International Journal of Cardiology 255 (2018) 221–228

Contents lists available at ScienceDirect

International Journal of Cardiology

journal homepage: www.elsevier.com/locate/ijcard

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

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ARTICLE INFO

Article history:
Received 20 July 2017
Received in revised form 17 November 2017
Accepted 5 December 2017

Keywords:
Acute coronary syndrome
Lifestyle
Maintenance
Motivational interviewing

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.
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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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[1] This author takes responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.

https://doi.org/10.1016/j.ijcard.2017.12.015
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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 between CR + F and CR + T, depending on actual findings, with adjustment for multiple testing. The required sample size was smaller than the number needed to evaluate cardiovascular risk profile differences. For logistic reasons, patient inclusion was restricted to the Rotterdam site of Capri for this part of the study.

2.6. Statistical analysis

Descriptive statistics were used to present baseline characteristics. Data on relative time in prolonged MVPA violated the normality assumptions, even after transformation. A large group of patients did not spend any time in prolonged MVPA, leading to a severe positive skew. Therefore, this outcome was dichotomized, and a value of '0' was given to those patients with no periods of prolonged MVPA and '1' to those patients with at least one period of prolonged MVPA.

Intention-to-treat (ITT) analysis with full datasets is preferred to avoid bias in RCTs [35]. However, patients who quit CR before T3m had no post-baseline accelerometry measurements; thus, a full ITT analysis was not possible. Only patients with at least one valid post-baseline physical behavior measurement were included in the analysis. A priori, it was decided to impute only missing baseline values and not post-baseline outcomes (study endpoints). We used generalized estimating equations (GEE) with exchangeable correlation structures to evaluate study endpoints. A GEE model was chosen because it corrects for missing values and because corrections are made for the dependency of observations within one individual [36]. GEE models use all available data of the dependent outcome and not only complete cases. Imputation of endpoints (in our case T3m, T12m, T18m) is therefore not needed [36]. First, overall models were made for each outcome measure, including group allocation, and baseline values of the outcome measure to correct for baseline differences between patients. Next, the factor time and an interaction term between group and time were added to the overall model to compare between-group differences at the different time points. For continuous variables, the regression coefficient (B) of the group variable (representing between-group differences) is displayed. For dichotomous variables, between-group differences are displayed as odds ratios (ORs). All models were adjusted for age and sex. Missing values at baseline were imputed five times (multiple imputation) by predictive mean matching, using all available baseline characteristics and physical behavior outcomes at all time points as predictors. For all analyses, pooled results are reported.

To evaluate possible bias, baseline values (using *t*-tests and Chi-square tests) were compared for patients included and excluded from the main analysis. Additionally, two sensitivity analyses were performed: (1) ITT analysis: identical GEEs on all randomized patients after multiple imputation (five times) of missing data on all time points; and (2) per-protocol (PP) analysis: identical GEEs on patients that attended at least 75% of all sessions.

