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Very brief intervention for physical activity behaviour change in cardiac rehabilitation: protocol for the 'Measure It!' effectiveness–implementation hybrid trial

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ABSTRACT

Introduction Physical inactivity is a risk factor for repeat cardiac events and all-cause mortality in coronary heart disease (CHD). Cardiac rehabilitation, a secondary prevention programme, aims to increase physical activity levels in this population from a reported low baseline. This trial will investigate the effectiveness and implementation of a very brief physical activity intervention, comparing different frequencies of physical activity measurement by cardiac rehabilitation clinicians. The Measure It! intervention (<5 min) includes a self-report and objective measure of physical activity (steps) plus very brief physical activity advice.

Methods and analysis This type 1 hybrid effectiveness–implementation study will use a two-arm multicentre assessor-blind randomised trial design. Insufficiently active (<150 min of moderate-to-vigorous physical activity per week) cardiac rehabilitation attendees with CHD (18+ years) will be recruited from five phase II cardiac rehabilitation centres (n=190). Patients will be randomised (1:1) to five physical activity measurements or two physical activity measurements in total over 24 weeks. The primary effectiveness outcome is accelerometer daily minutes of moderate-to-vigorous intensity physical activity at 24 weeks. Secondary effectiveness outcomes include body mass index, waist circumference and quality-of-life. An understanding of multilevel contextual factors that influence implementation, and antecedent outcomes to implementation of the intervention (eg, feasibility and acceptability), will be obtained using semistructured interviews and other data sources. Linear mixed-effects models will be used to analyse effectiveness outcomes. Qualitative data will be thematically analysed inductively and deductively using framework analysis, with the framework guided by the Consolidated Framework for Implementation Research and Theoretical Domains Framework.

Ethics and dissemination The study has ethical approval (University of Canberra (ID 11836), Calvary Bruce Public Hospital (ID 14-2022) and the Greater Western Area (ID 2022/ETH01381) Human Research Ethics Committees). Results will be disseminated in multiple formats for consumer, public and clinical audiences.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study will be the first to compare two frequencies of a very brief intervention to increase physical activity levels of cardiac rehabilitation attendees.
⇒ The hybrid effectiveness–implementation design will consider effectiveness and implementation concurrently, which has the potential to fast track implementation of positive findings in clinical practice.
⇒ If findings are positive, there is potential for scale-up at minimal cost as the intervention is simple, requiring minimal training and resources.
⇒ Limitations are the use of multiple assessors to collect outcome measures at each of the cardiac rehabilitation sites and the potential for contamination by inadvertently providing additional physical activity advice between measurements.

Trial registration number ACTRN12622001187730p.

INTRODUCTION

In people with coronary heart disease (CHD), physical inactivity and sedentary behaviour are risk factors for cardiovascular and all-causes of death.[1–6] Active people with CHD have a 50% lower risk of mortality, compared with inactive counterparts.[7] Sufficient physical activity reduces the impact of CHD, slows its progress and improves modifiable risk factors for recurrent cardiovascular disease and other chronic disease.[8–10] Consequently, in secondary prevention programmes such as cardiac rehabilitation, individuals are encouraged to meet the public health physical activity guidelines to improve health outcomes, that is, achieve at least 150 min of moderate-to-vigorous intensity physical activity per week.[11–13] Nevertheless, systematic reviews[14] report that physical activity is low in

cardiac rehabilitation attendees during and after cardiac rehabilitation, with as little as 10 min of moderate-to-vigorous intensity physical activity being completed per day.[15] Additionally, meta-analyses have found no difference in minutes per day spent in moderate-to-vigorous intensity physical activity between exercise-based cardiac rehabilitation and control groups.[14]

