Effects of a Dedicated Cardiac Rehabilitation Program for Patients With Obesity on Body Weight, Physical Activity, Sedentary Behavior, and Physical Fitness

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Original Research

Effects of a Dedicated Cardiac Rehabilitation Program for Patients With Obesity on Body Weight, Physical Activity, Sedentary Behavior, and Physical Fitness: The OPTICARE XL Randomized Controlled Trial

Iris den Uijl, PhD[1,*], Rita J.G. van den Berg-Emons, PhD[1], Madoka Sunamura, MD, PhD[2], Mattie J. Lenzen, PhD[3], Henk J. Stam, MD, PhD[1], Eric Boersma, PhD[3], Nicole C.C.W. Tenbült-van Limpt[4], Hareld M.C. Kemps, MD, PhD[4,5], Marcel L. Geleijnse, MD, PhD[3], Nienke ter Hoeve, PhD[1,2]

[1]Department of Rehabilitation Medicine, Erasmus University Medical Centre, Rotterdam, the Netherlands
[2]Capri Cardiac Rehabilitation, Rotterdam, the Netherlands
[3]Department of Cardiology, Thoraxcenter, Erasmus University Medical Centre, Rotterdam, the Netherlands
[4]Department of Cardiology, Máxima Medical Centre, Eindhoven/Veldhoven, the Netherlands
[5]Department of Industrial Design, Eindhoven University of Technology, Eindhoven, the Netherlands

*Address all correspondence to Dr den Uijl at: i.denuijl@erasmusmc.nl

Abstract

Objective. Previously published results of the OPTICARE XL open label randomized controlled trial showed no added value of OPTICARE XL CR, a dedicated cardiac rehabilitation (CR) program for patients with obesity, with respect to health–related quality of life (primary outcome). This clinical trial studied the effects of OPTICARE XL CR on several secondary outcomes, which included body weight, physical activity, sedentary behavior, and physical fitness.

Methods. Patients with coronary artery disease or atrial fibrillation and body mass index ≥ 30 were randomized to OPTICARE XL CR ($n = 102$) or standard CR ($n = 99$). OPTICARE XL CR was a 1-year group intervention, specifically designed for patients with obesity that included aerobic and strength exercise, behavioral coaching, and an aftercare program. Standard CR consisted of a 6- to 12-week group aerobic exercise program, supplemented with cardiovascular lifestyle education. Study end points included body weight, physical activity, sedentary behavior (accelerometer), and physical fitness (6-Minute Walk Test and handgrip strength), which were evaluated 6 months after the end of CR (primary endpoint) and 3 months after the start of CR.

Results. Six months after completion of either program, improvements in body weight, physical activity, sedentary behavior, and physical fitness were similar between the groups. Three months after CR start, patients randomized to OPTICARE XL CR showed greater weight loss (mean change = −3.6 vs −1.8 kg) and a larger improvement in physical activity (+880 vs +481 steps per day) than patients randomized to standard CR.

Conclusion. Patients allocated to OPTICARE XL CR lost significantly more body weight and showed promising results with respect to physical activity 3 months after the start of CR; however, these short-term results were not expanded or sustained in the longer term.

Impact. Patients with obesity do not benefit from standard CR programs. The new OPTICARE XL CR program showed its effects in the short term on weight loss and physical activity, and, therefore, redesign of the aftercare phase is recommended.

Keywords: Body Weight, Cardiac Rehabilitation, Obesity, Physical Activity, Physical Fitness, Sedentary Behavior

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Introduction

Exercise–based cardiac rehabilitation (CR) is recommended for patients with established cardiac diseases to manage risk factors and to promote a heart-healthy lifestyle.[1,2] Goals such as losing excessive body weight, increasing physical activity, decreasing sedentary behavior, and improving physical fitness are part of this healthy lifestyle. Particularly in patients with coronary artery disease (CAD) who are also affected by obesity, a healthy lifestyle is essential to prevent new life-threating cardiac events.[2] Recent evidence also indicates that losing weight and increasing physical activity reduce the recurrence of atrial fibrillation (AF) in patients with obesity.[3]

Although patients with cardiac disease who have comorbid obesity are referred to the same CR programs as patients without obesity, it is questionable whether standard CR is suitable for these patients. For instance, studies showed that a weight loss of 5 to 10%, which is known to be associated with a cardiovascular risk reduction, [4–6] is often not achieved during CR.[7,8] Patients with obesity also complete CR with a less favorable physical activity and sedentary behavior (SB) profile than patients with normal weight,[9] and physical fitness levels achieved during, as well as after, CR programs are suboptimal.[10,11]

