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The effect of a supervised exercise training programme on sleep quality in recently discharged heart failure patients

Jessica M Suna[1,2], Alison Mudge [1,4], Ian Stewart [2], Louise Marquart [3], Peter O'Rourke [3], Adam Scott[1,2]

1 Internal Medicine and Aged Care, Royal Brisbane and Women's Hospital, Australia

2 School of Exercise and Nutrition, Queensland University of Technology, Australia

3 Queensland Institute of Medical Research, Australia

4 School of Medicine, University of Queensland, Australia

Corresponding author (all stages):

Jessica M Suna, Internal Medicine and Aged Care, Royal Brisbane and Women's Hospital, Herston QLD 4029 Australia.

Email: Jessica_Suna@health.qld.gov.au

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Abstract

Background: Sleep disturbances, including insomnia and sleep disordered breathing, are a common complaint in people with heart failure and impair well-being. Exercise training (ET) improves quality of life in stable heart failure patients. ET also improves sleep quality in healthy older patients, but there are no previous intervention studies in heart failure patients.

Aim: This aim of this study was to examine the impact of ET on sleep quality in patients recently discharged from hospital with heart failure.

Methods: Sub-study of a multisite randomised controlled trial. Participants with a heart failure hospitalisation were randomised within 6 weeks of discharge to a 12 week disease management programme including exercise advice (n=52) or to the same programme with twice weekly structured exercise training (n=54). ET consisted of two one hour supervised aerobic and resistance training sessions, prescribed and advanced by an exercise specialist. The primary outcome was change in Pittsburgh Sleep Quality Index (PSQI) between randomisation and week 12.

Results: At randomisation, 45% of participants reported poor sleep (PSQI ≥ 5). PSQI global score improved significantly more in the ET group than the control group (-1.5 ± 3.7 vs. 0.4 ± 3.8, p=0.03). Improved sleep quality correlated with improved exercise capacity and reduced depressive symptoms, but not with changes in body mass index or resting heart rate.

Conclusion: 12 weeks of twice weekly supervised ET improved sleep quality in patients recently discharged from hospital with heart failure.

Keywords

Exercise, heart failure, physical activity, sleep.

Introduction

Poor sleep is a common complaint in heart failure (HF) patients. More than half of HF patients report difficulties initiating or maintaining sleep (1-3) and sleep-disordered breathing has been demonstrated in 40-75% (2-4). Insomnia is associated with impairments in daytime function, mood and quality of life (1-3, 5), and sleep-disordered breathing has been associated with poorer function and a worse prognosis (3, 6).

Exercise training has been shown to improve sleep quality in healthy older adults with sleep disturbances (7) and may reduce obstructive sleep apnoea (8). Potential mechanisms for the effect of exercise training on sleep quality include improved mood, sympathetic modulation, modified cytokine release and increased energy expenditure, which may result in weight reduction and ameliorate sleep apnoea (9). While several small studies have suggested that exercise training may improve total sleep time (10), sleep efficiency (11) and sleep-disordered breathing in HF patients (11-13), there has been little attention to the patient experience of sleep in this patient group (14).

The primary objective of this study is to examine the effect of a supervised, hospital-based exercise training programme on self-reported sleep quality in heart failure patients. Secondary objectives are to explore the association of sleep quality changes with changes in depressive symptoms, exercise capacity, resting heart rate and body weight as potential mediators of improved sleep quality.

Methods

This is a sub-study of the EJECTION-HF randomised controlled trial, which has been described in detail previously (15). Study recruitment for this sub-study was carried out between June 2009 and August 2011. Participants were identified within three hospital heart failure services in Queensland, Australia through active screening of Emergency Department, medical and cardiology ward admission lists and attendance at team meetings, as well as by physician and ward nursing referral. Potential participants were identified by specialist heart failure exercise staff at each site and referred to the research team for screening and consent within 6 weeks of hospital discharge. Participants were required to be admitted to hospital with symptomatic HF as a dominant clinical diagnosis and be able to regularly attend a 12 week disease management program and follow-up appointments. Exclusion criteria included terminal diagnosis; serious cognitive impairment precluding consent or adequate participation in the intervention; other serious physical impairment which would prevent program attendance and participation; implantable cardiac defibrillator (ICD) insertion within 4 weeks of programme commencement; cardiac resynchronisation therapy (CRT) within 6 months of programme commencement; awaiting cardiovascular procedure (revascularisation or surgery); completed a full 12 week regime of formal exercise rehabilitation in the past 12 month period; or not meeting safety criteria (refractory chest pain, uncontrolled cardiac arrhythmias, high-degree atrioventricular block, pacemakers which do not permit adequate heart rate response to exercise, uncorrected primary valvular disease, isolated pulmonary hypertension, poorly controlled symptomatic postural hypotension or obstructive cardiomyopathy) (16). The investigation conforms to the principles outlined in the Declaration of Helsinki and was approved by Human Research Ethics committees of all participating sites. Written informed consent was obtained from all participants.