Effective, time-efficient, low cost, and easily implementable physical activity interventions are needed in cardiac rehabilitation programmes for people with CHD. A possible solution may be using measurement reactivity and the mere-measurement effect.[16 17] These measurement effects lead to changes in the behaviour under investigation.[16 17] The Theory of Planned Behaviour suggests that an individual's future behaviour can be predicted by intention to perform the behaviour.[18] Intention is conceptualised through an individual's attitude towards the behaviour (ie, favourable or not), their subjective norm (ie, perception of how others view the behaviour) and their perceived control over performing the behaviour.[18] By participating in measurements related to a behaviour, patients can form a belief about that behaviour in terms of personal importance, importance of the behaviour as viewed by others (eg, their health professional) and their ability to perform it, potentially leading to changes in the behaviour (in this case, physical activity). Currently, the precise mechanism of action behind measurement reactivity and the mere-measurement effect remains to be determined, with a range of possible underlying mechanisms including Michie's behaviour change techniques of 'prompts/cues' and 'credible source'.[17 19]

Despite insufficient knowledge regarding the specific mechanism, there is evidence that measurement of physical activity alone can result in improvements in physical activity. Systematic reviews and meta-analyses[20 21] indicate that simply measuring physical activity levels in control groups as part of randomised studies of physical activity interventions, increases physical activity behaviour in up to one-third of studies. This pattern-of-findings indicates that with minimal intervention and resources, physical activity behaviour change may be achievable in a proportion of the population, although people with chronic disease may require additional support.[20] Additionally, more frequent measurement of physical activity (4 measures vs 2) by a health professional over 18 weeks has been found to increase physical activity levels within insufficiently active healthy adults.[22] Therefore, frequent measurement of physical activity embedded within cardiac rehabilitation programmes, with very brief advice by cardiac rehabilitation clinicians (any health professional involved in the delivery of cardiac rehabilitation), may be an intervention that can result in favourable increases in physical activity levels in people with CHD.

Wearable activity trackers and smartphone apps have also been found to increase physical activity in people with CHD and cardiac rehabilitation attendees in systematic reviews and meta-analyses.[23 24] Smartphone usage within cardiac rehabilitation is high, with approximately 70% of patients reporting that they have a smartphone.[25 26] However, alone and without suitable monitoring, wearable activity trackers and smartphone apps are unlikely to result in sustained increased physical activity levels.[26] A study conducted in Singapore with 800 employees found that wearable activity trackers stopped the reduction in physical activity seen in the control group over 12 months; however, at 12 months, only 10% of participants in the intervention groups were still wearing the devices.[27] Therefore, considering the potential impact of measurement of physical activity by health professionals and the effectiveness of wearable activity trackers and smartphone apps for people with CHD our research questions for this trial are:

1. Is very brief measurement of physical activity by cardiac rehabilitation clinicians on five occasions over 24 weeks more effective than two physical activity measurements in improving physical activity levels in insufficiently active adults with CHD?
2. What are the potential factors that can be leveraged to promote the implementation of this intervention, 'Measure It!', in cardiac rehabilitation programmes and the secondary care setting?

METHODS AND ANALYSIS

Study design

This type 1 hybrid effectiveness–implementation study[28] will use a two-arm multicentre assessor-blind randomised trial design (figure 1). Patients will be randomised to five physical activity measurements (intervention group) or two physical activity measurements (control group) in total over 24 weeks. Five phase II (outpatient) cardiac rehabilitation programmes in the Australian Capital Territory (n=2) and New South Wales (n=3) will participate in this study and recruit patients. Recruitment will be staggered over 52 weeks to allow sufficient time to achieve the required sample size based on the recruitment rates of our prior studies.[26] Recruitment for this study commenced in May 2023 and will cease in April 2024. All cardiac rehabilitation programmes involve exercise and education sessions delivered weekly for 1–2 hours over approximately 6 weeks. Cardiac rehabilitation staff will provide their usual programme including an education session on exercise and physical activity, with no additional encouragement for patients to increase physical activity beyond usual care.