The need for a CR program designed specifically for patients with obesity has regularly been advocated.[12,13] Previous research has pointed at benefits from a combination of nonweight-bearing aerobic exercises and muscle strength training in patients with cardiac disease who have obesity.[14,15] This type of training is preferred over the usually offered weight-bearing and mainly aerobic exercises during CR to prevent musculoskeletal complaints and facilitate weight loss. Additionally, standard CR comprises general counseling on a healthy lifestyle, but does not provide a peer group weight loss intervention specifically designed for patients with obesity or counseling toward a more active and less sedentary lifestyle or an aftercare program.[12,16]

We designed a 1-year, state-of-the art CR program for patients with cardiac disease who have obesity and studied the added value of this OPTICARE XL CR program in a multicenter randomized controlled trial (RCT). Results on the effectiveness of OPTICARE XL CR on the primary outcome health–related quality of life (HRQOL) as well as on psychosocial well-being were reported previously.[17] The aim of the current paper was to describe the effectiveness of OPTICARE XL CR as compared with standard CR on the secondary outcomes body weight, physical activity, SB, and physical fitness 6 months after completion of either program. Second, we assessed the short-term results of all outcomes 3 months after the start of CR. It was hypothesized that patients with obesity benefit more from this specific CR program than from standard CR.

Methods

Study Design and Setting

The OPTICARE XL study was an open label RCT (Fig. 1) in which HRQOL was the primary outcome of interest. Patients aged ≥18 years with obesity (body mass index [BMI] ≥30 kg/m^2) referred to CR with established CAD or nonvalvular AF were invited to participate. Patients with heart failure, left ventricular ejection fraction <40%, an implantable cardioverter defibrillator, psychological or cognitive impairments, severe comorbidities or who were not able to communicate in Dutch were not included.

Eligible patients were randomized in a 1:1 allocation ratio to OPTICARE XL CR or standard CR in each of the 3 Dutch participating centers: Capri Cardiac Rehabilitation Rotterdam, Capri Cardiac Rehabilitation The Hague, and Máxima Medical Centre Veldhoven. An independent researcher used a computer-generated block randomization scheme with a block size of 4 to allocate patients and subsequently prepared consecutively numbered, opaque, sealed randomization envelopes. Enrollment of participants was performed by study coordinators in each center who were unaware of the block size, and randomization was performed directly after baseline measurements.

OPTICARE XL CR and Standard CR

The OPTICARE XL CR group received a 1-year CR program that was designed for patients with obesity by health professionals, patients, and scientists of Capri Cardiac Rehabilitation and Erasmus University Medical Centre. This program was based on the European Society of Cardiology (ESC) guidelines for CR as applied in standard CR, as well as the Dutch dietary guidelines on food intake and food choices, and the Dutch Physical Activity Guidelines of the Health Council of the Netherlands.[1,18–20] The main aim of OPTICARE XL CR was guiding patients with obesity to a healthier lifestyle by combining several behavioral change techniques such as self-monitoring, goal setting, planning, receiving feedback, identifying barriers, and developing plans for relapse prevention.[21–23] By applying these techniques, awareness about a healthy lifestyle is created, which supports behavioral change.[24] The program consists of 2 parts:

- In part I of the OPTICARE XL CR program, 60- to 90-minute exercise sessions were provided twice a week for 12 weeks. These sessions comprised a combination of aerobic training with mainly nonweight-bearing exercises (eg, on cycle ergometer, rowing ergometer) and muscle strength training (using physical fitness equipment) aimed at expansion to activities with a higher caloric energy expenditure.[14,15] Exercise sessions were provided in groups of 6 to 8 patients. In addition to usual information sessions and facultative modules as offered in the standard CR program (see below), patients received 2 peer group coaching modules. Social workers and psychologists frequently assisted in both modules, and all therapists were trained in motivational interviewing.[25] The first was the *Healthy Weight module* and was provided once a week by a dietician. Each session started with measuring body weight and waist circumference to enhance self-monitoring, after which a different topic was discussed weekly (Fig. 2). The second module was the *Active Lifestyle module*, which was provided by a physical therapist once every 3 weeks. During this module, not only regular physical activity was stimulated, but there was also attention for the prevention of SB. Self-monitoring and goal setting were enhanced by using an activity tracker (Garmin VivoSmart HR XL). Every patient randomized to OPTICARE XL CR was offered an activity tracker for the duration of both parts of the OPTICARE XL CR program. Patients were encouraged to use the Garmin app on their smartphone, although self-monitoring was also possible

