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BMJ Open Comparison of telehealth and supervised phase III cardiac rehabilitation in regional Australia: protocol for a non-inferiority trial

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ABSTRACT

Introduction Exercise-based cardiac rehabilitation programmes (ExCRP) promote recovery and secondary prevention for individuals with cardiovascular disease (CVD). Despite this, enrolment and adherence to ExCRP in rural locations is low. Telehealth programmes provide a convenient, home-based intervention, but concerns remain about compliance to exercise prescription. This paper presents the rationale and protocol design to determine if telehealth delivered ExCRP is not inferior to supervised ExCRP for improving cardiovascular function and exercise fidelity.

Method and analysis A non-inferiority, parallel (1:1), single-blinded randomised clinical trial will be conducted. Fifty patients with CVD will be recruited from a rural phase II ExCRP. Participants will be randomly assigned to telehealth or supervised ExCRP and prescribed three weekly exercise sessions for 6 weeks. Exercise sessions will include a 10 min warm up, up to 30 min of continuous aerobic exercise at a workload equivalent to the ventilatory anaerobic threshold and a 10 min cool down. The primary outcome will be change in cardiorespiratory fitness as measured by cardiopulmonary exercise test. Secondary outcome measures will include change in blood lipid profile, heart rate variability, pulse wave velocity, actigraphy measured sleep quality and training fidelity. Non-inferiority will be confirmed if intention-to-treat and per-protocol analyses conclude the same outcome following independent samples t-test with $p < 0.025$.

Ethics and dissemination Research ethics committees at La Trobe University, St John of God Health Care and Bendigo Health approved the study protocol and informed consent. Findings will be published in peer-reviewed journals and disseminated among stakeholders.

Trial registration number ACTRN12622000872730p; pre-results.

INTRODUCTION

Cardiovascular disease (CVD) remains the leading cause of death and disability worldwide with an increase in prevalence expected due to an ageing and insufficiently active population.^{1–3} Improved treatment and management of acute cardiovascular events have increased survival rates with the residual

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This non-inferiority clinical trial is low cost and scalable, ensuring external validity to address poor participant access in exercise-based cardiac rehabilitation programmes in regional areas.
- ⇒ The specific exercise prescription and provision of easily accessible training logs with objectively measured exercise intensity facilitates accurate calculation of training fidelity and dose-response adaptations to exercise interventions.
- ⇒ Randomisation with concealed allocation, analysis of primary outcomes conducted by blinded assessors and protocol registration will minimise potential bias.
- ⇒ A limitation will be participants and clinical staff administering the treatment will be aware of group allocation.

population at risk of subsequent complications and increased total morbidity.^{4–6} Consequently, effective secondary prevention and post-event care are imperative to support disease management and reduce total health burden.⁷

Exercise-based cardiac rehabilitation programmes (ExCRP) are multiphase secondary prevention strategies incorporating education and behavioural change interventions to improve future health outcomes for people with CVD.^{8–9} Transitioning from in hospital to community-based programmes, ExCRP facilitates several physiological adaptations including increased mitochondrial biogenesis, cardiac remodelling, reversal of metabolic decoupling, reduced sympathetic tone and augmented cholesterol and triglyceride profiles.^{8–10} These adaptations translate to significant improvements in autonomic modulation, endothelial function, lipoprotein profile, glucose metabolism, cardiorespiratory fitness and an overall reduction in future health risks among patients with

coronary artery disease.^{8 10} Outpatient ExCRP (phase II) is sufficient to elicit improvements in the aforementioned measures of cardiac function,¹¹ however, long-term exercise participation is necessary for disease management.¹²