Participants

Eligible patients must be ≥18 years old; be enrolled in a hospital-based phase II cardiac rehabilitation programme; have stable CHD and be receiving medical treatment±revascularisation (eg, coronary artery bypass graft surgery and percutaneous coronary intervention), or have had a myocardial infarction. Patients must be insufficiently active (<150 mins of self-reported moderate-to-vigorous physical activity/week) and have a wearable activity tracker, smartphone (step tracker app)

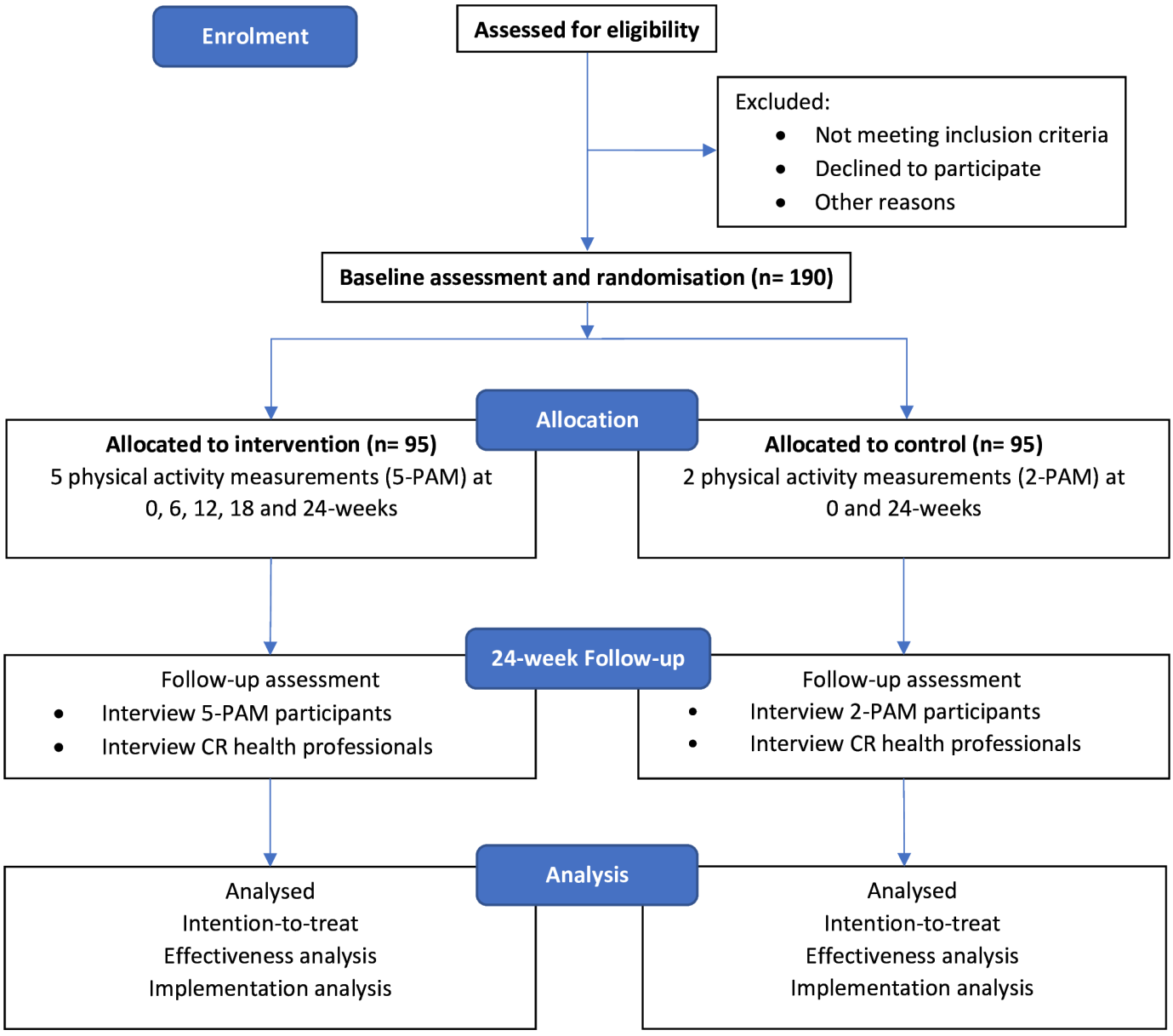

Figure 1 Flow of participants through the Measure It! trial. CR, cardiac rehabilitation; PAM, physical activity measurement.

or computer/tablet. If patients do not have an activity tracker or smartphone but have a computer/tablet, they will be provided with a Fitbit Inspire. All patients must be planning to reside in the area for the next 6 months.