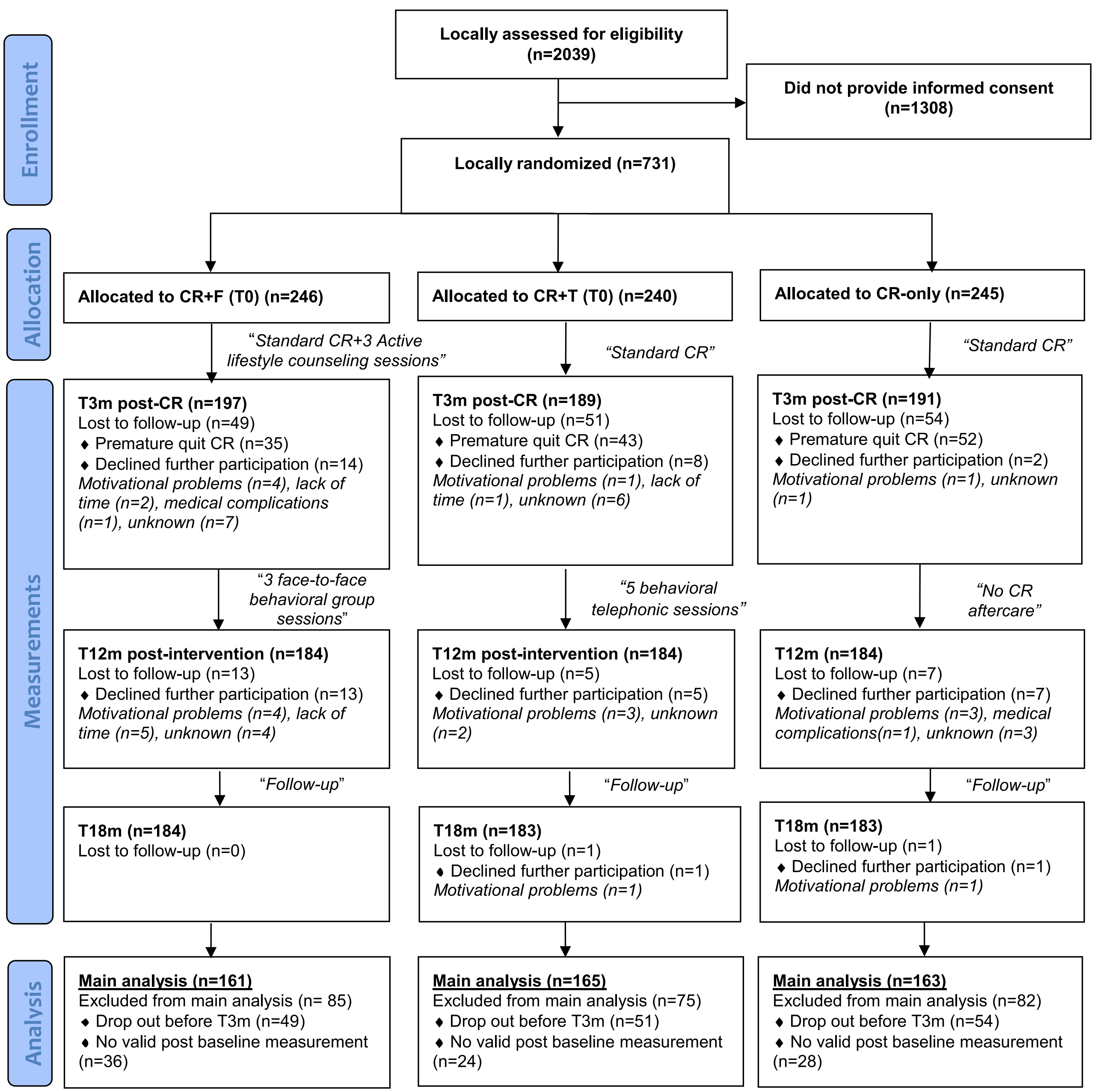

Fig. 1. Consort flow diagram. CR = cardiac rehabilitation; CR + F = cardiac rehabilitation plus face-to-face group counseling; CR + T = cardiac rehabilitation plus telephonic counseling; CR-only = standard cardiac rehabilitation; m = month.

A P value <0.05 was considered significant. All analyses were performed using SPSS version 20 (IBM Corp., Armonk, USA).

3. Results

3.1. Patients

A total of 731 patients with ACS were randomized (Fig. 1), 130 patients quit CR prematurely, and 112 additional patients did not have a post-baseline measurement. The 242 patients who did not complete the study were, on average, 4.5 years younger ($P < 0.001$), more likely to have had a past MI (13% vs 7%, $P = 0.011$), and more likely to smoke (65% vs 34%, $P < 0.001$). The remaining 489 patients who were included in the main analysis had a mean age of 59 years, and most were treated with percutaneous coronary intervention (Table 1).

3.2. Outcomes

At each time point, 69% to 86% of patients provided usable physical behavior measurements (Appendix 2). Unsuccessful measurements resulted from technical problems, failure of measurements to meet the minimum required duration, or patient inability to visit the rehabilitation center for application of the accelerometer due to lack of time or motivation. At T0, 86 (17.5%) missing physical behavior outcomes were imputed. At other measurement times, missing data was not imputed.

Table 1
Baseline participant characteristics ($n = 489$).