Community-based ExCRP (phase III) promotes exercise participation with reduced levels of supervision to support long-term physical activity and associated health benefits.^{13 14} However, enrolment in phase III ExCRP and subsequent participation rates are often less than prescribed^{15–18} with a lack of perceived benefit, low levels of motivation^{19–21} and poor access in regional areas identified as primary barriers.^{22 23} Telehealth programmes that use home-based training with online support have been hypothesised to improve exercise participation.^{24 25} Despite additional cost in the provision of exercise sensors and access to web-based applications, telehealth has comparable or decreased individual and societal health-related expenditure.²⁶ Demonstrated accessibility and cost-effectiveness, without elevating adverse events despite less supervision,^{24 27} telehealth programmes were extensively adopted during the COVID-19 pandemic.²⁸ However, the perceived improvements in programme accessibility associated with telehealth programmes are commonly measured by sessional attendance.²⁵ An approach that fails to quantify participants' compliance with the training intensity and duration.^{29 30} Given the specific association of exercise dose (frequency, intensity and type of exercise) with physiological adaptation, valid measures of exercise compliance are essential when evaluating the efficacy of ExCRP. By failing to consider all elements of exercise prescription (compliance and adherence) the fidelity of ExCRP has not been systematically demonstrated. Therefore, further work is needed to consider exercise fidelity when comparing cardiovascular adaptation including cardiorespiratory fitness, lipid profile, autonomic modulation and arterial compliance to supervised ExCRP.

Aim

The primary aim of this non-inferiority trial is to determine if telehealth delivered ExCRP is non-inferior to supervised ExCRP to elicit changes in peak oxygen consumption ($\text{VO}_{2\text{peak}}$ (primary outcome)) with additional comparisons conducted for lipid profile, autonomic modulation, arterial compliance and quality of life. The secondary aim is to compare the fidelity of prescribed exercise in each intervention.

Hypotheses

The primary hypothesis is that telehealth delivered ExCRP is not inferior to supervised delivered ExCRP for inducing improvements in cardiorespiratory fitness as assessed by $\text{VO}_{2\text{peak}}$. Comparisons for improvements in lipid profile, autonomic modulation, arterial compliance and quality of life will also demonstrate non-inferiority of telehealth ExCRP. A second hypothesis is that objectively monitored telehealth delivered ExCRP will result

in comparable exercise prescription fidelity to supervised delivered ExCRP.

METHODS

Study design

Telehealth delivery is unlikely to elicit substantially greater improvements in cardiovascular function when compared with the established effect of supervised ExCRP. Therefore, a 6-week, two-arm parallel, randomised non-inferiority trial with blinding of the outcome assessor and data analyst will be conducted. Standardised assessment of primary and secondary outcomes will be conducted at baseline prior to randomisation and after completion of the exercise intervention. Mean and SD of testing follow-up time will be reported in the final report. An overview of the study design is provided in figure 1 (Consolidated Standards of Reporting Trials diagram).

The trial has been prospectively registered with the Australian New Zealand Clinical Trial Registry with approval provided by the relevant institutional Human Research Ethics Committees. This protocol has been guided by The Standard Protocol Items: Recommendations for Interventional Trials reporting checklist (online supplemental file A).³¹

Participant eligibility and recruitment

We will recruit 50 participants, aged 18 years or older with a recent diagnosis of CVD following completion of an outpatient (phase II) comprehensive cardiac rehabilitation programme.

Participants will be excluded if they have any condition for which exercise or exercise testing is contraindicated or have musculoskeletal or neurological conditions that prevent them from completing the exercise testing. Those diagnosed with CVD risk factors in the absence of CVD, congenital heart disease, diagnosis of heart failure (defined as previously documented left ventricular ejection fraction $\leq 45\%$), hypertrophic cardiomyopathy, or have received a heart transplant will be excluded. In addition, participants will be excluded if they do not have access to a phone for telehealth delivery or have limitations in English language production or comprehension skills that precluded them from understanding the consent form.

To facilitate participants from a wide range of socioeconomic background, recruitment will be conducted from two publicly funded and private hospitals in regional Victoria, Australia. Both hospitals service regional and rural communities and offer phase II comprehensive cardiac rehabilitation programmes.