Patients will be excluded if they have a primary diagnosis of atrial fibrillation, spontaneous coronary artery dissection or aortic or mitral valve replacement. Patients must have no serious medical conditions or functional impairments that could limit participation in moderate intensity physical activity. This includes New York Heart Association classes II–IV symptoms of heart failure (or documented signs and symptoms of chronic heart failure with ejection fraction <45%), uncontrolled arrhythmias, severe chronic obstructive pulmonary disease, uncontrolled hypertension or diabetes, symptomatic peripheral artery disease or unstable angina. Patients will be excluded if they are unable to wear an accelerometer due to disability (eg, confined to a wheelchair) or if their smartphone or computer/tablet is not compatible with the Fitbit app, if applicable. Patients must have adequate English language and cognitive skills to participate in the study as interpreters are not available at all sites and the research team are English speaking.

Patients will be given an information sheet by their cardiac rehabilitation clinician with details of the study at their initial cardiac rehabilitation assessment. If patients are interested in participating, the cardiac rehabilitation clinicians will determine if they are eligible and if so, patients must provide written consent to participate in the study (online supplemental file 1). At baseline, patient's sociodemographic information will be collected (eg, education level, relationship and employment status and the presence of any other chronic diseases). Accelerometry-measured moderate-to-vigorous physical

activity, body mass index, waist circumference and quality-of-life (AQoL-6D) will also be collected at baseline.

Randomisation

An investigator in a remote location and not involved in recruitment or assessments will use a computer to generate a random number sequence which is consecutively numbered. After patient baseline measures have been completed, the investigator will be contacted via telephone or email by the assessing cardiac rehabilitation clinician to reveal random allocation to one of two groups (1:1 ratio): five physical activity measurements (5-PAM) or two physical activity measurements (2-PAM) in total over 24 weeks. Randomisation will occur at an individual patient level.

Intervention: Measure It!

Measure It! includes both a self-report and objective measure of physical activity combined with physical activity advice provided by the patient's cardiac rehabilitation clinician. Patients will be asked about their current level of physical activity using the Physical Activity Vital Sign (On average how many days per week do you engage in moderate or greater physical activity?; On average how many minutes per day do you engage in activity at this level?), taking less than 30 s to complete.[29] Patients will also be asked to provide the average number of steps per day they completed in the last week according to their wearable activity tracker or smartphone app. The physical activity guidelines will be very briefly discussed (2 min) at each measurement. An example of the very brief physical activity advice provided is 'moderate intensity physical activity means you should be able to talk in full sentences but not sing', or 'any activity is better than none'. Cardiac rehabilitation clinician's will be free to provide very brief physical activity advice of their choice that is most appropriate for their patient. Patients will be encouraged to safely increase their physical activity levels during the 24 week intervention period aiming to progress towards the public health physical activity guidelines, that is, accumulate 150–300 min of moderate intensity physical activity or 75–150 min of vigorous intensity physical activity or a combination of both each week.[30] The 'Measure It!' intervention is in addition to usual care and will be delivered face-to-face at baseline (2-PAM and 5-PAM), 6 (5-PAM, end-cardiac rehabilitation programme) and 24 weeks (2-PAM and 5-PAM) but may be delivered via telehealth at 12 (5-PAM) and 18 weeks (5-PAM) depending on the site-specific cardiac rehabilitation model. From our pilot study, the total time required for measuring physical activity and provision of brief advice was less than 5 min, classifying this as a very brief intervention.[22 31] To ensure intervention fidelity, participating cardiac rehabilitation clinicians will receive face-to-face or online training and a study manual covering all measurement procedures, risk communication (recommended levels of physical activity to improve health outcomes) and very brief physical activity advice. Training will be provided by the research team in a half-day workshop prior to recruitment, with support provided (in person or online) throughout the study.

Outcome measures

Effectiveness outcomes

The primary effectiveness outcome measure is physical activity measured over 7 days using accelerometry and reported as min/day of moderate-to-vigorous physical activity. The secondary effectiveness outcome measures include body mass index, waist circumference and quality-of-life (AQoL-6D). Physical activity promotion practices from participating cardiac rehabilitation clinicians and costs will also be collected. Outcome measures will be collected at 24 weeks (end-intervention; figure 1). To maintain assessor-blinding, outcome measures will be completed by cardiac rehabilitation clinicians at each site trained in all procedures and not aware of group status.