Baseline assessment included collection of descriptive demographic data, medical history and medications from the medical record and baseline measurement of outcome variables (see below). Following this assessment, participants were randomly assigned either to a 12 week disease management programme (DMP) of education and self-management support including standard exercise advice (control), or to the same DMP with the addition of a structured exercise training programme designed and supervised by a physiotherapist and/or clinical exercise physiologist (intervention). Randomised allocation was performed by the study statistician in blocks of 10 stratified across hospital sites using computer-generated random number lists, and provided to the study coordinator in consecutive sealed envelopes. The coordinator was not involved in screening or clinical assessments, which were performed by a research assistant who remained blinded to group allocation.

Participants randomised to the control arm received a comprehensive DMP from the multidisciplinary heart failure service including (1) education on the physiology, medications and management of HF; (2) education on the role of exercise in HF and provision of a home-based graduated exercise programme; (3) written materials to support education; (4) telephone, clinic and/or in-home follow-up to monitor symptoms and response to therapy; (5) medication titration (if appropriate) according to protocols and in consultation with physician; and (6) a patient diary for recording weight, medications and symptoms. Education was provided both one-to-one and in weekly one-hour group sessions for 12 weeks.

Those randomised to the intervention arm received the same DMP as the control group with the addition of twice-weekly hospital based supervised group exercise classes of approximately 1 hour duration for 12 weeks. Classes were based on current evidence-based recommendations

for HF and consisted of a 10 minute warm-up followed by 20-30 minutes of aerobic exercise and 20-30 minutes of concentric and eccentric resistance exercise, balance and stretching. Exercises were tailored to the participant's capabilities. At the completion of these exercises there was a 10 minute cool down period. Exercise prescription followed the FITT guidelines for best practice prescription and progression according to ACSM guidelines (16).

Aerobic exercise intensity was measured using the modified 20-point Borg rating of perceived exertion (RPE) scale (17). Participants were instructed to exercise within a RPE range between 9-13, where 9 was considered fairly light and 13 was considered somewhat hard. Initial workloads for the resistance exercises were determined by the prescribing exercise specialist. When an individual was able to achieve 3 sets of 10 repetitions with an RPE of 9-13, intensity was progressed. The minimum work to rest ratio was 1:2.

Participants in both study groups were provided with education and written support for a home exercise programme in accordance with National Heart Foundation (NHF) guidelines (18). The home programme was prescribed at week one, and was reviewed weekly for the duration of the study. The home programme included aerobic and resistance exercises using minimal equipment. An exercise goal of a minimum of four sessions per week of 30 minutes duration was encouraged. The home program is described in detail in Supplementary Material 1.

Outcome measures

Outcome and explanatory variables were measured at baseline (randomisation) and week 12. Sleep quality was measured using the Pittsburgh Sleep Quality Index (PSQI) (19). This self-rated index takes five to ten minutes to complete and assesses sleep quality during the previous

month. The survey assesses seven components of sleep quality including subjective sleep quality (1 item), sleep latency (2 items), sleep duration (1 item), habitual sleep efficiency (3 items), sleep disturbances (9 items), use of sleeping medication (1 item) and daytime dysfunction (2 items). Each component score is weighted equally on a 0-3 scale. The seven component scores are summed to give a global PSQI score. The global PSQI score has a range of 0-21 with higher scores indicating worse sleep quality (20). Scores of 5 or greater indicate poor sleep, and previous studies suggest a minimal clinically important difference of 3 points (19, 21).

Depressive symptoms were measured using the Geriatric Depression Scale (GDS) (22). This validated 15-item questionnaire was specifically developed for use in an unwell, elderly populations due to its simple yes/no format. Exercise capacity was measured using the 6 minute walk test (6MWT) on a 25 metre walking track (23). This sub-maximal exercise test measures the distance an individual is able to walk at a comfortable pace in 6 minutes and has been used extensively in HF patients to examine functional capacity because of its simplicity, safety and low-cost. Body weight (kg) and height (metres) were assessed using standard procedures at each visit to obtain BMI (kg/m^2). Resting heart rate was measured by the research assistant using standard procedures at each visit. Exercise specialists at each of the participating institutions recorded participation in exercise classes across the 3 month period.