Characteristics	CR + F ($n = 161$)	CR + T ($n = 165$)	CR-only ($n = 163$)
Male, n (%)	129 (80)	141 (86)	131 (80)
Age in years, mean (SD)	58.8 (9)	58.2 (9)	59.1 (8)
Partnered, n (%)[a]	116 (81)	116 (87)	125 (84)
Employed, n (%)[b]	78 (61)	75 (62)	72 (53)
Education, n (%)[c]			
High	38 (27)	44 (33)	40 (27)
Intermediate	97 (67)	83 (62)	101 (68)
Low	9 (6)	6 (5)	7 (5)
Therapeutic intervention at index event, n (%)			
No revascularization	12 (7)	15 (9)	14 (8)
PCI	130 (81)	124 (75)	129 (79)
CABG	20 (12)	27 (16)	21 (13)
Cardiac history, n (%)			
Myocardial infarction	9 (6)	15 (9)	11 (7)
Angina	8 (5)	10 (6)	11 (7)
PCI	12 (8)	15 (9)	16 (10)
CABG	2 (1)	1 (1)	4 (3)
Stroke/TIA	9 (6)	3 (2)	4 (3)
Risk factors, n (%)			
Diabetes	19 (12)	18 (11)	21 (13)
Dyslipidemia	45 (28)	64 (39)	75 (46)
Family history	87 (54)	80 (49)	93 (57)
Smoking (pre-ACS)	62 (39)	61 (37)	49 (30)
Hypertension	70 (44)	68 (41)	68 (42)
Overweight	126 (79)	127 (77)	124 (76)
Medication, n (%)			
Acetylsalicylic acid	157 (98)	161 (98)	160 (98)
Oral anticoagulant	8 (5)	11 (7)	6 (4)
Thienopyridine	137 (86)	131 (79)	142 (87)
Cholesterol lowering medication	157 (98)	159 (96)	160 (98)
Beta-blocker	136 (85)	141 (86)	136 (83)
ACE inhibitor	116 (73)	115 (70)	116 (71)
Angiotensin II receptor blocker	19 (12)	22 (13)	21 (13)
Calcium blocker	19 (12)	24 (15)	19 (12)
Nitrate	70 (44)	50 (30)	57 (35)
Diuretic	17 (11)	23 (14)	19 (12)
Psychotropic	6 (4)	13 (8)	11 (7)

CR + F = cardiac rehabilitation plus face-to-face group counseling; CR + T = cardiac rehabilitation plus telephonic counseling; CR-only = standard cardiac rehabilitation; PCI = percutaneous coronary intervention; CABG = coronary artery bypass graft; TIA = transient ischemic attack; ACS = acute coronary syndrome.
[a] Data missing for $n = 17$ (CR + G), $n = 31$ (CR + T), and $n = 14$ (CR-only)
[b] Data missing for $n = 33$ (CR + G), $n = 44$ (CR + T), and $n = 28$ (CR-only)
[c] Data missing for $n = 17$ (CR + G), $n = 32$ (CR + T), and $n = 15$ (CR-only).

3.2.1. Intervention effects of CR + F compared to CR-only

Fig. 2 displays observed study endpoints over time (for exact values see Appendix 3). With respect to volume of physical behavior, there were no overall intervention effects for MVPA time (between-group difference = 0.24%; 95% CI = −0.27 to 0.76; $P = 0.349$) and SB time (between-group difference = 0.39%; 95% CI = 0.82 to 1.59; $P = 0.529$). However, we did find overall intervention effects for step count (between-group difference = 0.45 steps/min of wear time; 95% CI = 0.03 to 0.86; $P = 0.035$) and for prolonged MVPA (OR = 2.01; 95% CI = 1.30 to 3.14; $P = 0.002$; Table 2). Overall effects were also noted for achieving ≥6500 steps/day (OR = 1.77; 95% CI = 1.20 to 2.60; $P = 0.004$; Table 2).

Those patients randomized to CR + F participated in extra PA counseling sessions between T0 and T3m. Compared to CR-only patients, CR + F patients at T3m improved their step count with 0.59 steps per min of wear time more (95% CI = 0.09 to 1.09; $P = 0.021$). This difference corresponds to an additional 513 steps per 14.5 h of daytime waking hours. Furthermore, the odds of having prolonged MVPA periods ≥10 min were 2.14 times higher in the CR + F group compared to CR-only (95% CI = 0.99 to 4.62; $P = 0.054$). Those patients randomized to CR + F also participated in a face-to-face, after-care program between T3m and T12m. Although between-group differences in increases in step count were not maintained long-term, the odds of spending time in prolonged MVPA were still 1.86 times higher at T12m (95% CI = 1.04 to 3.32; $P = 0.037$) and 1.91 times higher at T18m (95% CI = 1.05 to 3.44; $P = 0.033$) compared to CR-only.