A triaxial commercial accelerometer (ActiGraph GT3X, Fort Walton Beach, FL) will be used to objectively assess moderate-to-vigorous physical activity. Device-based measurement of physical activity has lower levels of variability for validity and reliability compared with self-report measures.[32] Patients will be asked to wear the accelerometer on their right hip, while awake, for 7-consecutive days at baseline and 24 weeks, returning the accelerometer via mail in the reply-paid package provided. All data will be sampled and downloaded as raw data (30 Hz), converted to 15 s epochs (time interval), and then counts per minute (cpm) using the Actilife software.[33 34] A 'count' is the unit of measure for activity for ActiGraph's activity monitors.[35] Data will be screened, excluding data if: <10 hours per day wear time (non-wear defined as >60 consecutive minutes where there is zero activity, with no allowance of epochs with counts above zero) and less than 4 days of valid data.[33 34 36] The Sasaki vector magnitude three cut-points will be used to determine time spent in moderate-to-vigorous physical activity (≥2690 cpm).[33 34 36 37] To measure sedentary behaviour, the vector magnitude cut-point will be used (<150 cpm), categorising light physical activity as 150–2689 cpm.[33 34 36 38] These cut-points have not been validated in CHD participants, although they have been used in prior research in this population.[33 34 39] Both cut-points have been validated in younger, generally healthy participants[37 38] and currently no cut-points are available for people with CHD. Estimating daily time spent in physical activity and sedentary behaviour will be calculated by dividing the total time spent (minutes) in each threshold by the number of valid days.

Height (m), weight (kg) and body mass index (BMI; kg/m^2) will be recorded using a calibrated set of scales and a stadiometer. Waist circumference will be measured in centimetres using a stretch-resistant tape measure. The waist circumference will be recorded as the midpoint between the lower margin of the lowest palpable rib and the top of the iliac crest.[40]

The Assessment of Quality of Life (AQoL)−6D is a self-administered health-related quality of life questionnaire.

The AQoL-6D was developed in Australia and scored using weights derived from a sample of the Australian population.[41] It has 20 items, takes 2–3 min to complete and has six dimensions—independent living, mental health, coping, relationships, pain, senses and provides an overall multiattribute utility score. The AQoL has evidence to support its reliability and validity in community settings and the multiattribute utility score from the instrument is suitable for use in economic evaluations.[42 43]

Cardiac rehabilitation clinicians will be asked to complete an online survey that includes general descriptive questions (eg, age, gender, years of experience and average number of patients seen per week) preintervention and postintervention. They will also be asked about their physical activity promotion practices, perceived role in physical activity promotion, barriers to promotion, feasibility of different strategies, knowledge of the physical activity guidelines and personal physical activity levels using a validated survey.[44] Additionally, cardiac rehabilitation clinicians will be asked to record patient admission diagnosis and the number of cardiac rehabilitation sessions completed.

Healthcare resource use will also be collected from a healthcare provider perspective throughout the trial. This will include both trial-intervention resource use (eg, cardiac rehabilitation clinician's time) and non-trial intervention healthcare use which may be impacted (eg, hospital visits; Medicare and Pharmaceutical Benefit Scheme items from Services Australia, where patients have consented to access). Healthcare resource use collected during the trial will be used to inform a subsequent economic evaluation.

