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Effects of two behavioral cardiac rehabilitation interventions on physical activity: A randomized controlled trial

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ABSTRACT

Background: Standard cardiac rehabilitation (CR) is insufficient to help patients achieve an active lifestyle. The effects of two advanced and extended behavioral CR interventions on physical activity (PA) and sedentary behavior (SB) were assessed.
Methods: In total, 731 patients with ACS were randomized to 1) 3 months of standard CR (CR-only); 2) 3 months of standard CR with three pedometer-based, face-to-face PA group counseling sessions followed by 9 months of aftercare with three general lifestyle, face-to-face group counseling sessions (CR + F); or 3) 3 months of standard CR, followed by 9 months of aftercare with five to six general lifestyle, telephonic counseling sessions (CR + T). An accelerometer recorded PA and SB at randomization, 3 months, 12 months, and 18 months.
Results: The CR + F group did not improve their moderate-to-vigorous intensity PA (MVPA) or SB time compared to CR-only (between-group difference = 0.24% MVPA, $P = 0.349$; and 0.39% SB, $P = 0.529$). However, step count (between-group difference = 513 steps/day, $P = 0.021$) and time in prolonged MVPA (OR = 2.14, $P = 0.054$) improved at 3 months as compared to CR-only. The improvement in prolonged MVPA was maintained at 18 months (OR = 1.91, $P = 0.033$). The CR + T group did not improve PA or SB compared to CR-only.
Conclusions: Adding three pedometer-based, face-to-face group PA counseling sessions to standard CR increased daily step count and time in prolonged MVPA. The latter persisted at 18 months. A telephonic after-care program did not improve PA or SB. Although after-care should be optimized to improve long-term adherence, face-to-face group counseling with objective PA feedback should be added to standard CR.

1. Introduction

Physical behavior comprises both physical activity (PA) and sedentary behavior (SB) [1]. Patients with acute coronary syndrome (ACS) who have higher levels of moderate-to-vigorous intensity PA (MVPA; e.g., brisk walking or biking) have more favorable cardiovascular risk profiles and lower cardiac mortality [2,3]. Independent of PA time, SB time is also related to health outcomes such as Body Mass Index (BMI) and mortality [4,5]. In addition to the total time (volume) of physical behavior, the way physical behavior is distributed (accumulated in shorter or longer periods) might be important. For example, it has been suggested that MVPA yields greater health benefits when accumulated in periods lasting at least 10 min [6–8]. With regard to SB, regular active breaks may counteract the harmful effects of prolonged sedentary periods [9].

An important goal of cardiac rehabilitation (CR) for patients with ACS is the adoption of a healthy lifestyle. Although CR reduces cardiovascular risk factors, improves quality of life, and improves physical fitness [10,11], standard CR seems insufficient to improve the amount of PA performed outside the supervised CR settings [12,13]. Furthermore, standard CR generally does not target SB, and although some SB improvements do occur, patients with ACS remain sedentary following program completion [13].

We hypothesized that patients with ACS need more guidance to improve physical behavior. Adding behavioral interventions with self-regulation techniques, such as self-monitoring and goal-setting, seems the most promising approach [14,15]. Findings from previous studies that investigated the effectiveness of adding behavioral interventions aiming to improve daily PA to CR [16–18] are limited because they rely largely on self-reported measures of PA that have poor validity and reliability [19]. Additionally, most protocols were designed to

Abbreviations: ACS, acute coronary syndrome; CR, cardiac rehabilitation; GEE, generalized estimating equation; MVPA, moderate-to-vigorous physical activity; OPTICARE, optimal cardiac rehabilitation; PA, physical activity; SB, sedentary behavior.

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evaluate short-term effectiveness only and the investigated novel behavioral interventions often were not integrated into existing CR programs. To successfully implement behavioral components into daily clinical practice, pragmatic trials are needed that use existing infrastructure.