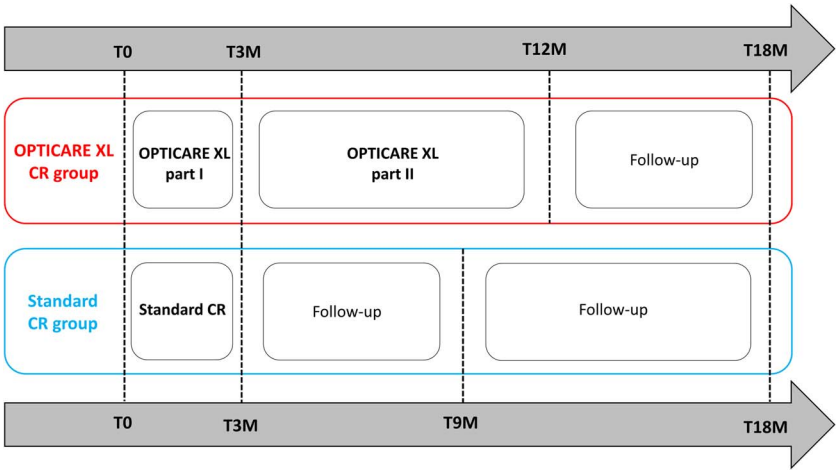

Figure 1. Patients were randomized in 1 of 2 groups. Within each group, 4 measurements were performed within 18 months. Part I of the OPTICARE XL CR program lasted 3 months, part II lasted the following 9 months. Standard CR lasted for 3 months. CR = cardiac rehabilitation; M = month.

Topics addressed in Healthy Weight Module of the OPTICARE XL CR program:

- Goal setting (SMART method)
- Consciously eating
- Different types of eating behavior
- Snacks between meals
- Going out to eat
- Salt
- How to make recipes more attractive
- Carbohydrates and sugars
- Determine portion sizes
- E-health
- Barriers
- Reading food labels

Figure 2. List of topics addressed in the Healthy Weight Module of the OPTICARE XL CR program.

without using this app. The activity tracker was used for motivational purposes only, therefore, we did not collect or used data from the activity trackers.

- Part II consisted of a 9-month aftercare program, which included 6 booster sessions comprising topics of the *Healthy Weight* and *Active Lifestyle modules* and provided time for questions or topics brought in by patients. Peer support was further created by a group chat on the mobile phone in which participation was voluntary.

Standard CR was based on the ESC guidelines.[1,2] Patients allocated to this group received 60- to 90-minute exercise sessions (mainly weight-bearing activities such as walking, jogging, sports) twice a week in groups of 10 to 25 patients, including both patients who are obese and who are not obese. The total duration was 6 to 12 weeks. Exact duration of the CR program depended on progression and goals of the patient as determined by a multidisciplinary team (consisting of physiotherapists, nurses, psychologist or social workers, dieticians, cardiologists, and sport physicians). Exercise training was complemented with group information sessions on risk factors for cardiovascular diseases and facultative counseling modules on a healthy diet, stress management, or smoking cessation. Individual psychological counseling was offered on indication.

Outcomes and Assessments

Data on sex, age, BMI, reason for referral to CR, marital status, educational level, work status, and presence of cardiac risk factors were collected at the start of CR for descriptive purposes. Marital status (partnered or unpartnered), educational level (low, intermediate or high), and work status (employed or unemployed) were collected by a questionnaire developed for the purpose of the study. Cardiovascular risk factors were collected from medical files. Assessment of all outcomes was performed by scientific researchers not involved in the treatment of patients, both during baseline and during follow-up.

Outcomes included body weight, physical activity, SB, and physical fitness. Assessment of outcomes:

- Body weight (kg) was measured without shoes and pockets emptied on a calibrated weight scale (Seca 813).
- Physical activity and SB were objectively measured by an ActiGraph GT3X+. Patients were instructed to wear the accelerometer on the right hip for 7 consecutive days during waking hours, except during showering or swimming. Only when patients wore the device for at least 4 days and 660 minutes per day, the measurement was included in the analysis. Nonwear time was defined as a minimum of 60 minutes of consecutive zero counts. Data were sampled at 30 Hz and processed in ActiLife software. The intensity level of each 15 second epoch was determined by using the following cut-points: $\leq$37.5 counts were marked as SB, $>$37.5 and $<$672.5 counts as light physical activity (LPA), and $\geq$672.5 counts as moderate-to-vigorous physical activity (MVPA).[26–28] Duration of time spent in LPA, MVPA, and SB expressed as a percentage of total wear time was used to describe physical activity and SB. Additionally, steps per day were calculated.

- Physical fitness was measured by means of 2 tests: the 6-Minute Walk Test (6MWT) and a handgrip strength test. The 6MWT is a reliable and valid submaximal test to evaluate aerobic capacity, and was performed according to the American Thoracic Society guidelines over a 30-meter-long walking track.[29,30] The number of meters walked after 6 minutes was used as the outcome measure. Hand grip strength is commonly used as a measure of overall muscle strength and was assessed by using a hydraulic hand dynamometer (Jamar).[31] Patients were asked to hold the dynamometer with maximal force for 3 seconds while maintaining a 90° elbow flexion while seated. Three trials per hand were performed, starting with the dominant hand. The average of 3 trials of the dominant hand was used as the outcome measure.