The local cardiac rehabilitation coordinators will provide all eligible attendees with recruitment flyers on entering and exiting the programme beginning on 22 August 2022. Attendees will be encouraged to contact the research team via email, phone call or by completing a Research Electronic Data Capture (REDCap) survey, a web-based application developed to capture data

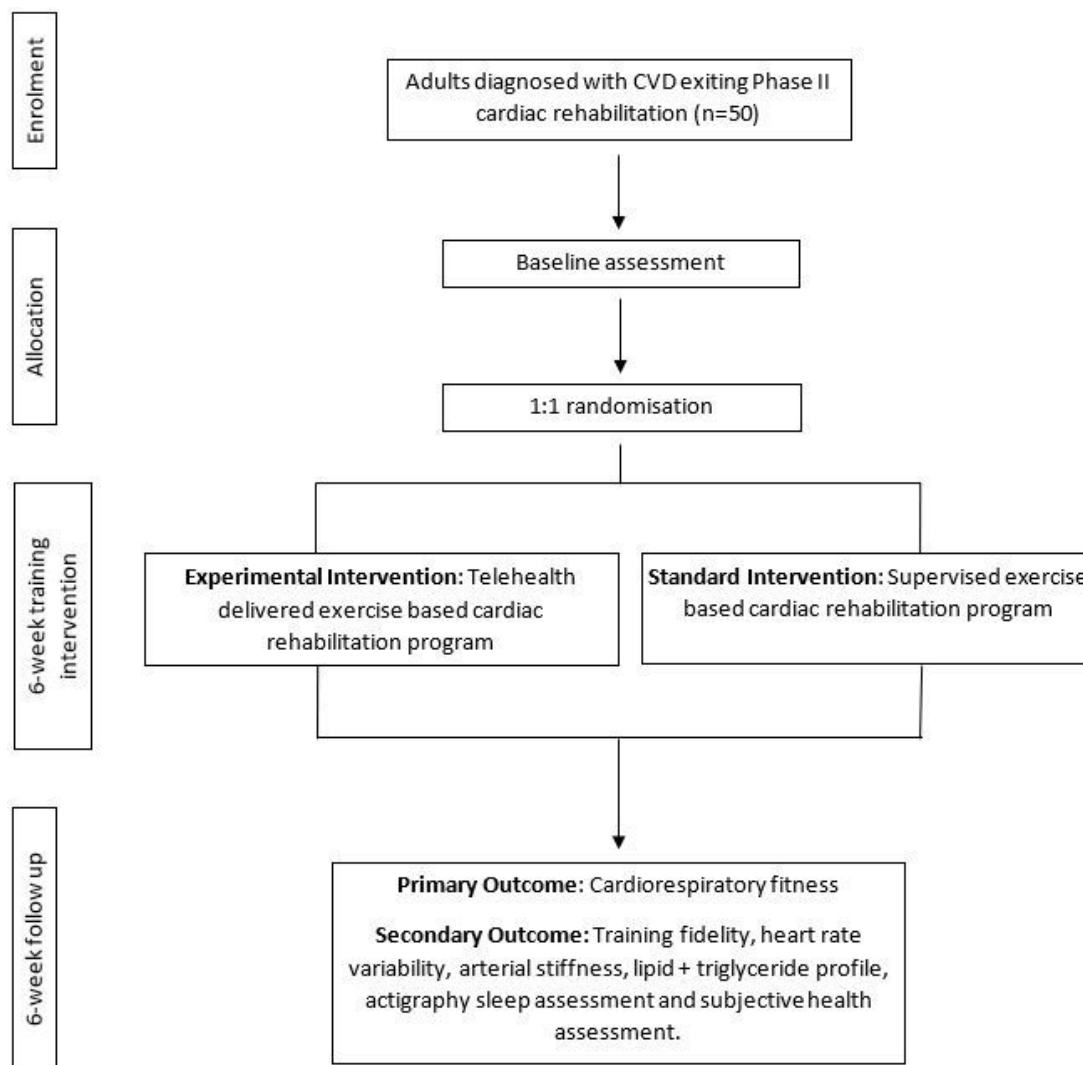


Figure 1 The CONSORT (Consolidated Standards of Reporting Trials) flowchart. CVD, cardiovascular disease.

for clinical research (Vanderbilt University, Nashville, Tennessee, USA). Following initial screening, eligible individuals will be provided with a participant information statement (online supplemental file B) and written informed consent will be sought before data collection.

