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Results of the Sedentary Intervention Trial in Cardiac Rehabilitation (SIT-CR Study): A pilot randomized controlled trial☆,☆☆

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ABSTRACT

Background: Sedentary time (ST) is negatively associated with cardiometabolic health and fitness. Traditional cardiac rehabilitation (CR) programming may not significantly reduce ST. The objectives of the study were to assess the feasibility and practicality of activPAL devices for measuring ST in CR, and whether prompting cues to interrupt sedentary behaviour can decrease ST and improve clinical outcomes.
Methods: An 8-week, two-arm pilot randomized controlled trial allocated coronary artery disease patients to either a control (usual care CR) or intervention (CR + sedentary prompts from an activPAL3-VT) group. Primary outcomes included: recruitment; acceptability; completion; and, adherence rates. Secondary outcomes included changes in: ST; physical activity (PA); cardiometabolic health; psychosocial health; and, fitness.
Results: Forty participants (16 females; 19 intervention; 62 ± 10 years) were randomized. Outcome data were available for 95% of participants. All but one participant completed the full intervention. Most (73%) intervention participants felt the prompts had somewhat changed their sedentary behaviour. At baseline, participants spent 47% of their day sedentary. No significant group differences in changes for any of the ST, PA or fitness outcomes were observed. The mean group difference for post-intervention ST (controlling for baseline) was 30.3 min/day (95% CI: −51.7, 112.2) in favour of the intervention. The intervention group reported significantly better physical health and had a lower ratio of total cholesterol-to-high density lipoprotein when compared to controls.
Conclusions: It is feasible to use activPAL devices to measure ST in a CR setting. Further studies are needed to assess the effectiveness of multi-component sedentary behaviour interventions.

1. Background

Exercise-based cardiac rehabilitation (CR) reduces rates of total and cardiovascular-related mortality and morbidity among patients with coronary artery disease (CAD) [1, 2]. Although current CR guidelines focus on moderate-to-vigorous intensity physical activity (MVPA) targets (≥30 min of MVPA on ≥5 days/week), sedentary behaviour is increasingly shown to be a strong and modifiable risk factor for heart disease independent of physical activity (PA) levels [3, 4]. Sedentary behaviour is different from physical inactivity (absence of MVPA); it includes activities of low energy expenditure (≤1.5 metabolic equivalents) in a sitting, reclining or lying position [5].

Recent studies reporting on sedentary time (ST) in enrolled CR patients and graduates have shown that the majority of wakeful time is spent being sedentary (5–14 h/day) [6–9]. This is unfortunate given the negative effects of ST on cardiometabolic health and clinical outcomes (e.g. higher body mass index [BMI], waist circumference [WC] and HbA1c; lower high-density lipoprotein cholesterol [HDL-C] and health-related quality of life [HRQoL]; increased arterial stiffness; and, greater hospitalizations) [4, 6, 10–18]. It is important to ascertain whether current programming reduces ST or if targeted interventions are required. Previous evidence has suggested that PA-focused interventions do not generally result in clinically meaningful reductions in ST [19]. Biswas et al. recently examined self-report and device-based ST and found that it remained consistent over a 3-month CR program [7]. There have, however, been no studies examining the feasibility of adding a sedentary behaviour intervention to CR programming and whether these interventions can further improve cardiometabolic health and clinical outcomes. The use of cues and prompts from wearable technology may offer a feasible way to reduce ST in this population

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[20]. Evidence suggests interventions using education and prompts/cues have potential for reducing ST [21]. Self-monitoring and prompts increase self-efficacy for behaviour change; two of the four techniques comprising Social Cognitive Theory [22]. They are also key components of Operant Conditioning; a behaviour change theory often used in PA interventions which relies on consequences and self-management techniques [23].