At T3m and T12m, patients in the CR + F group were more likely to meet ≥6500 steps/day compared to those in the CR-only group (OR = 2.00; 95% CI = 1.19 to 3.35; $P = 0.009$; and OR = 1.81; 95% CI = 1.07 to 3.09; $P = 0.028$, respectively). This difference was no longer significant at T18m.

3.2.2. Intervention effects of CR + T compared to CR-only

There were no overall intervention effects for MVPA time (B = −0.15%; 95% CI = −0.65 to 0.34; $P = 0.544$) or step count (B = −0.14 steps/min of wear time; 95% CI = −0.58 to 0.30; $P = 0.536$). There were also no intervention effects noted with respect to SB time, PA distribution, and SB distribution (Table 2).

3.3. Outcome sensitivity analyses

For the sensitivity ITT analysis, all 731 randomized patients were analyzed after imputation at all time points. This analysis showed smaller intervention effects compared to the main analysis. The 428 patients who did participate in at least 75% of scheduled sessions were analyzed in the sensitivity PP analysis. That analysis showed slightly larger effects (Appendices 4 and 5).

4. Discussion

Neither the novel behavioral CR interventions improved MVPA time (e.g., brisk walking or sports activities) compared to standard CR. However, results from the CR + F group showed that integrating pedometer-based face-to-face group PA counseling into the initial phase of CR improved PA by an additional 500 steps/day, which is an encouraging result. PA distribution over time also improved, with MVPA accumulating more often in prolonged periods of at least 10 min, which is recommended for optimal health. As patients in the CR + F group progressed through the face-to-face after-care program, improvements in step count partly diminished. However, improvements in prolonged PA were maintained. The CR + T group experienced no benefit compared to CR-only.