Randomisation and blinding

After baseline assessment, participants will be randomly allocated to either the telehealth delivered or supervised delivered ExCRP group, using permuted block (blocks of 8), by a computer programme (www.randomizer.org). To prevent selection bias, the allocation sequence will be generated by an independent member of the research team (MK) and concealed from the investigator enrolling and assessing participants, in sequentially numbered, opaque, sealed envelopes. Assessments will be collected by researcher's blind to group allocation (LCH and JH). Researchers blinded to group allocation will analyse the data. It is not possible to blind participants or therapists to group allocation.

Intervention description

Exercise intervention

Participants will be prescribed three exercise training sessions per week for 6 weeks. Training will be individually prescribed at a workload equivalent to the ventilatory anaerobic threshold (VAT) identified during baseline cardiopulmonary exercise testing (CPET).³² Specifically, the heart rate (HR) and workload in watts (W) at the time point where VAT is identified will be used in exercise prescription. Training sessions will consist of three phases:

Warm up

In accordance with general exercise guidelines and frameworks for cardiac rehabilitation, participants will complete a dynamic warm up to progressively increase HR.^{33–35} The warm up will be a duration of 10 min consisting of light callisthenics (marching on the spot, body weight squats and lunges) and aerobic activity (stationary cycling or walking at 80% VAT).

Aerobic training

Participants will be prescribed continuous aerobic exercise at individual VAT. The absolute mechanical workload corresponding with VAT during the exercise test will be the initial starting intensity of exercise and guided by HR measured and Rating of Perceived Exertion (RPE; 6–20 scale) reported at the same workload. If aerobic exercise is completed using an exercise mode other than cycling, the intended exercise intensity will be converted to relative energy expenditure in metabolic equivalents (METs) using metabolic equations and an equivalent mechanical workload will be calculated for the preferred exercise modality using the relevant metabolic equations.³⁶ Exercise will initially be prescribed for up to 30 min per session with exercise terminated if participants' HR exceeds 15 beats above the prescribed rate (corresponding to that at VAT) or an RPE greater than two points above the rating corresponding to VAT. If average sessional HR is 10 beats less than HR observed at VAT during CPET despite achieving the prescribed exercise workload, workload will be increased by 10% for the same exercise duration. If sessional RPE is two points or more less than RPE corresponding to that at VAT in three consecutive sessions despite achieving the recommended workload, total duration will be extended by 5 min. If both occur during the same session, intensity will be increased by 10% and RPE reassessed before a change in duration.

Cool down

Given the recent diagnosis of a cardiac event and likelihood of deconditioned state, an extended cool down is recommended.³⁷ Participants will complete 5 min of light aerobic activity (<80% VAT) and 5 min stretching of major muscles to complete each session.

Supervised delivered ExCRP

The supervised delivered ExCRP will be conducted on-site at the university and serve as the standard intervention. Participants will complete the continuous aerobic exercise on a stationary cycle ergometer (mode used during CPET) or treadmill with workload converted to an equivalent treadmill speed and grade.³⁶ A training schedule will be provided and supervised by an accredited/registered exercise or healthcare professional with participants offered the opportunity to nominate preferred training times. Participants will exercise at the same time as other individuals completing the trial with a maximum participant to supervisor ratio for the group of 8:1. Intensity of the training sessions will be monitored and recorded in 5 min intervals using an HR monitor (Polar Electro Oy, Kempele, Finland) and RPE to measure compliance to the prescribed workload. During one session per week a member of the research team who has been trained in the delivery of integrated motivational interviewing and cognitive behavioural therapy (MI-CBT) techniques will employ open-ended questions, affirmations, reflections and summaries to encourage motivation and self-efficacy to be physically active and achieve the recommended

exercise dose during the intervention.³⁸ Examples of the MI-CBT approach include discussing the participants goals and expectations from the exercise intervention, past experiences with physical activity programmes, how to identify potential barriers to long-term physical activity and strategies to overcome the identified barriers.