Statistical analysis

Primary analyses were conducted on an intention-to-treat basis. Differences in patient characteristics between study groups were compared using chi squared tests for categorical variables and one way analysis of variance (ANOVA) for continuous variables.

The primary outcome variable of change in global sleep quality from baseline to week 12 was compared between groups using one way analysis of variance, which was also used to examine differences for each of the subscales. To enhance clinical meaning, changes was also categorised into improved, unchanged or worse sleep at 12 weeks compared to baseline, based on the proposed minimal clinically important difference of 3 points, and differences between groups compared using chi squared testing.

Univariate analysis using general linear models were used to assess the relationship between sleep quality and potential mediating factors (change in depression, exercise capacity, body mass index and resting heart rate). Based on the results of univariate analysis, significant variables were used as adjusting covariates in analysis of covariance (ANCOVA) to assess whether the intervention was an independent modifier of sleep quality after adjusting for a single covariate.

Analyses were completed using SPSS, with an alpha level of less than 0.05 considered to indicate statistical significance. Sample size was determined using estimates of effect sizes from previous studies (24, 25). In order to demonstrate a mean difference on 3 points on the PSQI, with baseline scores between 9.0 and 6.0 (alpha 0.05), it was estimated that a sample size of 28 patients in each group would provide 80% power. Assuming a 20% drop out rate by 12 weeks, this would require enrolment of 34 patients per group.

Results

During the study period, 973 patients admitted to participating institutions with a heart failure related admission that had been referred to the heart failure service were screened for study inclusion (Figure 1). Seventy-four percent of these were not recruited because eligibility criteria were not met (n=712). Of these patients, 334 (47%) were unable to attend, 169 (24%) were unsafe to exercise, 103 (14%) had a serious physical impairment, 36(5%) a serious cognitive impairment, 28 (4%) were greater than 6 weeks from hospital admission, 22 (3%) had a life expectancy of less than 6 months, 20 (3%) were awaiting cardiovascular surgery or procedure. Ten patients were not able to participate for other reasons such as history of non-compliance, completed exercise program within past 12 month period, discharged to non-participating HF service. In order to determine potential participants' eligibility in the study the research assistant collaborated with treating heart failure clinicians. Where the patient had a history of non-compliance with heart failure treatment or recommendations and where the treating team did not believe they would comply with or attend an exercise program they were not approached for participation in the study (n=3).

A further 139 eligible patients chose not to participate. Six patients did not complete a baseline PSQI and were therefore not included in the study. One hundred and six individuals (11 %) were randomised: 54 to intervention and 52 to control. No participants officially withdrew from the study during the intervention period. Twenty-six participants (10 intervention, 16 control) were lost to follow-up. Four participants (4%) died (1 myocardial infarction, 3 arrhythmia), 1 (1%) was unable to attend due to illness, 2 (2%) returned to work and 19 (18%) did not attend due to time commitments or inconvenience. .There were no significant differences in the characteristics of patients who completed the study and those that were lost to follow-up. The median attendance at scheduled exercise classes was 16 sessions over 12 weeks (IQR 10-21).

A summary of randomisation, patient flow and retention through the course of the trial is shown in Figure 1. No exercise related adverse events were experienced by any participants during the study.

Baseline characteristics of patients in each of the study groups are shown in Table 1. Most participants were male and Caucasian with NYHA class 2 symptoms. A quarter (25%) had preserved left ventricular function (EF ≥45%). Groups were similar except for slightly lower use of key evidence –based medications in the intervention group. Almost 40% of participants had depressive symptoms, and the majority (80%) were overweight or obese (BMI ≥25).

Using a PSQI cut-off of ≥5, 45% of participants reported poor sleep quality at baseline. Poor sleep was more likely in females (71% of females reported poor sleep versus 40% of males, p=0.005), and those with severe (class IV) heart failure symptoms (92% class IV patients vs. 40% class I-III, p=0.001). Participants with poor baseline sleep quality also reported significantly worse depression scores (mean (SD) GDS good sleepers 3.6 (3.1) vs. 6.1 (3.9) poor sleepers, p<0.001).