Study Endpoints

The primary study endpoint of the OPTICARE XL study was HRQOL. Outcomes related to this endpoint are described separately.[17] The current paper focusses on the following secondary outcomes: change in body weight, physical activity, SB, and physical fitness from the start of CR to 6 months post-CR. This meant that we compared the change from the start of CR to 9 months after the start of CR in the standard CR group with the change from start of CR to 18 months after the start of CR in the OPTICARE XL CR group. Additionally, changes in these outcomes were also assessed on the short-term, namely at 3 months after the start of the program (change T0-T3M in standard CR group vs change T0-T3M in OPTICARE XL CR group).

Sample Size Calculation

The sample size calculation was based on an estimated effect on HRQOL, which is described separately.[17] A total of 200 patients were needed in our study.

Statistical Analyses

Baseline data were depicted for the OPTICARE XL CR and standard CR group separately. In case of a normal distribution, continuous variables are depicted as mean ± standard deviation (SD), and as median (25th to 75th percentile) otherwise. Categorical data are displayed as numbers and percentages.

Changes in study endpoints were studied by linear mixed-effect models. Treatment allocation (OPTICARE XL CR or standard CR) was modeled as fixed effect and "time" (baseline or follow-up measurement) as random effect. Treatment × time interaction was added to study change differences in study endpoints between the randomly allocated treatments. All models were corrected for age and sex (fixed effects).

The main analysis was based on the intention-to-treat principle. To gain insight into the effects in patients who actually followed the program, we also performed a per-protocol analysis. Patients who attended at least 75% of the exercise training sessions (both OPTICARE XL CR and standard CR) and at least 75% of the *Healthy Weight module* and *Active Lifestyle module* (OPTICARE XL CR) were included in the per-protocol analysis.

All analyses were performed in R Statistical software (Version 1.3.1093, RStudio Team (2020). RStudio: Integrated Development Environment for R. RStudio, PBC, Boston, MA, http://www.rstudio.com/). For all tests, a 2-sided *P*-value < .05 was considered statistically significant.

Table 1. Baseline Characteristics of the Study Population ($n = 201$)[17,a]

Characteristic	OPTICARE XL CR ($n = 102$)	Standard CR ($n = 99$)
Males, *n* (%)	68 (66.7)	78 (78.8)
Age, y[b]	59.0 (10.0)	59.2 (8.8)
BMI, (kg/m^2)[c]	34.4 (4.7)	34.1 (4.6)
Referred to CR for, *n* (%)		
• CAD	62 (60.8)	71 (71.7)
• AF with ablation	7 (6.9)	4 (4.0)
• AF without ablation	33 (32.4)	24 (24.2)
Marital status, *n* (%)		
• Partnered	71 (74.7)	69 (77.5)
• Unpartnered	24 (25.3)	20 (22.5)
Missing[d]	*7*	*10*
Educational level, *n* (%)		
• Low	8 (8.5)	*5* (5.7)
• Intermediate	58 (61.7)	65 (73.9)
• High	28 (29.8)	18 (20.5)
Missing[d]	*8*	*11*
Work status, *n* (%)		
• Employed	50 (53.2)	*56* (66.7)
• Unemployed	44 (46.8)	28 (33.3)
Missing[d]	*8*	*15*
Risk factors, *n* (%)		
• Family history of CVD	48 (47.1)	50 (50.5)
• Diabetes	29 (28.4)	28 (28.3)
• Hypertension	*57* (55.9)	*57* (57.6)
• Dyslipidaemia	33 (32.4)	49 (49.5)
• Smoking before CR	33 (32.4)	25 (25.3)

[a]AF = atrial fibrillation; CAD = coronary artery disease; CR = cardiac rehabilitation; CVD = cardiovascular disease. [b]Normally distributed: mean (SD). [c]Not normally distributed: mean (IQR). [d]Data not available.

Role of the Funding Source

The funders played no role in design, conduct, or reporting of this study.

Results

Patient Population

A total of 698 patients with obesity were screened for eligibility, of which 201 were included and randomized to OPTICARE XL CR ($n = 102$) or standard CR ($n = 99$) between February 2017 and January 2019 (Fig. 3). Problems with transportation, not wanting to participate in scientific research, and lack of time were most often reported as reasons for declining participation. Baseline characteristics were similar in both treatment arms (Tab. 1). Patients had a mean (SD) age of 59.1 (9.4) years, and 73% were male. Last measurements were performed in July 2020.

Wear Time and Success of Accelerometer Measurements

Overall, average accelerometer wear time was 14.1 (SD = 1.1) hours per day, and 64.7% of measurements were successful. Unsuccessful measurements were mainly due to failure to wear the accelerometer for a sufficient amount of hours and days, or refusal to wear the accelerometer due to discomfort.