To date, most research using direct measures of PA and ST in CR populations have used accelerometers (e.g., ActiGraph) which have proven limited for measuring ST and postural changes [24]. Alternatively, activPALs have the capability to discern between postures which can significantly increase knowledge of movement patterns among CR participants and are often referred to as the gold standard for free-living monitoring of ST [24, 25]. Additionally, the activPAL VTAP model offers direct feedback via prompts to the wearer regarding ST. These prompts have the capacity to reduce ST and increase interruptions of prolonged sitting. The objectives of the Sedentary Intervention Trial in Cardiac Rehabilitation (SIT-CR) study were to assess: 1) the feasibility and usability of activPAL devices for measuring ST in a CR setting; and, 2) whether prompting cues to interrupt ST using a VTAP monitor can: decrease ST and improve clinical outcomes; enhance HRQoL; increase self-efficacy to reduce ST/increase PA; address symptoms of anxiety and depression; increase MVPA and aerobic capacity; and, influence aortic stiffness beyond the benefits derived from standard CR.

2. Methods

2.1. Study design

SIT-CR was a single-centre, two-arm pilot randomized controlled trial (RCT). SIT-CR was registered at Clinicaltrials.gov (#NCT02821962) and carried out in accordance with the intervention description and replication (TIDieR) checklist [26] and CONSORT guidelines for randomized pilot and feasibility trials [27]. This study received approval from the Ottawa Health Science Network Research Ethics Board (#20160336-01H).

This pilot-RCT involved 40 individuals; treatment assignments were generated and placed in sealed numbered envelopes by a statistician from the Cardiovascular Research Methods Centre at the University of Ottawa Heart Institute (UOHI). Participants were stratified by sex and randomized in a 1:1 ratio to either the control (usual care CR) or intervention (CR + prompts from VTAP) group. Participants and study staff delivering the intervention were not blinded to group allocation. Staff conducting fitness tests were blinded to allocation.

2.2. Study participants

Patients were eligible for inclusion if they: were referred to an on-site CR at the UOHI; were ≥18 years; had a confirmed diagnosis of CAD; understood English or French, and; were willing and able to provide informed consent. Exclusion criteria included: already attending CR; unwillingness to wear monitors; current use of an activity monitor with sedentary prompts; unable to attend follow-ups; cognitive impairment; history of postural hypotension; or, inability in the opinion of the Medical Director, to participate.

2.3. Procedures

A week prior to their first CR class, participants visited the UOHI to: provide written, informed consent; complete a brief questionnaire (includes questions on socio-demographics, self-reported sitting time, self-efficacy to reduce ST/increase PA, and HRQoL), and; undergo measures of body mass, resting blood pressure (BP), heart rate (HR), and aortic stiffness. Participants were asked to fast for 4-hours (except water and medications), refrain from exercise for 12-hours, and forgo alcohol for 48-hours prior to the visit. Participants were then provided with an activPAL3 (PAL Technologies, Glasgow, UK) to wear on their right thigh during waking time for seven days prior to their first CR class. This device did not provide prompts. Other measures including height, WC, symptoms of anxiety and depression, and blood work were collected as part of usual CR procedures and abstracted from patients' charts.

A second study visit occurred one week later following the second CR class at which time participants were asked to complete a submaximal exercise test and then randomized. Participants in the intervention were provided with a VTAP monitor. Both groups continued with regular CR programming. Measures were repeated during the last/8th week of CR (9th week of RCT).

Regular CR included supervised twice weekly exercise sessions over an 8-week period at the Minto Prevention and Rehabilitation Centre at the UOHI. The 1-hour on-site exercise classes focused on aerobic and strength exercise led by a physiotherapist. CR participants also had access to resources including nutrition counseling, smoking cessation, diabetes and stress management, and psychosocial support. The CR programme is free and open to patients who: have experienced a myocardial infarction, undergone coronary artery bypass graft (CABG) or other heart surgery; have a diagnosis of heart failure; are waiting to receive or have received a heart transplant; and, those having undergone angioplasty or pacemaker/defibrillator implants are all eligible to participate in CR. The programme does not currently include a component focused on reduction of ST.

2.3.1. Intervention

Intervention group participants were provided with a VTAP monitor following the week of activPAL3 wear to be worn on the front of a thigh during waking hours for weeks 1–7 (similar to how the activPAL3 was applied). The monitor provided real-time feedback via alerts once the wearer had been sedentary for 30 consecutive min and required 2 min of standing/movement to reset. Alerts are delivered by way of gentle vibrotactile feedback ('buzzing'/mild vibration). Each week participants were provided with a fully charged VTAP due to limited battery (7–10 days) and a wear-time journal.