Participants allocated to intervention had a significantly greater improvement in global sleep quality and in the component scores for sleep quality and sleep disturbance (Table 2). The greater improvement in the sleep disturbance component was driven largely by reduced difficulty breathing at night. The mean difference between groups was smaller than the minimal clinically significant difference (3 points). However, analysis by category showed that participants in the intervention group were significantly more likely to have a clinically

meaningful improvement of 3 or more points, and less likely to have a meaningful deterioration, than the control group (p=0.016) (Figure 2).

Improvements in global sleep quality between baseline and week 12 correlated with improvements in geriatric depression score (p<0.001) and exercise performance (p=0.04), but not changes in BMI (p=0.55) or resting heart rate (p=0.99) (Figure 3). The intervention was associated with a statistically significant (p=0.016) mean improvement of 2 points on the global PSQI score, after adjustment for improvements in depression and exercise performance (Table 3).

Discussion

In this randomised controlled trial, almost one half of participants reported poor sleep, similar to previous studies in heart failure patients (1, 3, 5). Those with poorer sleep were more likely to be female, with more advanced heart failure and more depressive symptoms. These characteristics have been shown to predict poorer exercise tolerance (26) and lower participation in exercise rehabilitation in HF patients (27).

Structured exercise training improved global sleep quality in this trial. Improvements in self-reported global sleep quality with exercise training have been demonstrated in previous controlled intervention studies of middle-aged and older adults with sleep disturbances (7). No previous controlled intervention study in heart failure patients has assessed sleep quality. A small trial of an outdoor walking programme found improvements in total sleep time measured by actigraphy and improved quality of life, although the increased light exposure with outdoor exercise is a potential confounder (10). Several studies have documented improvements in

obstructive and/or central sleep apnoea with aerobic or mixed aerobic/resistance training, independent of changes in body mass index (11-13), which may explain the reductions seen in sleep disturbance sub-scores in our study. These studies have also demonstrated improvements in heart failure biomarkers and muscle sympathetic nerve activity in the exercise groups. An uncontrolled cohort study of intensive supervised exercise training in patients with cardiac disease (including coronary disease and acute heart failure) reported improvements in PSQI global scores as well as depressive symptoms, exercise capacity and BMI (14).

We recognise a number of limitations in this study. Firstly, the study only enrolled recently hospitalised heart failure patients, who may report a higher rate of sleep disturbance, and generalisablity may be limited by the relatively low consent rates which are common in complex intervention studies in older ill populations. However, rates of poor sleep are similar to those reported in previous cohort studies in heart failure (1, 3, 5) and our sample included women, elderly patients and those with preserved systolic function who are often excluded from research studies, providing a reasonably representative patient sample. Secondly, fewer patients in the control arm completed follow-up, partly due to higher observed mortality. This would be expected to result in sicker patients in the intervention follow-up group, which would reduce the magnitude of any measured benefits. Thirdly, the benefits of exercise in heart failure are well accepted and so it was not ethical to prevent the control group from exercising. Almost three quarters of participants self-reported meeting physical activity guidelines at three month follow-up, and this contamination effect combined with incomplete adherence in the exercise training group would also tend to reduce the observed difference between groups. Fourthly, the intervention group received twice weekly contact with programme staff (compared to once weekly for the control group), and this increased social contact may have had a confounding

effect on outcomes including depression and sleep. It may also have resulted in changes in medication use, although the high rates of evidence-based heart failure prescribing in both groups at baseline make it unlikely that this would be a major source of bias. Finally, the self-report instrument used may be subject to bias and outcome expectancy in an intervention where participants could not be blinded. The study would be strengthened by concurrent objective measures of sleep and the functional outcomes of poor sleep such as daytime sleepiness and fatigue. Objective measurement of sleep and wake cycles through actigraphy presents a cheap, unobtrusive way to measure sleep in the home setting.

Despite these weaknesses, this study demonstrates the potential of exercise training to produce meaningful improvement in poor sleep, which is an important and common adverse symptom in heart failure patients. This information may motivate heart failure patients with poor sleep to participate in exercise rehabilitation, and encourage greater referral to established exercise rehabilitation programmes by health professionals for this vulnerable patient group. Larger, well designed trials to assess objective and subjective measures of sleep disturbance and its consequences will help to clarify the emerging role of exercise training as an important non-pharmacological therapy for heart failure.

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Conflict of interest

None declared.

Research ethics

Written consent was obtained from local ethics committees including the Royal Brisbane and Women's Hospital Human Research Ethics Committee (2008/001), The Prince Charles Hospital Human Research Ethics Committee (EC2722) and Metro South Health Service District Human Research Ethics Committee (2009/100)

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