Telehealth delivered ExCRP

Participants randomly allocated to the telehealth delivered ExCRP will attend on-site training for the first three sessions (week 1) before continuing the exercise programme away from the university (weeks 2–6) and serve as the experimental intervention. Participants will choose their preferred mode of aerobic exercise (walking, jogging or cycling) based on exercise preference and access to equipment. To ensure standardised exercise intensity between intervention arms, participants will be provided with a target HR as well as the exercise intensity that correlates to the workload at individual VAT. Each participant will be provided with a Polar Unite fitness watch (Polar Electro Oy, Kempele, Finland) to objectively measure HR response. Participants will be required to log their training data and sessional RPE online using the Polar Flow software (Polar Electro Oy, Kempele, Finland) secured by login and password, allowing the research team to monitor adherence and training intensity weekly. Finally, participants will be required to attend a weekly audio or audio-visual meeting to discuss training adherence and compliance. MI-CBT will be incorporated into the weekly audio/audio-visual meeting for participants in the telehealth delivered ExCRP with a trained member of the research team implementing the same MI-CBT strategies as the supervised group.

Outcome measures and data collection

Outcome measures will be collected by experienced members of the research team with familiarity of all testing measures. Participants will be asked not to discuss any aspect of the intervention with the assessor to protect assessor blinding.

Cardiovascular fitness

The primary outcome of interest is training induced changes in VO_{2peak} . A symptom-limited CPET, widely considered the gold standard for assessing cardiopulmonary capacity and risk stratification among ExCRP participants,³⁹ will be conducted at the baseline and follow-up assessments.

Participants will complete the CPET on a cycle ergometer (Excalibur Sport; Lode B.V. Groningen, Netherlands) using a ramp protocol. The test will consist of stationary cycling at a cadence of 60–70 revolutions per minute, with starting resistance of 10–30 W, increasing by 10–15 W per minute depending on current activity levels until symptom-limited or volitional exhaustion is reached. HR (Polar Electro Oy, Kempele, Finland) and RPE will be monitored throughout the test and peak values will be recorded at cessation of the test. Oxygen

consumption will be measured by indirect calorimetry (TrueOne 2400; ParvoMedics Sandy, Utah, USA). $\dot{V}O_{2peak}$ will be determined as the highest period of oxygen consumption achieved by each participant averaged over 30 s, with post analysis conducted to assess maximum HR, RPE response and VAT via the ventilatory equivalents and V-slope method.³²

Cardiovascular function and sleep quality

Central arterial pressure waveform and pulse wave velocity will be determined using pulse wave analysis as a non-invasive assessment of arterial stiffness.⁴⁰ Participants will arrive in a fasted state and rest supine for 5 min before analysis is carried out using applanation tonometry according to the manufacturer's instructions (SphygmoCor XCEL PWA & PWV; AtCor Medical Holdings, Australia). Heart rate variability (HRV) will be used to assess autonomic function with abnormal HRV, including hyperactive sympathetic influence, an independent risk factor for cardiovascular mortality.⁴¹ Holter monitoring will be conducted continuously for 24 hours using a 5-lead Holter (ARmedilog; Schiller, Switzerland). Beat-to-beat interval data will be exported and analysed for HRV and arrhythmia assessment post-intervention. Finally, participants will be required to wear a wrist-mounted sleep watch (ActiGraph GTX3; ActiGraph, Florida, USA) on the non-dominant wrist and complete a sleep diary for 7 days. Previous research has established a link between poor sleep quality (duration and continuity) with increased risk of developing adverse cardiac conditions including ischaemic heart disease.⁴² Actigraphy provides a validated and non-invasive assessment of sleep quality without the necessity of specialised equipment and expertise required for polysomnography.⁴³

Blood analyses

A venous blood sample will be collected following an overnight fast and analysed for serum triglycerides (mmol/mol), total cholesterol (mmol/mol), high-density lipoprotein cholesterol (mmol/mol), glycated haemoglobin (mmol/mol) and low-density lipoprotein cholesterol (mmol/mol) calculated using the Friedewald equation.⁴⁴ Blood samples will be drawn from an antecubital vein using a 19-gauge needle into two EDTA containing tubes and two serum-separator tubes (SST). One SST and EDTA tube will be transported as a whole blood sample to a commercial laboratory for immediate analysis, while one SST and EDTA will be centrifuged, and serum/plasma will be aliquoted into cryotube and stored at -80°C to enable future analysis.

