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Research

# Home-based telerehabilitation is not inferior to a centre-based program in patients with chronic heart failure: a randomised trial

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#### KEY WORDS

Cardiac failure Exercise Telemedicine Telerehabilitation Physical therapy

### ABSTRACT

Question: Is a 12-week, home-based telerehabilitation program conducted in small groups non-inferior to a traditional centre-based program in terms of the change in 6-minute walk distance? Is the telerehabilitation program also non-inferior to a centre-based program in terms of functional capacity, muscle strength, quality of life, urinary incontinence, patient satisfaction, attendance rates, and adverse events? Design: Randomised, parallel, non-inferiority trial with concealed allocation, intention-to-treat analysis and assessor blinding. Participants: Patients with stable chronic heart failure (including heart failure with reduced or preserved ejection fraction) were recruited from two tertiary hospitals in Brisbane, Australia. Intervention: The experimental group received a 12-week, real-time exercise and education intervention delivered into the participant's home twice weekly, using online videoconferencing software. The control group received a traditional hospital outpatient-based program of the same duration and frequency. Both groups received similar exercise prescription. Outcome measures: Participants were assessed by independent assessors at baseline (Week 0), at the end of the intervention (Week 12) and at follow-up (Week 24). The primary outcome was a between-group comparison of the change in 6-minute walk distance, with a non-inferiority margin of 28 m. Secondary outcomes included other functional measures, quality of life, patient satisfaction, program attendance rates and adverse events. Results: In 53 participants (mean age 67 years, 75% males), there were no significant betweengroup differences on 6-minute walk distance gains, with a mean difference of 15 m (95% CI -28 to 59) at Week 12. The confidence intervals were within the predetermined non-inferiority range. The secondary outcomes indicated that the experimental intervention was at least as effective as traditional rehabilitation. Significantly higher attendance rates were observed in the telerehabilitation group. Conclusion: Telerehabilitation was not inferior to a hospital outpatient-based rehabilitation program in patients with chronic heart failure. Telerehabilitation appears to be an appropriate alternative because it promotes greater attendance at the rehabilitation sessions. Trial registration: ACTRN12613000390785. [Hwang R, Bruning J, Morris NR, Mandrusiak A, Russell T (2017) Home-based telerehabilitation is not inferior to a centre-based program in patients with chronic heart failure: a randomised trial. Journal of Physiotherapy XX: XX-XX]

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### Introduction

Exercise-based rehabilitation has emerged as a safe and effective intervention for patients with chronic heart failure and is now recommended as standard practice.<sup>1,2</sup> Specifically, exercise-based rehabilitation increases physical function, improves quality of life, and lowers hospital admission rates.<sup>3</sup> Despite this, participation in rehabilitation remains low.<sup>4</sup> Reported barriers to participation include transport difficulties, financial cost, embarrassment about participation, and program availability.<sup>4,5</sup> Telerehabilitation may be an alternative approach that could alleviate some of these barriers.

Telerehabilitation is the delivery of rehabilitation services at a distance via telecommunication technologies, such as telephone,

internet and videoconference.<sup>6</sup> This delivery model has been successfully trialled in patients with various cardiopulmonary diseases.<sup>6–9</sup> In a pilot study of home-based rehabilitation delivered via a tablet computer, all participants with chronic obstructive pulmonary disease (COPD) remained actively participating in the program after 1 year, and (although statistically non-significant) COPD-related hospital costs were reduced by an average of 27%.<sup>7</sup> In people with chronic heart failure, a home-based telerehabilitation program was delivered individually three times per week for 8 weeks, using mobile phones for voice communication and electrocardiogram transmission.<sup>8</sup> This program produced equivalent increases in peak oxygen consumption and quality of life as a centre-based program of the same duration and frequency.<sup>8</sup> Home-based telerehabilitation could also have similar benefits in

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other outcomes (such as functional exercise capacity and balance) for patients with chronic heart failure.

International experience shows that rehabilitation programs for people with heart failure can be delivered using various models, including centre-based, home-based or a hybrid of these approaches. For example, home-based and centre-based cardiac rehabilitation programs have been shown to be equally effective in improving health-related quality of life and reducing mortality rates in patients with heart disease.<sup>9</sup> A flexible or remote model has also been proposed to improve attendance.<sup>4</sup> However, the feasibility of a group-based, video-linked telerehabilitation program delivered into the home has not yet been investigated in patients with chronic heart failure.

The aim of the present study was to determine the efficacy and safety of a short-term, real-time, group-based heart failure rehabilitation program delivered into each participant's home via an online telerehabilitation system.

Therefore, the research questions for this randomised trial were:

- 1. Is a 12-week, home-based telerehabilitation program conducted in small groups non-inferior to a traditional centre-based program in terms of the change in 6-minute walk distance?
- 2. Is the telerehabilitation program also non-inferior to a centrebased program in terms of functional capacity, muscle strength, quality of life, urinary incontinence, patient satisfaction, attendance rates, and adverse events?