In the OPTImal CArdiac REhabilitation (OPTICARE) RCT, standard CR and two advanced and extended behavioral CR interventions (one using face-to-face group counseling and one using individual telephonic counseling) were evaluated in patients with ACS. The OPTICARE trial was designed as a pragmatic trial in an outpatient rehabilitation setting. The primary objective described in this paper was to evaluate the short-term and long-term effectiveness of the novel behavioral CR interventions on PA volume. The secondary aim was to evaluate SB volume as well as PA and SB distribution over time.

2. Methods

2.1. Study design

The OPTICARE study is an RCT that has been described in detail elsewhere [20]. OPTICARE is registered at ClinicalTrials.gov (NCT01395095).

2.2. Setting and participants

Patients referred to Capri Cardiac Rehabilitation (an outpatient rehabilitation center with several locations in the Netherlands) between November 2011 and August 2014 were invited to participate. Inclusion criteria were ACS diagnosis, age > 18 years, and proficiency in Dutch. Exclusion criteria were the presence of severe physical and/or cognitive impairments that could limit CR participation. The OPTICARE protocol was approved by the Medical Ethics Committee of the Erasmus Medical Center in Rotterdam, the Netherlands (MEC-2010-391). All patients provided written informed consent.

2.3. Randomization and intervention

Patients were randomized by trained research assistants using sequentially numbered, opaque and sealed envelopes that were prepared by an independent statistician who used a computer random number generator. Patients were randomized (1:1:1) to one of the following groups (see for the timeline of the interventions also Appendix 1):

1) *CR-only*: Standard CR was in line with the guidelines [2,21] and comprised two 75 min group exercise sessions per week for 3 months consisting of gymnastic exercises, running/brisk walking, sports activities and relaxation exercises. Additionally, patients were invited to participate in educational sessions addressing healthy diet, emotional coping, and cardiovascular disease risk factors. When indicated, patients could participate in group counseling sessions addressing diet, stress management, and smoking cessation, or an individual psychologic program. Only general information was given on health benefits of PA. SB was not addressed. There was no aftercare at the end of the 3 month CR program (initial phase).
2) *CR + F*: During the initial phase patients participated in standard CR as described above with the addition of three face-to-face, group PA counseling sessions (four to eight patients per session) lasting 75 min each. The sessions were facilitated by a physical therapist trained in motivational interviewing [22]. The content of the sessions was based on the following evidence-based behavioral change techniques: information about health behavior, self-monitoring, goal setting, feedback, barrier identification, and relapse prevention [14,23,24]. Pedometers (Yamax Digiwalker SW-200) were used to provide daily PA feedback and to facilitate goal-setting. The physical therapist coached the patient to set specific and realistic personal PA goals. In addition, a booklet with assignments focusing on goal setting, barrier identification and relapse prevention was used. Information was provided about the health benefits of breaking up SB time.
   After the initial 3 month period, a 9 month after-care program was offered that consisted of three face-to-face group sessions (six to eight patients per session). Every session consisted of a 1 h exercise program followed by a 1 h behavioral counseling program. The exercise program served as self-monitoring of aerobic capacity and also intended to stimulate interaction between patients in the group. The counseling sessions focused on permanent adoption of a healthy lifestyle (healthy diet, optimal PA, smoking cessation, medication adherence and stress management), but also on psychosocial problems. During the sessions information on health consequences of health behaviors was repeated and there was a focus on relapse prevention. The behavioral counseling sessions were led alternatingly by a physical therapist, a social worker, and a dietician who were all trained in motivational interviewing.
3) *CR + T*: Patients participated in the initial phase only in standard CR (see CR-only). After the initial 3 month period, a 9 month telephonic after-care program was offered that was based on the COACH program [25]. This program consisted of five to six individual telephone coaching sessions with specialized nurses who were trained in motivational interviewing [22]. Patients received information on risk factors and were encouraged to measure their coronary risk factors (cholesterol, blood pressure, glucose, weight) and define personal goals. Furthermore, psychosocial problems were discussed and patients were coached to develop a personal plan for a heart-healthy lifestyle (diet, PA, smoking cessation, medication adherence). During follow-up calls, progress was discussed. At the end of every phone call patients received a written overview of the topics that were discussed and the agreements made. SB was not addressed.