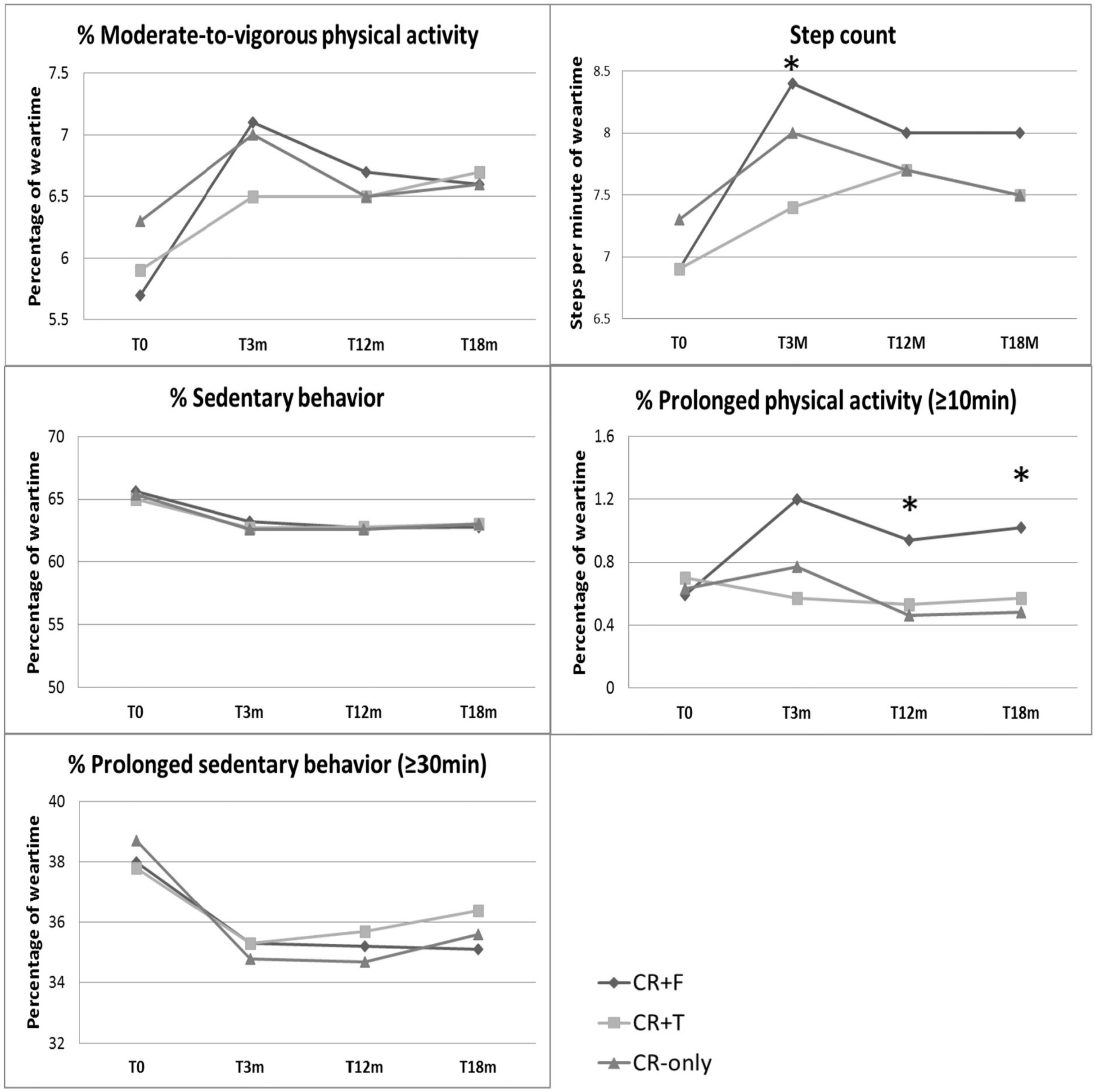

Fig. 2. Volume of physical behavior and distribution over time. Abbreviations as in Fig. 1. *Significant intervention effect for CR + F compared to CR-only.

Consistent with previous intervention studies in healthy subjects [37], our results show that achieving lasting PA change is a challenge. Nevertheless, we were encouraged by improvements in the CR + F group daily step count. A previous study showed that 6500 steps per day corresponds to the minimum energy expenditure (1500 kcal/week) needed to prevent disease progression in patients with ACS [28]. After the initial phase of CR and after completion of the after-care program, more patients in the CR + F group met this step count goal compared to those in the CR-only group (62% vs 47% at T3m; 60% vs 47% at T12m). In addition to step volume improvement, there were long-lasting improvements in time in prolonged MVPA compared to CR-only. Nevertheless, this improvement did not translate to differences in achievement of 150 min/week of exercise in prolonged MVPA. Adherence rates with this last guideline may be underestimated, however, because the guideline is based on self-report, whereas our data were objectively measured [38].

In a previous publication, we concluded that the novel interventions do not result in relevant improvements in cardiovascular risk factors such as lipid profile, blood pressure, BMI and waist circumference [39]. This could suggest that the improvements we found with regard to PA were insufficient to yield improvements in cardiovascular health. An alternative explanation is that the association between PA and cardiovascular health is masked by the effects of cardio protective medication. The majority of patients were taking aspirins, statins, beta-blockers, and ACE-inhibitors which resulted in already well-controlled lipids and blood pressure at baseline ('ceiling effect'). Regardless of the correct explanation, adoption of an active lifestyle remains important since PA can influence cardiovascular mortality through other pathways (e.g. by improving coronary blood flow, augmenting cardiac function or enhancing endothelial function) [40]. In addition, PA was previously found to be associated to other health outcomes such as fitness and several chronic diseases [40,41].

Time spent sedentary remained high for all groups. Although general advice was given to CR + F participants about the health benefits of regularly breaking up SB time, the focus of these sessions concerned PA; this focus might explain the lack of effects. Likewise, the CR + T group

Table 2
Main analysis: generalized estimating equation models[a] of intervention effects.