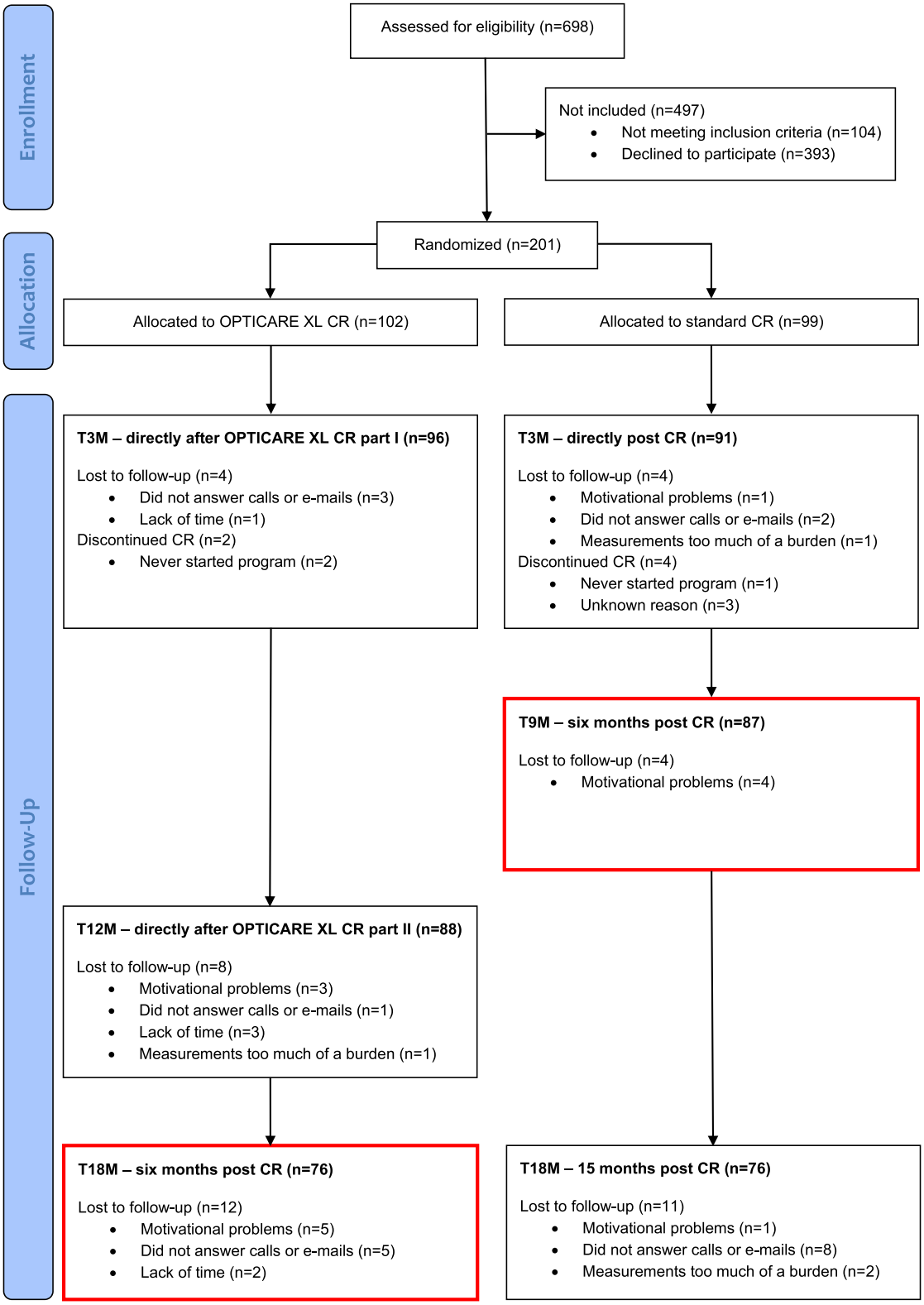

Figure 3. Included patients were randomized into 1 of 2 groups: OPTICARE XL CR ($n = 102$) or standard CR ($n = 99$). Six months post-CR (primary study endpoint), 26 patients in the OPTICARE XL CR group, and 12 patients in the standard CR group were lost to follow-up. Reasons for lost to follow-up were motivational problems, not answering calls or e-mails, and lack of time.