2.4. Measurements

2.4.1. Physical behavior measurement and processing

Measurements were performed directly after randomization (T0), at completion of standard CR (T3m, 3 months after randomization), completion of after-care (T12m, 12 months after randomization), and 6 months after completion of after-care (T18m, 18 months after randomization) (Appendix 1). Measurements were performed by trained research assistants. Both patients and testers were not blinded to group allocation.

Patients were asked to wear a tri-axial accelerometer for 8 consecutive days during waking hours. Because consensus is lacking for how to process accelerometer data (e.g., determination of epoch length and cut-off points), the existing literature was consulted to determine data processing procedures, which have been described previously [13]. In short; data were sampled at 30 Hz. The ActiGraph converts accelerations on three axes (vertical, horizontal and perpendicular axes) into activity counts and steps. Steps were processed using Actilife software. Counts were summed over a sampling interval (epoch) of 15 s using Actilife software and further processed using Matlab version R2011b. The vector magnitude (a composite measure of counts on the three axes) was used for analysis. Data were only included in the analysis when the accelerometer was worn for at least 4 days with a minimum of 660 min per day. In our data, a minimum of 660 min/day proved to be the most optimal threshold, which is a threshold that minimizes excluding measurements of patients that spend a long time in bed and maximizes excluding measurements of patients that did not wear the Actigraph a full valid [13] Non-wear time was defined as a minimum of 60 min of consecutive zeros. After subtracting the non-wear from the data, each 15 s epoch was categorized as:

- MVPA: activities of ≥672.5 counts [26]
- Light activity: activities of >37.5 and <672.5 counts [26]
- SB: activities of ≤37.5 counts [27]

2.4.2. Physical behavior outcomes

After data processing, the following outcome measures were obtained:

Volume of physical behavior

- Duration of time spent in MVPA and SB, expressed as a percentage of wear time
- Step count, expressed as average steps per minute of wear time

Distribution of physical behavior over time

- Prolonged MVPA was defined as periods of at least 10 min, in accordance with recommendations [2,8]. In daily life, short MVPA interruptions seem reasonable (e.g., waiting for a traffic light). Therefore, a maximum of four (*not necessarily consecutive*) non-MVPA epochs were allowed during a prolonged MVPA period. Total time spent in prolonged MVPA was expressed as a percentage of wear time.
- Prolonged SB was defined as periods lasting at least 30 min. Although clear recommendations for SB are lacking, this time was chosen because interrupting SB every 30 min seems to be a feasible target for interventions. A sedentary period could include multiple short interruptions with a maximal duration of three *consecutive* 15 s epochs of non-SB time. Thus, we defined a prolonged SB period as ending after at least 1 min of continuous non-SB. Total time spent in prolonged SB periods was expressed as percentage of wear time.

Attaining physical behavior recommendations

- We investigated whether patients were meeting physical behavior recommendations. We calculated the number of patients that walked at least 6500 steps/day, which has been previously recommended for prevention of cardiac disease progression [28,29].
- We also calculated whether participants met a target of ≥150 min of prolonged MVPA bouts per week [30]. This guideline is consistent with those addressing secondary prevention of cardiovascular disease [3,31,32]. Because not all participants wore an accelerometer for a full week, we calculated the number of participants achieving a mean of 21.4 min of prolonged MVPA/day (150 min/7 days). For SB, currently no guidelines are available.

2.5. Sample size calculation

This RCT was designed to evaluate effects on cardiovascular risk profile (described in a separate paper) and physical behavior (current paper). A sample size calculation was performed for both outcome measures. Based on previous studies [33,34], it was hypothesized that patients randomized to CR + T or CR + F would reach a mean of 25 (±20) and 32 (±23) MVPA min/day at T18 m, respectively, compared with a mean of 16 (±13) MVPA min/day in patients randomized to CR-only. To show differences between the newly developed interventions and CR-only with 80% power (based on a two-sided test with alpha = 0.05), 202 patients were needed per treatment arm. A drop-out rate of 20% was anticipated, thus the recruitment was targeted to enroll 245 patients per arm, or 735 total patients. This study size was sufficient to enable a post-hoc comparison