure and control blood cholesterol, medication adherence, quitting smoking (where relevant) and engaging in activities to enhance psychological well-being. A bank of 100 challenges were developed for this purpose based on national guidelines and then reviewed by an expert multidisciplinary panel, which included leading clinicians (cardiologists, nurses, a physiotherapist, dietitians, exercise scientist) as well as academics and researchers. Coins can also be earned by completing real-world missions, health quizzes and playing games, which increase in difficulty as the user progresses. Users can compete with others including their friends via the community leader board. Performance can be assessed by entering and tracking their own health data over time through graphs.

The heart avatar appearance and animation was developed in consultation with a purposive sample of older people who had CHD and aims to personalise the effects of health behaviours undertaken²⁵ (figure 2). The beta version of the app was tested and evaluated by CR participants (n=18) who were requested to interact with the app most days over 2 weeks. Feedback on understanding and usefulness was collected during five focus groups. Changes made based on this feedback included an introduction to the app and game purpose, acknowledging the serious nature of CHD and the serious intent of the game (YouTube video tutorials and a Facebook page). Other changes included brief pop-up instructions for each part of the app when it is first used, weekly push notifications to use the game if not being used for 7 days (ceasing at 21 days), open availability on the app store for family and friends, easier tracking and data entry through syncing with a wearable tracker (FitBit Flex), easy-to-read graphs on their data, easy log-in and forgotten password tab and visual reminder of scrolling.

The app is standalone and completely automated, with the exception of congratulatory emails. These emails are

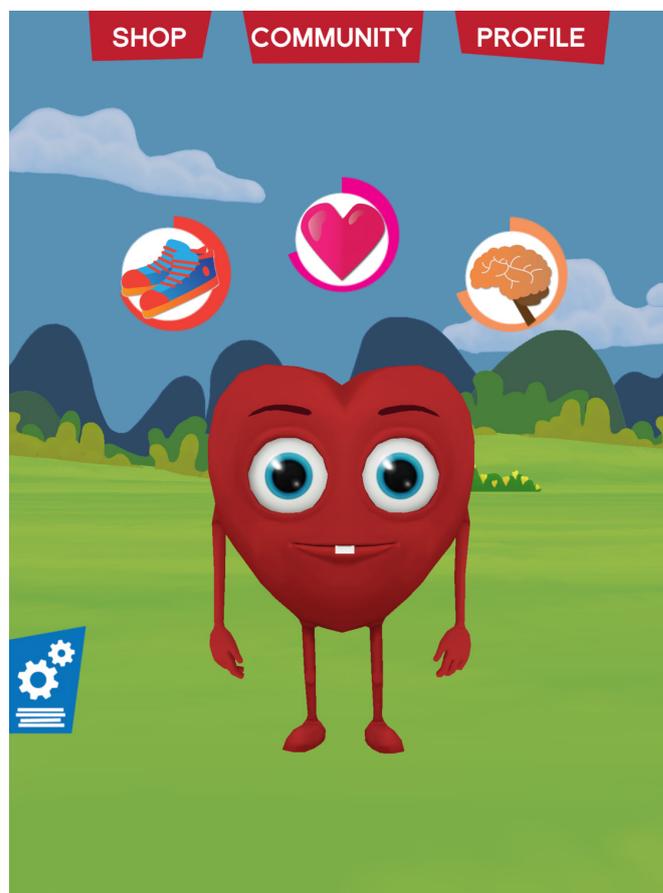


Figure 2 MyHeartMate avatar.

written by research staff using a template when the app automatically generates an email to the staff that a participant has reached a key goal for the first time such as 'My blood pressure is less than 130/90 for the first time', or 'My weight is in the healthy range for the first time'. These are more tangible rewards for using the app, and are expected to result in improved user perception of the app and increased likelihood of continuing to use the app and continuing to record user achievement of real-world missions in the app.

Study outcomes

The primary outcome of the study is improvement (difference between intervention and control groups) in physical activity in terms of metabolic equivalent of task minutes/week (MET-min/week), as measured by the wearable activity tracker FitBit Flex.²⁶ Physical activity has been selected given the strong association with survival in CHD patients.²⁷ Automated upload ensures blinding of assessment. Secondary outcomes include improvement (difference between intervention and control groups) in physical activity components, lipid levels, BMI and waist circumference, blood pressure, dietary intake, psychological state, medication adherence, cardiac events including MI, death or any hospital presentation or admission, participation in CR or other secondary prevention strategies and visits to healthcare providers. Outcomes and measures are provided in detail in online supplementary

table 2.^{28–30} Additional outcomes assessed include engagement with the *MyHeartMate* app. The combined/absolute number of modifiable risk factors above/below target thresholds will be calculated. Participants will be assessed during an in-person interview by research staff at 6 months. Additional data collected will be used to characterise the sample, enable subgroup analyses and insight into app uptake. These data include age, gender, marital status, employment, ethnicity, home language, education level and residential suburb.