Implementation outcomes

Contextual factors influencing implementation and antecedent outcomes to implementation of the intervention (eg, feasibility and acceptability) will be evaluated. Semistructured interviews will be conducted with patients and treating cardiac rehabilitation clinicians, purposively sampled[45] to achieve representation of these participants at each cardiac rehabilitation programme site, across the intervention implementation period and across patient ages and clinician levels (eg, managers, nurses and physiotherapists). In studies of this nature, the exact number of participants needed for interviews is not known in advance but becomes known during iterative collection and analysis. It is estimated that 25 interview participants (patients and clinicians) will be required to obtain representation of these characteristics. Sampling participants will continue until the point at which no new concepts or categories are formed and when there is no need for further elaboration of the concepts or categories.[46] Qualitative data collected will also include observations of the cardiac rehabilitation programme context, field notes taken by the research team, and documents referred to in interviews. The Consolidated Framework for Implementation Research (CFIR)[47] and Theoretical Domains Framework (TDF)[48] will be used to understand multilevel contextual factors that influence the extent of implementation success or failure, why the physical activity intervention works or does not work and how the intervention should be optimally implemented. Interviews will be led by an experienced qualitative researcher following implementation of the intervention. Patients and cardiac rehabilitation clinicians will be asked about the acceptability of the intervention and implementation strategies using the Acceptability of Intervention Measure (AIM), a valid and reliable scale,[49] which will be electronically administered following each interview. All interviews will be audio-recorded and professionally transcribed verbatim.

Sample size

The sample size calculation for the two-arm study is based on an effect size of 0.53 found in a cardiac rehabilitation study using a wearable activity tracker to increase moderate-to-vigorous physical activity min/day.[50] This is similar to the effect size of 0.58 found between the higher-measurement-frequency group and the lower-measurement-frequency group reported in our pilot study.[22] With a two-sided significance test at a 5% alpha level and power of 80%, the total sample size required is 114 (57 per arm). Allowing for a 40% drop out rate over the 24 week study period,[26] the final sample size is 190 (95 patients in each arm).

Data analysis

Effectiveness analysis

Data analysis will be conducted by a statistical analyst blinded to group allocation and not directly involved in the study. Analyses will be carried out following the intention-to-treat principle. Linear (for continuous outcome data) and generalised linear (for binary and count outcome data) mixed-effects models will be used for between group comparisons at 24 weeks and interactions analyses adjusting for baseline measures (eg, accelerometry-measured moderate-to-vigorous physical activity) as well as demographic characteristics, such as age, gender, education and employment levels,[51] and other potential clinical covariates, such as cardiac rehabilitation programme site and number of sessions attended and number of comorbidities. All analyses will be conducted using either SPSS, Stata or R statistical packages. Significance level will be set at $p<0.05$.

Implementation analysis

Qualitative data analysis will be conducted inductively using interpretive description to generate themes and subthemes, and deductively using framework analysis[52] to map the data to the CFIR and TDF. Together, the analyses will provide direction for a future implementation trial, should the intervention be successful and demonstrated to be resource efficient. The trustworthiness and rigour of the qualitative analysis will be maintained through member checking of transcripts, reflexive journaling, being led by a researcher experienced in qualitative and implementation science research and triangulation of

the results (mixed-methods) across informants (patients, cardiac rehabilitation clinicians) and data sources (observational, interview and AIM survey data). Interview findings and domains of the CFIR and TDF will be examined to determine whether any contextual factors distinguish between the study conditions ('Measure It!' frequency). The contextual factors consistently relating to the extent of implementation success (or failure) across all cardiac rehabilitation clinicians will be identified.

Data management

Participant paper and electronic files will be maintained in secure storage and on a password-protected computer throughout the project. Data will then be stored at the University of Canberra for a period of at least 15 years after publication after which it will be destroyed according to university protocols. Non-numerical data will be coded as per predefined coding definitions. Data entry screening will be conducted at the time of data entry to ensure no inconsistencies between paper-based and electronic data.

Patient and public involvement

Consumers will be equal partners in all study stages, including as members of the Project Advisory Group. This includes the Australian Cardiovascular Health and Rehabilitation Association (ACRA), the peak body which provides support and advocacy for multidisciplinary health professionals to deliver evidence-based best practice across the continuum of cardiovascular care in Australia, who are a partner in this project. The Project Advisory Group will be established in the first quarter of this project and will include a cardiac rehabilitation clinician from each of the participating sites (n=5), a patient who has completed cardiac rehabilitation, an ACRA representative and the chief investigator.

Consumers have had direct involvement in the project design by providing feedback on our current study using a smartphone app and activity tracker to reduce sedentary behaviour.[53] Cardiac rehabilitation attendees have suggested that an activity tracker is useful to increase physical activity levels but talking to someone about their progress would be valuable, providing some accountability (unpublished). Consumers will play an important role in identifying what is needed to encourage cardiac rehabilitation attendees to move more and for cardiac rehabilitation clinicians to implement 'Measure It!' into routine practice.