Training fidelity

To facilitate a direct comparison between delivery modes, the fidelity of telehealth and supervised ExCRP will be assessed. Fidelity will be assessed via the product of exercise compliance, defined by the percentage of exercise performed at the prescribed intensity for the prescribed duration, and training adherence, defined by

the percentage of weekly sessions of exercise attended by each participant. Polar Flow will be used to monitor individual sessions for telehealth delivered ExCRP, with Polar HR monitors used for supervised delivered ExCRP.

Subjective health assessment

During the baseline assessment process and at follow-up, participants will be required to complete a general health and information questionnaire developed by the research team to collect demographic information, current diagnosis, medication and Likert scale ratings and opinions on their rehabilitation experience during and following completion of the phase II cardiac rehabilitation programme and a global rating of change in health during this time. Additional standardised questionnaires will be completed including the Medical Outcomes Study 36-item Short Form (MOS SF-36), The International Physical Activity Questionnaire (IPAQ), the Duke Activity Status Index (DASI) and 21-item Depression Anxiety Stress Scale (DASS). All questionnaires will be completed prior to exercise testing online via REDCap or where necessary using a hard copy paper version.

The MOS SF-36 provides an estimate of eight domains of health-related quality of life including physical functioning, role-physical, role-emotional, bodily pain, general health, vitality and social functioning, used to monitor changes in generic functional health and well-being.⁴⁵ The IPAQ will be used to assess the average amount of physical activity completed by the participants in the previous week.⁴⁶ The DASI will be used to assess daily activities such as personal care, ambulation, household tasks and recreation activities to assess functionality and independence.⁴⁷ Finally, the DASS questionnaire will be used to assess participants' self-reported measures of depression, anxiety and stress.⁴⁸

Adverse events

To determine the safety of the intervention all exercise-related adverse events will be documented. Serious adverse events will be defined as death, cardiac arrest and syncope, with minor adverse events including musculoskeletal injuries, angina and palpitations. The supervised group will be monitored in all sessions, while the telehealth group will be instructed to immediately inform the research coordinator of any adverse events, with progress reviews conducted during the weekly telehealth call. An independent health professional will be responsible for reviewing any adverse events with recruitment ceasing if multiple serious adverse events are attributable to the study.

Management and monitoring

Study data will be collected in a combination of hard copy (data collection sheets and questionnaires) and electronic data, captured via Polar Flow and REDCap which is hosted by the primary research institution. Hard copy information will be transferred to an electronic format and stored using a unique participant number assigned

by the research team. The primary investigator (BC) will oversee all general processes for the study including securing and managing ethical and regulatory approvals, document and questionnaire preparation, auditing measurement standardisation and data entry procedures, while recruitment will occur at the hospitals that deliver phase II cardiac rehabilitation by a local coordinator. The primary investigator, with documented training in Good Clinical Practice will monitor the conduct of the trial, verifying the protection of the rights and well-being of participants, ensure obtained data is accurate, complete and checked against source documents, and that the study is being conducted consistently with the approved protocol in accordance with the Good Clinical Practice guidelines and ethical requirements. This will be completed through annual reports submitted to the approving Human Research Ethics Committees, with any alterations or amendments communicated to all parties.

Patient and public involvement

The research project was developed to assess the effectiveness of current ExCRP in regional areas with outcomes used to inform future practices. To achieve this members of the in-hospital ExCRP team were engaged during the study design phase to ensure protocols are reflective of current clinical requirements. Additionally, members of the community were involved in the respective institutional ethics committees that assessed the study design. Patients were not provided an opportunity to assess study conduct or burden but are provided individual results via post project feedback sheets.