Physical behavior		CR + F (n = 161) vs CR-only (n = 163)			CR + T (n = 165) vs CR-only (n = 163)		
		B[b]	CI	P	B[b]	CI	P
Volume							
MVPA	Overall	0.24	−0.27:0.76	0.349	−0.15	−0.65:0.34	0.544
(% of wear time)	ΔT0–T3m	0.34	−0.24:0.92	0.245	−0.48	−1.01:0.04	0.073
	ΔT0–T12m	0.22	−0.42:0.85	0.502	−0.11	−0.78:0.55	0.736
	ΔT0–T18m	0.08	−0.62:0.77	0.832	0.17	−0.52:0.86	0.621
Step count	Overall	**0.45**	**0.03:0.86**	**0.035***	−0.14	−0.58:0.30	0.536
(nr of steps per min of wear time)	ΔT0–T3m	**0.59**	**0.09:1.09**	**0.021***	−0.44	−0.91:0.03	0.067
	ΔT0–T12m	0.22	−0.30:0.74	0.408	−0.06	−0.66:0.53	0.835
	ΔT0–T18m	0.44	−0.16:1.03	0.150	0.12	−0.48:0.72	0.692
SB	Overall	0.39	−0.82:1.59	0.529	0.35	−1.07:1.77	0.632
(% of wear time)	ΔT0–T3m	0.59	−0.80:1.98	0.404	0.51	−0.98:1.99	0.505
	ΔT0–T12m	0.44	−1.12:2.00	0.583	0.40	−1.49:2.29	0.679
	ΔT0–T18m	0.10	−1.62:1.83	0.905	0.10	−1.86:2.06	0.918
Distribution							
MVPA bout > 10 min	Overall	**2.01**	**1.30:3.14**	**0.002***	1.02	0.69:1.50	0.935
(% of wear time)[c]	ΔT0–T3m	2.14	0.99:4.62	0.054	0.77	0.42:1.45	0.425
	ΔT0–T12m	**1.86**	**1.04:3.32**	**0.037***	1.30	0.76:2.25	0.341
	ΔT0–T18m	**1.91**	**1.05:3.44**	**0.033***	0.83	0.48:1.44	0.505
Prolonged SB (≥30 min)	Overall	0.76	−1.02:2.53	0.403	1.08	−0.98:3.14	0.303
(% of wear time)	ΔT0–T3m	0.57	−1.56:2.69	0.602	0.80	−1.52:3.12	0.499
	ΔT0–T12m	1.42	−0.79:3.63	0.208	1.36	−1.09:3.81	0.277
	ΔT0–T18m	0.29	−2.15:2.73	0.815	1.14	−1.56:3.85	0.408
Achieving guidelines, %							
150 min prolonged	Overall	1.60	0.97:2.64	0.069	1.02	0.58:1.77	0.957
MVPA/week[c]	ΔT0–T3m	1.75	0.89:3.47	0.107	0.81	0.37:1.75	0.590
	ΔT0–T12m	1.60	0.80:3.17	0.184	1.00	0.47:2.12	0.995
	ΔT0–T18m	1.45	0.71:2.98	0.306	1.32	0.65:2.66	0.409
6500 steps/day[c]	Overall	**1.77**	**1.20:2.60**	**0.004***	0.90	0.60:1.34	0.594
	ΔT0–T3m	**2.00**	**1.19:3.35**	**0.009***	0.90	0.54:1.51	0.700
	ΔT0–T12m	**1.81**	**1.07:3.09**	**0.028***	0.87	0.51:1.47	0.606
	ΔT0–T18m	1.45	0.83:2.52	0.190	0.92	0.53:1.59	0.768

CR + F = cardiac rehabilitation plus face-to-face group counseling; CR + T = cardiac rehabilitation plus telephonic counseling; CR-only = standard cardiac rehabilitation; MVPA = moderate-to-vigorous physical activity; SB = sedentary behavior; m = months. Bold values indicate significant results.

[a] All analyses were adjusted for baseline values, sex, and age. The CR-only group is the referent group for all analyses.

[b] The regression coefficient (B) represents the between-group difference and thus the intervention effect relative to CR-only at the specified time point.

[c] For dichotomous variables odds ratios are displayed.

* $P < 0.05$.

did not improve their time in SB after PA counseling. Previous studies support the finding that PA interventions do not affect sedentary time [15].

To our knowledge, this is the first study investigating the effects of a physical behavior counseling program integrated into the initial phase of multidisciplinary CR. A large meta-analysis summarizing the effect of PA interventions among healthy subjects found improvements in step count of the same magnitude as seen in CR + F participants in our study [37].