Table 2. Outcomes at the Start and 6 Months Post-CR[a]

Outcome	Measurement Point	OPTICARE XL CR[b]	Standard CR[b]	Difference in Change Between Standard CR and OPTICARE XL CR, *P*
Body weight, kg (*n* = 201)	Start of CR	103.5 (99.7 to 107.4)	102.4 (98.1 to 106.7)	.959
	Six months post-CR	101.1 (97.1 to 105.0)	99.9 (95.6 to 104.2)	
	Δ	−2.5 (−4.0 to −0.9)[c]	−2.5 (−4.0 to −1.1)[c]	
Steps per day (*n* = 169)	Start of CR	5190 (4487 to 5893)	5364 (4533 to 6196)	.919
	Six months post-CR	5473 (4637 to 6310)	5695 (4812 to 6579)	
	Δ	283 (−372 to 939)	331 (−312 to 974)	
% in LPA (*n* = 169)	Start of CR	28.8 (27.1 to 30.5)	28.0 (26.0 to 30.0)	.885
	Six months post-CR	30.0 (27.9 to 32.0)	29.0 (26.9 to 31.2)	
	Δ	1.2 (−0.5 to 2.8)	1.0 (−0.6 to 2.6)	
% in MVPA (*n* = 169)	Start of CR	5.6 (4.8 to 6.5)	5.5 (4.5 to 6.5)	.992
	Six months post-CR	6.2 (5.2 to 7.3)	6.1 (5.0 to 7.1)	
	Δ	0.6 (−0.3 to 1.4)	0.6 (−0.3 to 1.4)	
% in SB (*n* = 169)	Start of CR	65.6 (63.4 to 67.7)	66.5 (64.0 to 69.0)	.895
	Six months post-CR	63.8 (61.3 to 66.3)	64.9 (62.3 to 67.6)	
	Δ	−1.7 (−3.7 to 0.2)	−1.5 (−3.5 to 0.4)	
Distance 6MWT, m (*n* = 185)	Start of CR	489 (469 to 510)	485 (462 to 508)	.915
	Six months post-CR	525 (501 to 549)	521 (497 to 546)	
	Δ	35 (18 to 53)[c]	37 (21 to 53)[d]	
HGS, kg (*n* = 201)	Start of CR	33.0 (31.2 to 34.8)	33.0 (31.0 to 35.0)	.984
	Six months post-CR	34.7 (32.8 to 36.7)	34.8 (32.7 to 36.8)	
	Δ	1.8 (0.5 to 3.0)[c]	1.7 (0.6 to 2.9)[c]	

[a]Results are based on multivariable linear mixed-effect modeling. Patients were included in the analysis if at least one measurement (baseline or follow-up) was available. 6MWT = 6-Minute Walk Test; CR = cardiac rehabilitation; HGS = handgrip strength; LPA = light physical activity; MVPA = moderate-to-vigorous physical activity; SB = sedentary behavior. [b] Values are expressed as mean (95% CI). [c]Significant (within group) change over time ($P < .05$). [d]Significant (within group) change over time ($P < .0001$).

At the start of CR, patients allocated to OPTICARE XL CR had a slightly higher average (SD) wear time per day (14.2 [1.1] vs 13.8 [1.0] hours; $P = .014$) and a higher percentage of successful measurements (90.2 vs 72.7%, $P = .005$) than patients allocated to standard CR (Suppl. Tab. I). Six months post-CR, average wear time and percentage of successful measurements were not significantly different between the 2 study groups.

Long-Term Changes in Body Weight, Physical Activity, Sedentary Behavior, and Physical Fitness

Six months post-CR, body weight, distance walked on the 6MWT, and handgrip strength improved significantly within patients allocated to OPTICARE XL CR as well as within patients allocated to standard CR, but the changes were similar in both treatment arms (Tab. 2). Mean body weight decreased in the OPTICARE XL CR group from 103.5 to 101.1 kg (mean change = −2.5; 95% CI = −4.0 to −0.9) and from 102.4 to 99.9 kg (mean change = −2.5; 95% CI = −4.0 to −1.1) in the standard CR group (between-group difference, $P = .959$).

Outcomes of physical activity and SB did not change significantly within groups, nor between groups (Tab. 2).

Short-Term Changes in Body Weight, Physical Activity, Sedentary Behavior, and Physical Fitness

In the first 3 months after the start of CR, body weight decreased significantly more in the OPTICARE XL CR group from 103.5 to 99.9 kg (mean change = −3.6; 95% CI = −4.4 to −2.8) than in the standard CR group, in which body weight decreased from 102.4 to 100.6 (mean change = −1.8; 95% CI = −2.6 to −1.0) (between-group difference, $P = .002$) (Tab. 3).

Patients allocated to OPTICARE XL CR showed a significant improvement in steps per day from 5226 to 6106 (mean change = 880; 95% CI = 357 to 1403), which was not significantly larger than the improvement from 5397 to 5878 steps per day (mean change = 481; 95% CI = −111 to 1073) in the standard CR group (between-group difference, $P = .324$). Both groups showed significant improvements in the percentage of wear time in LPA, MVPA, and SB, as well as in the distance walked on the 6MWT and handgrip strength, without significant between-group differences.