### Method

### Design

A two-group, parallel, non-inferiority trial with blinded outcome assessors was undertaken. Participants were randomised to either: an experimental group, who were provided with a 12week home-based telerehabilitation program delivered twiceweekly; or a control group, who were provided with a traditional centre-based program of the same duration and frequency. Consenting participants were allocated 1:1 using a non-blocked random allocation sequence. Allocation was concealed through the use of opaque, sealed and numbered envelopes, and administered by an experienced, independent researcher at a central location. While the treating healthcare professionals could not be blinded to group allocation, participants were asked not to disclose their group allocation to the blinded assessors. All assessments were undertaken at the hospitals using a standardised protocol at baseline (Week 0), immediately after completion of the rehabilitation program (Week 12) and at follow-up 12 weeks later (Week 24). The assessors were 19 hospital physiotherapists with an average of 9 years of work experience in physiotherapy.

### Participants, therapists and centres

Patients were recruited from cardiology and general medical wards of two tertiary hospitals in Brisbane, Australia, between July 2013 and February 2016. The patients who were recruited had a recent hospital admission for heart failure and were referred to heart failure services. Patients were eligible if they: had a diagnosis of chronic heart failure confirmed by an echocardiogram (heart failure with reduced or preserved ejection fraction), presented with clinical heart failure symptoms, and were aged over 18 years. Patients were excluded if they: did not meet safety screening criteria as outlined by the Australian exercise guidelines for patients with chronic heart failure,<sup>1</sup> such as symptomatic severe aortic stenosis and significant ischaemia at low exercise intensity; lived in an institution such as a nursing home; lived more than an hour driving distance from the treating hospital; or had no support

person at home, which was important for those recruited to the home-based telerehabilitation program for safety reasons. Healthcare professionals at each site were in prescribing exercise for patients with chronic heart failure.

### Intervention

The control group received a centre-based rehabilitation program based on current recommended guidelines encompassing education, aerobic and strength training exercise.<sup>1</sup> This traditional heart failure rehabilitation program was led by physiotherapists over a 12-week period; it consisted of 60 minutes of exercise per session, two sessions per week, at the treating hospital. Each session consisted of a 10-minute warm-up, 40-minutes of aerobic and strength exercises, and a 10-minute cool-down. Exercise intensity commenced at 9 (very light) and gradually progressed towards 13 (somewhat hard) on the rate of perceived exertion scale.<sup>10</sup> Exercise prescription was tailored to the participant's goal and the treating physiotherapist continuously reviewed it to ensure appropriate progression. The control group attended education sessions at the hospital on the same day as the exercise sessions. These sessions were delivered by a multidisciplinary team including the nurse, dietitian, physiotherapist, occupational therapist, social worker and pharmacist. The topics that were covered included self-management, nutritional counselling, physical activity counselling, psychological interventions, medications and risk factor management, where appropriate. Participants were provided with additional home exercises to be undertaken three times per week, at a similar intensity as prescribed for the supervised exercise sessions.

The telerehabilitation program was delivered via a synchronous videoconferencing platform<sup>a</sup> across the internet to groups of up to four participants within the home. Two-way audiovisual communication enabled interaction of all parties, and the physiotherapist guided participants through an exercise program similar to the control group. This approach enabled the physiotherapist to watch participants performing the exercises and provide real-time feedback and modification, as required, as well as facilitating peer support from other participants. A groupbased program was selected because many people undertaking cardiac rehabilitation value the guidance from healthcare professionals and enjoy the group interaction and social support.<sup>4</sup> Participants were provided with additional home exercises similar to the control group. Educational topics were delivered as electronic slide presentations with embedded audio files,<sup>b</sup> which were recorded from the education sessions delivered for a centre-based program. Participants were encouraged to watch the designated presentation individually or with their support person, in their own time in preparation for subsequent online group discussions. A 15-minute interaction period was held at the start of each telerehabilitation session to facilitate these discussions. A range of resources were accessed through the videoconferencing platform to facilitate these discussions, such as screen and document sharing, collaborative drawing and chat functions.

Telerehabilitation equipment was loaned to participants, as required, including a laptop computer,<sup>c</sup> a mobile broadband device<sup>d</sup> connected to 3G wireless broadband internet,<sup>e</sup> an automatic sphygmomanometer,<sup>f</sup> a finger pulse oximeter,<sup>g</sup> free weights and resistance bands. Participants received an equipment familiarisation session either in-person at the hospital or during a home visit, which covered operating the laptop, accessing the online videoconferencing software<sup>a</sup> and using the monitoring equipment. An equipment manual with written and pictorial instructions was also supplied. Telephone contact details to access technical support were included in the event that participants needed additional assistance or encountered technical difficulties. Participants were guided to self-monitor and verbally report their blood pressure, heart rate and oxygen saturation levels at the start of each rehabilitation session. Other measurements such as

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