Sample size calculation

If there is truly no difference between the standard and experimental interventions, then 20 participants are required in each arm (40 participants in total) to be 80% sure that the lower limit of a one-sided 97.5% CI (or equivalently a 95% two-sided CI) will be above the non-inferiority limit of $-3.5 \text{ mL} \times \text{kg}^{-1} \times \text{min}^{-1}$.⁴⁹ One MET ($3.5 \text{ mL} \times \text{kg}^{-1} \times \text{min}^{-1}$) was considered the minimum clinical difference (non-inferiority limit) due to its association with reduced cardiovascular mortality.^{50 51} An SD of the primary outcome measure (oxygen uptake) in a regional cardiac rehabilitation population of $3.9 \text{ mL} \times \text{kg}^{-1} \times \text{min}^{-1}$ was used from preliminary data collected by our research group. To allow for up to 20% participant dropout rate, similar to that reported by Price *et al*,⁵² the initial target is to recruit 50 participants.

Statistical analysis

Statistical analyses will be performed using SPSS software (V.26.0 SPSS, Chicago, Illinois, USA). Baseline characteristics will be summarised using descriptive statistics, with data reported as mean $\pm$ SD or mean and 95% CIs. Non-inferiority will be confirmed if intention-to-treat (ITT) and per-protocol analyses conclude the same outcome.^{53 54} To allow ITT, missing data will be filled by bringing the last known data forward.⁵⁵ Per-protocol

analysis will include only those participants who complete at least 80% of training sessions (80% adherence). If non-inferiority is confirmed, then superiority will be evaluated by considering if the lower bound of the 95% CI for the mean difference in changes between telehealth delivered ExCRP and supervised delivered ExCRP at the conclusion of the intervention is above zero. The comparison between intervention groups in terms of change from pre-intervention to post-intervention will be assessed using independent sample Student's t-tests. Analysis of covariance regression model will be used to evaluate the treatment effect on the primary outcome between the two-treatment groups, adjusting for baseline measure and age.

DISCUSSION

This non-inferiority trial is designed to determine if telehealth ExCRP is not less effective than supervised ExCRP in eliciting changes in $\text{VO}_{2\text{peak}}$ (primary outcome) and other key markers of cardiovascular health among patients with CVD. Telehealth interventions present an opportunity to overcome pre-existing barriers to exercise adherence by increasing accessibility to ExCRP. However, a robust evidence base is needed for telehealth interventions to be adopted in-to ExCRP practice. A non-inferiority trial design enables researchers to develop this evidence base.

Telehealth interventions are usually completed at-home which raises unique concerns regarding compliance to appropriate exercise intensity and overall dose.⁵⁶ The proposed telehealth intervention is designed to support adherence and compliance through addressing previously identified barriers to exercise participation among patients during ExCRP. The anticipated lack of perceived benefit and motivation to maintain post-event exercise,^{19 20} which has potential to negatively impact training fidelity through reduced exercise compliance, is primarily addressed in these interventions through the provision of integrated MI-CBT support. MI-CBT techniques facilitate motivation and self-efficacy among participants, translating to increased amounts of physical activity.³⁸ To further enhance training fidelity by supporting training compliance, participants will be provided with real-time objective feedback on exercise intensity (HR monitor), while the online training log allows the research group to monitor and quantify duration, frequency and intensity of exercise. Therefore, a telehealth delivered ExCRP programme providing MI-CBT supported home-based individualised exercise training has potential to have similar fidelity as supervised delivered ExCRP while addressing the well-documented lack of access to phase III ExCRP that exists in regional areas.

ETHICS, DISSEMINATION AND IMPACT

The study protocol and the informed consent form were approved by the Human Research Ethics Committees

at La Trobe University, St John of God Health Care and Bendigo Health. In the design of this proposal, the fulfilment of ethical principles has been considered: the value of the research question, methodological rigour, that investigators are scientifically qualified and the protocol has been independently evaluated. The results will be reported in accordance with the Consolidated Standards of Reporting Trials,⁵⁷ with the intention of publishing in a peer-reviewed journal in a punctual and accurate way. Research findings and corresponding ExCRP service implications will additionally be disseminated among stakeholders. De-identified data will be published on the sponsoring institutions open access repository (OP[A]L). We anticipate that if the telehealth delivered ExCRP is demonstrated, a feasible model of ExCRP will be established, increasing participant access, saving resources and improving cardiovascular health outcomes with the potential of influencing clinical practice guidelines.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

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