Per-Protocol Analysis

A total of 65 of 102 patients (63.7%) of the OPTICARE XL CR group and 69 of 99 patients (69.7%) of the standard CR group met the criteria for the per-protocol analyses. Results are shown in Supplemental Tables II and III. No significant between-group differences in body weight, physical activity, sedentary behavior, and physical fitness were observed 6 months after CR.

Three months after the start of CR, patients allocated to OPTICARE XL CR showed, on average, a significantly larger reduction in body weight from 102.4 to 98.5 (mean change = −3.9; 95% CI = −4.9 to −2.9) compared with an average change of −1.9 kg in the standard CR group (95% CI = −2.8 to −0.9) (between-group difference, $P = .003$).

Discussion

This paper described the added value of the 1-year OPTICARE XL CR program compared with standard CR on secondary outcomes reflecting a heart-healthy lifestyle in patients with cardiac disease who are obese. Three months after the start, we observed a significantly greater mean weight loss in patients allocated to OPTICARE XL CR than in

Table 3. Outcomes at the Start and 3 Months After the Start of CR[a]

Outcome	Measurement Point	OPTICARE XL CR[b] (*n* = 102)	Standard CR[b] (*n* = 99)	Difference in Change Between Standard CR and OPTICARE XL CR, *P*
Body weight, kg (*n* = 201)	Start of CR	103.5 (99.7 to 107.2)	102.4 (98.2 to 106.5)	.002[d]
	Three months after start	99.9 (96.1 to 103.6)	100.6 (96.4 to 104.7)	
	Δ	−3.6 (−4.4 to −2.8)[c]	−1.8 (−2.6 to −1.0)[c]	
Steps per day (*n* = 171)	Start of CR	5226 (4533 to 5919)	5397 (4577 to 6216)	.324
	Three months after start	6106 (5375 to 6838)	5878 (5017 to 6738)	
	Δ	880 (357 to 1403)[d]	481 (−111 to 1073)	
% in LPA (*n* = 171)	Start of CR	28.9 (27.3 to 30.5)	27.8 (25.9 to 29.7)	.763
	Three months after start	31.0 (29.3 to 32.7)	29.6 (27.6 to 31.6)	
	Δ	2.1 (0.9 to 3.2)[d]	1.8 (0.4 to 3.1)[d]	
% in MVPA (*n* = 171)	Start of CR	5.7 (4.8 to 6.5)	5.4 (4.4 to 6.4)	.353
	Three months after start	6.9 (6.0 to7.8)	6.2 (5.1 to 7.2)	
	Δ	1.2 (0.6 to 1.8)[d]	0.8 (0.1 to 1.5)[d]	
% in SB (*n* = 171)	Start of CR	65.4 (63.4 to 67.4)	66.8 (64.4 to 69.1)	.544
	Three months after start	62.1 (60.1 to 64.2)	64.2 (61.7 to 66.6)	
	Δ	−3.2 (−4.6 to −1.9)[c]	−2.6 (−4.2 to −1.0)[d]	
Distance 6MWT, m (*n* = 186)	Start of CR	490 (469 to 512)	489 (464 to 513)	.497
	Three months after start	535 (513 to 556)	525 (500 to 550)	
	Δ	44 (30 to 59)[c]	37 (20 to 53)[c]	
HGS, kg (*n* = 201)	Start of CR	33.0 (31.2 to 34.8)	33.1 (31.1 to 35.0)	.411
	Three months after start	34.2 (32.4 to 36.0)	34.8 (32.8 to 36.8)	
	Δ	1.2 (0.3 to 2.1)[d]	1.7 (0.8 to 2.6)[d]	

[a]Results are based on multivariable linear mixed-effect modeling. Patients were included in the analysis if at least one measurement (baseline or follow-up) was available. 6MWT = 6-Minute Walk Test; CR = cardiac rehabilitation; HGS = handgrip strength; LPA = light physical activity; MVPA = moderate-to-vigorous physical activity; SB = sedentary behavior. [b] Values are expressed as mean (95% CI). [c]Significant (within group) change over time ($P < .0001$). [d]Significant (within group) change over time ($P < .05$).

patients allocated to standard CR. Patients allocated to OPTICARE XL CR also significantly improved their steps per day, although this improvement was not significantly larger than the improvement in standard patients receiving CR. During the first 3 months after the start of CR, the time spent in different intensity levels of physical activity and in SB, as well as physical fitness outcomes significantly improved within both groups, without significant between-group differences. However, 6 months after the completion of either program, which was our primary endpoint, no significant between-group differences were observed, implying no added value of OPTICARE XL CR.