Trial management

The Research Team will regularly discuss, monitor and manage any actual, potential and emerging risks such as low recruitment rates, drop-outs, intervention fidelity, safety, data management and ethical issues, then calculate risk using a risk stratification tool developed by the research team prior to commencement of the trial. This oversight will occur informally via phone or online (email and teleconference), or formally in monthly research team meetings, and will involve site visits to participating cardiac rehabilitation programmes.

Project Advisory Group meetings will be held biannually. The function of the advisory group is to offer opportunities for interactive processes between researchers, clinicians and community members. The advisory group will provide guidance and practical input on how the study can be conducted and how results can be disseminated, discussing actual, potential and emerging risks such as low recruitment rates, drop-outs, intervention fidelity, safety, data management and ethical issues.

If an adverse event occurs while a patient is taking part in the study, they will be managed immediately in line with university and hospital policies and procedures. If there is an adverse event that is related to the intervention, the chief investigator will be made aware of group allocation and will discuss continuation of the patient's involvement with the research team. Any adverse events will be reported to the ethics committee and advisory group. A database of adverse events will be kept and reported accordingly.

The ethics applications allow for different recruitment, intervention and outcome measure scenarios depending on the COVID-19 public health, hospital and University recommendations at the time of recruitment and measurement, completing a University COVID-19 Project Risk Assessment and Mitigation Plan (RAMP). The RAMP includes risk stratification (low, medium or high risk for COVID-19 transmission) and has been approved by the University as well as the Human Research Ethics Committees. If a patient, cardiac rehabilitation clinician or research assistant tests positive to COVID-19, all people in contact with that person will be advised and act according to public health, hospital and University recommendations at the time.

Any changes to the protocol will be discussed with the research and clinical teams, and the Project Advisory Group and reported to the Human Research Ethics Committees, funder and trial participants. The final trial data set will be accessed by the research team. Data will be available on request from the corresponding author on completion of this trial.

Impact

Large-scale problems require scalable solutions. 'Measure It!' is a simple and innovative approach to physical activity promotion within cardiac rehabilitation geared to prevent and manage further heart disease by promoting healthy behaviours. Taking advantage of possible measurement reactivity and the common use of wearables and apps in cardiac rehabilitation, this novel intervention will allow routine promotion of physical activity. This is a new approach to solving the problem of lack of time, which is the number one barrier to physical activity promotion within clinical consultations as reported by health professionals.[54 55] Cardiac rehabilitation clinicians have many opportunities to promote physical activity, with one-third of people with heart disease referred to cardiac

rehabilitation programmes in Australia.[56] Yet, physical activity levels are low in this population. Establishing whether higher frequency 'Measure It!' provides a time, resource efficient and effective approach to targeting people with heart disease who attend cardiac rehabilitation will help advance this field. These findings have real-world potential to drive changes in current health delivery practice by directly informing cardiac rehabilitation and secondary prevention services, in turn leading to improved health for a large number of people with CHD.

ETHICS AND DISSEMINATION

Ethics approval has been received from the University of Canberra (ID 11836), Calvary Bruce Public Hospital (ID 14–2022) and the Greater Western Area (ID 2022/ETH01381) Human Research Ethics Committees.

This trial will develop robust, scalable and context-specific implementation strategies for 'Measure It!' that can be tested in future to promote physical activity behaviour change and move towards sustainable implementation if the effectiveness of the intervention is supported. Results will be published in peer-reviewed journals, presented at conferences, shared on social media and our partners will promote the new evidence and consensus recommendations and clinical guidelines (where appropriate) through their networks and digital platforms to consumers and clinicians, as well as to State and Federal governments. Results will inform the development of policy and evidence-based programmes within cardiac rehabilitation. Practice guidelines will be produced for ACRA, and these will be presented to cardiac rehabilitation clinicians in-person and via webinars, allowing for direct translation into practice.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting or dissemination plans of this research. Refer to the Methods section for further details.

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