2.4. Study outcomes

Primary outcomes were assessed by examining recruitment rates; acceptability of the activPAL devices adjudged by an evaluation survey concerning experience wearing the monitors (Supplemental Table 1); completion and drop-out rates; and, intervention adherence.

The secondary outcome was change in daily ST (sitting + lying time) measured by an activPAL3 activity monitor before and during the final week of an 8-week CR programme to align with CR programme outcomes. Participants were required to have ≥4 days and ≥10 h/day of wear time for results to be considered valid [28].

Tertiary outcomes included changes between baseline and follow-up in activPAL3-derived: time spent in prolonged periods of sitting >30 and >60 min; number of sit-to-stand transitions; time spent sitting, lying, standing, stepping and in MVPA (>100 steps/min); and, steps/day. Body mass (kg) was measured to the nearest 0.1 kg in light clothing without shoes using a Seca scale (#634, U.S.) and used to calculate BMI (kg/m^2). Height (nearest 0.5 cm), WC (nearest 0.5 cm) and blood test results including total cholesterol (TC), HDL-C, low density lipoprotein cholesterol (LDL-C), triglycerides, TC-to-HDL ratio (TC-HDL), fasting plasma glucose, and HbA1c were determined. Self-reported symptoms of anxiety and depression (Hospital Anxiety and Depression Scale (HADS [29]) and exercise levels (modified Godin Leisure-Time Exercise Questionnaire [30]) were abstracted from CR charts. Pulse wave velocity (measure of aortic stiffness; PWV) and BP and HR were measured using a Mobil-O-Graph NG (IEM GmBH, Germany) following 5 min of rest and an average of three measurements used. Participants reported self-efficacy to reduce ST/increase PA using a validated questionnaire [31]. HRQoL was measured using the Short Form Health Survey, Version 1 (SF-36); we report on the physical and mental health summary measures. Finally, changes in maximal aerobic power ($V\dot{O}_{2max}$) were estimated using submaximal modified Bruce ramp treadmill tests [32]. The test was stopped once participants reached 85% of estimated age-predicted maximum HR ([207-(0.7*age)]- 30 bpm if taking β-blockers); or if they could not continue [33]. An estimation of $V\dot{O}_{2max}$ was calculated using the American College of Sports Medicine (ACSM) walking equation [32] and results also presented as total minutes.

2.5. Statistical considerations

2.5.1. Sample size calculation

Pilot/feasibility studies are generally not designed with the power to detect intervention effects, which is the intention of future definitive trials. However, to provide guidance, we estimated a sample size using G*Power Version 3.1.9.2. A total sample of 32 participants, 16 per arm, was needed to detect a 91 min/day difference in ST (average reduction from sedentary interventions [19]) at a 0.05 significance level with 80% power, accounting for an additional 10% not completing the trial, and 5% for data missing at random, assuming a standard deviation of 94 min/day [6].

2.5.2. Analysis strategies

Baseline clinical and socio-demographic characteristics were compared between groups. Outcome variables were screened to determine whether they met assumptions of normally distributed random variables with equal variances using the Shapiro-Wilk test. Changes in outcomes were calculated as follows: follow-up values subtracted from baseline values. Group differences in changes in the outcomes were examined using independent *t*-tests for parametric variables and Wilcoxon Mann-Whitney *U* tests for nonparametric variables. We used χ^2 tests for between group analyses for categorical variables. Analyses of covariance were also used to examine differences in follow-up outcome measures adjusting for baseline values and to calculate intervention effect sizes ($\eta 2$). Effect sizes were considered as small ($\eta 2 = 0.01$), medium ($\eta 2 = 0.06$) or large ($\eta 2 = 0.14$) [34]. A complete case analysis was performed. Analyses were performed using SPSS v24 (IBM Corp, NY, USA).

3. Results

3.1. Participants

Between August 2016 and July 2017 we screened 347 individuals. Of these, 136 were eligible, 82 were approached and 40 (16 females, 24 males) were randomized (Fig. 1). Baseline characteristics are shown in Supplemental Table 2. At baseline, participants spent an average of

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