After the initial phase of CR, the CR + F group participated in a face-to-face after-care program focused on multiple lifestyle components. Previous studies investigating the effectiveness of such interventions have mainly relied on less well-validated self-reported PA [17–19]. A previous study that used objective pedometry to measure intervention effectiveness showed larger and longer-lasting effects in daily step count compared to our study [42]. However, patients in that study were measured using the same (non-blinded) pedometers as used during the investigated intervention for feedback, which may have biased their findings. Our study adds the finding that increased step count does not necessarily translate to increased MVPA time. A possible explanation is that a part of the walking activities was classified as light intensity. Another explanation is that the extra walking activities were compensated for by decreasing other MVPA activities. Future research is needed to determine whether increasing total stepping activities (independent of intensity) or increasing total MVPA time is more important for health.

In contrast to our study, two previous studies investigating the effects of the COACH program on which our telephonic after-care program (CR + T) was based, did show PA improvements [25,43]. These outcomes were also self-reported, which may explain the discrepancy between those studies and our present study.

Although the increases in step count achieved by the CR + F group are encouraging, optimization of the intervention is needed. Results of our study suggest future directions. Firstly, our finding that patients responded to objective feedback on walking activities (in our study provided by pedometers) by increasing their daily step count is consistent with a previous review that emphasized the importance of self-monitoring for PA change [14]. Possibly, our counseling sessions could be improved by not only providing feedback on walking activities, but also on volume and distribution of total MVPA and SB, which is possible with new technologies. Secondly, our after-care programs that focused on several heart-healthy lifestyle components simultaneously were ineffective in improving PA compared to the pedometer-based counseling sessions during the initial phase of CR. Like Conn et al. [37,44], we hypothesize that for successful improvements in physical behavior, sessions may need to focus exclusively on PA and SB. Studies investigating the effects of CR after-care programs focusing solely on PA have provided inconsistent results thus far, suggesting that further research is needed to determine the optimal format [45,46]. Patients probably require ongoing attention, which could be feasible using E-health solutions [47].

Although after-care optimization is needed, we recommend that face-to-face group counseling sessions, including objective PA feedback, be added to standard CR. The CR + F intervention was imbedded in an existing and reimbursed CR program and consisted of a small number of additional sessions performed in groups. Therefore, costs of the intervention are estimated to be relatively low. However, for successful implementation and reimbursement, a detailed economic evaluation of our intervention is needed.

4.1. Limitations

We included only patients who had at least one follow-up measurement. This method may have biased our results. To test for bias, we performed two sensitivity analyses. Because between-group differences were more pronounced in patients attending at least 75% of sessions and less pronounced when we performed a stricter ITT analysis that included all randomized patients, our results are probably valid primarily in more adherent patients.

Objective PA measurement is the method of choice, as it is more valid than self-reported measures [19]. However, accelerometry also has limitations. Firstly, cut-off points used for PA intensity categories were developed for a healthy population. Consequently, PA intensity may be underestimated for patients with lower fitness levels. Secondly, incorrect categorizing of "standing still" as "SB" in our study cannot be ruled out. Finally, participants were aware that their PA was being measured, which may have influenced their behavior. Because our measurement period lasted at least 4 days, we expect this effect to be minimal and equal between groups.

5. Conclusions

None of the investigated novel CR programs were successful in increasing total MVPA. However, adding three pedometer-based, face-to-face group counseling sessions that focused exclusively on changing physical behavior during the initial phase of CR was effective in improving daily step count and increasing time spent in prolonged MVPA. After the face-to-face after-care program focusing on several healthy lifestyle components ended, only improvement in prolonged MVPA was maintained. The intervention was not successful in changing SB. The telephonic after-care program that focused on several healthy lifestyle components did not improve PA or SB. Although after-care optimization is needed to improve long-term adherence, we recommend that face-to-face group counseling sessions including objective PA feedback be added to standard CR.

Acknowledgements

The authors thank participating patients, personnel of Capri Cardiac Rehabilitation who collected data and served as coaches for the CR + F study arm, and nurses from Zilveren Kruis-Achmea who served as coaches for the CR + T study arm. We thank Myrna van Geffen, Verena van Marrewijk, and Saskia Versluis for recruiting patients, organizing the challenging study logistics, and collecting data. We also thank the medical students from Erasmus MC who assisted with data collection.

Acknowledgement of grant support

This was an investigator-initiated study, but it was co-financed by Capri Cardiac Rehabilitation Rotterdam (the Netherlands) and the Zilveren Kruis-Achmea healthcare insurance company (the Netherlands)

Disclosures

The authors report no relationships that could be construed as a conflict of interest.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijcard.2017.12.015.

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