Process measures

Level of competence with technology will be assessed at baseline using two questions on confidence,¹⁰ and the e-Health Literacy Scale with eight items.³¹ Engagement with the app will be assessed using the app log file for number and type of challenges and quizzes undertaken, total coins earned and completion of profile data. Communication by staff for the congratulatory emails will be timed and noted in detailed logs. Assessment of contamination to the control group will be undertaken by scanning the user registry log of the app.

MyHeartMate acceptability and feasibility will be assessed through a questionnaire after the 6-month follow-up assessment. Items will include acceptability of the game format, reminders, identification of game aspects participants liked or disliked, their perceptions of the utility of game aspects for their cardiac health, use of tutorial videos and suggestions for improvement.

Potential facilitators and barriers to the effectiveness of the app will be assessed through four focus groups of a subsample of 20–25 participants of intervention group participants. Recruitment will occur on the basis of ensuring diversity in gender, age and geography. Sampling will occur until theoretical saturation (no new themes emerge), which is expected to occur at 20–25 interviews.³² Focus groups will be facilitated by research staff independent of the recruiting and outcomes assessment staff. Focus groups will address individual app use, likes and dislikes, the effectiveness of different game aspects for behaviour change, including monitoring and tracking and participation in the community leaderboard, the appropriateness of the visual elements, the ease and understanding of the app features, language and content, and any discussion or sharing of the app with others. All interviews will be audiorecorded and transcribed, and entered into NVIVO V.7 for analyses. An iterative process of reading, identifying themes and checking will be used for analyses.³²

Patient and public involvement

Cardiac patients' preferences in relation to using mobile apps and activity trackers¹⁰ were assessed and directly informed app development and design. Volunteers (past patients) who support CR in Northern Sydney Local Health District also provided feedback on the app interface and avatar appearance. Patients were not involved in designing the study. Study participants will receive

a summary of the study results by email at the study conclusion.

Statistical considerations

Study data will be analysed using intention-to-treat principles. The primary analysis will use analysis of covariance with baseline values of the study outcome measures used as covariates where appropriate for continuous variables. This method will be used for the primary outcome of MET-min/week and for secondary outcomes of mean daily step count and minutes of moderate-vigorous exercise, lipid levels, BMI, waist, blood pressure, anxiety and depression at 6 months. Categorical variables (smoking, achieving risk factors at guideline level) will be compared using χ^2 tests for categorical variables. Additionally, relative risks, with 95% CIs will be calculated to compare groups using log-binomial regression.

Sample size has been calculated based on detecting a difference of 345 (SD 114) MET-min/week between the control and intervention groups based on the TEXT ME secondary prevention study in a similar population.²⁹ Assuming $r=0.5$ correlation between baseline and final outcome measurement with $\alpha=0.05$ and power $(1-\beta)=0.95$, the required sample size is 164 patients per group, assuming a 1:1 allocation ratio for control and intervention groups. The total sample size, of 328 with an additional allowance of 20% loss to follow-up, is 394 patients.

ETHICS AND DISSEMINATION

The study will be administered by the University of Sydney. A research management committee including experts in large-scale trials, CHD treatment, qualitative analyses and translation into practice, will be overseeing the design and conduct of the research. The study is guided by, and adheres to, the National Health and Medical Research Council of Australia ethical guidelines for human research. All participants will have provided written and informed consent, verified by a witness. No reimbursement is provided to study participants. The study findings will be disseminated via publication of peer-reviewed manuscripts, and presentations at international conferences, as well as through media publications. It is anticipated that the findings will help to inform future developments in the delivery of secondary prevention of CHD.

Strengths and limitations

A strength of the study is that recruitment is from ethnically, culturally and socioeconomically diverse sites; however, external generalisability is limited by the English language requirements and single city context. An additional strength is the use of multiple objectively assessed outcomes, including physical activity; however, several outcomes are self-report, which has inherent risk of bias, for example, from poor recall and social

desirability, and these data are collected by non-blinded staff. Contamination of the control group is possible as participants may choose to use the app.

CONCLUSIONS

This study will evaluate a novel strategy of accessing secondary prevention support for reducing CHD risk factors in patients at high risk of further CHD events. No published study has evaluated a game-based mobile app designed specifically for CHD patients in a randomised controlled trial; therefore, this study will be the first to provide rigorous data on effectiveness of this approach in CHD patients.

Smartphone technology has the potential to address many of the obstacles CHD patients face in accessing secondary prevention programmes. However, strategies are not clearly articulated in study methods or engagement with individual components is poorly quantified. The study will address these deficits and explore relationships between strategies and outcomes. Furthermore, the app may be used in conjunction with evidence-based programmes such as CR to provide additional support for behaviour change and scaled-up for large numbers of CHD patients.

The *MyHeartMate* study will test the efficacy of a game-based smartphone app to improve CHD risk factors and lifestyle behaviours in patients who have CHD. The *MyHeartMate* app provides a potential platform for smartphone apps for secondary prevention in patients with other chronic diseases, and, as an openly available app, the potential for standalone access to large numbers of people affected by CHD and their families.

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Competing interests None declared.

Patient consent for publication Not required.

Ethics approval The study has received Human Research Ethics approval from Northern Sydney Local Health District and governance approval from all recruitment sites.

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