Individuals who are affected by obesity have a higher risk on cardiac diseases, diabetes mellitus, hypertension, and dyslipidaemia.[32] Therefore, weight reduction in patients with cardiac disease and comorbid obesity is of paramount importance. We observed a significantly greater weight loss in the OPTICARE XL CR group than in the standard CR group (−3.6 kg vs −1.8 kg resp.) in the first 3 months after the start of either program. The weight loss observed in the standard CR group is comparable to weight loss found in other studies in patients with obesity attending standard CR.[7,8] More weight loss in patients allocated to OPTICARE XL CR points at potential added value of the new program. Although the weight loss achieved in OPTICARE XL CR was still <5% (namely 3.5%), which is stated as the minimum weight loss to decrease cardiac risk,[4–6] one can question whether a weight loss of ≥5% is achievable within a time frame of 3 months. The Obesity Management Task Force of the European Association for the Study of Obesity and the American Heart Association Task Force on Practice Guidelines and The Obesity Society state that a weight loss of 5 to 15% in a 6-month period is realistic and recommended.[33,34] Unfortunately, the initial additional benefits of the OPTICARE XL CR were not further expanded nor maintained during the aftercare phase.

Increasing daily physical activity levels during and after CR is known to be a challenge for patients with cardiac disease in all BMI classes.[9] In patients with cardiac disease who have obesity, sufficient physical activity is an essential component in improving cardiac health and achieving weight loss.[4,35] It is estimated that a number of 6500 steps per day is needed to comply with current recommendations for daily physical activity for secondary prevention of cardiovascular disease.[36] Patients in our study did not reach this threshold; however, we observed a significant mean improvement of 880 steps per day in the OPTICARE XL CR group within the first 3 months. Although this improvement was not significantly larger than the improvement of 481 steps per day in the standard CR group, the numerical difference does indicate a potential added value of OPTICARE XL CR on physical activity. However, improvements in steps per day did not sustain up to 6 months post-CR, within neither of the 2 groups. Time spent in LPA and MVPA improved equally within both groups during the first 3 months and did not sustain in the longer term, which suggests no short-term or long-term additional benefit of the OPTICARE XL CR program. For LPA and MVPA, no threshold levels are established yet for patients with cardiac disease who are obese, but it has been shown that less time in LPA and MVPA is related to a higher risk of all-cause mortality.[37] Thus, since steps per day were not maintained after ending OPTICARE XL CR part I and no additional gains were observed in LPA and MVPA levels, future research should focus on developing effective methods to increase physical activity in daily life in patients with obesity.

Preventing SB was also a topic frequently discussed during the *Active Lifestyle module* of OPTICARE XL CR. Even

though our patients significantly decreased their SB during the first 3 months of either program, decreases were no longer observed 6 months post-CR. Patients in both study groups still spent over 9 hours per day sedentary at 6 months post-CR, while it is known that every hour increase above 7 hours of sedentary time per day is associated with a 5% increase in all-cause mortality.[38] Thus, preventing SB in patients with cardiac disease who are obese still deserves extra attention during CR.

We hypothesized that a CR program specially designed for patients with obesity, including a combination of aerobic and strength training in smaller groups with only peers who are obese, would result in larger improvements in physical fitness than standard CR. Patients within both study groups showed significant improvements in 6MWT distance above the minimal clinically important difference of 25 meters previously reported for patients with CAD,[39] but without significant between-group differences. Handgrip strength at baseline and 3 months after the start of CR in the present study was comparable to pre- and post-CR values in a previous study in 666 patients with cardiac disease and a mean BMI of 29.0 kg/m^2.[40] To our knowledge, a minimal clinically important difference in handgrip strength is not yet established in patients with cardiac disease. Since improvements in physical fitness outcomes were seen in both study groups and were sustained on the long-term, we conclude that OPTICARE XL CR has no added value regarding improving physical fitness. Nonetheless, we would still advise to provide a combination of aerobic and strength training in patients with obesity because of the lower risk on musculoskeletal complaints and higher chance to facilitate weight loss.[14,15]

Altogether, we observed minimal improvements in parameters of a heart-healthy lifestyle within both study groups at our primary endpoint 6 months after the completion of either program. Body weight decreased significantly more in patients allocated to OPTICARE XL CR within the first 3 months. Improvements in steps per day were promising on the short-term, though not maintained on the long-term. These findings indicate that finding the optimal CR program for patients with obesity remains a challenge. To further expand the initial benefits, we would advise to redesign the aftercare phase of the OPTICARE XL CR program. During our trial period, we performed semistructured interviews with health professionals, organized patient meetings, and frequently discussed results with scientists, thereby gathering information that can be used to evaluate and redesign the program. A suggestion for redesign, which was suggested during interviews with health professionals, could be the use of digital platforms to guide patients toward an active and healthy lifestyle when face-to-face counseling stops. The frequency of sessions during part II of the program (only 6 in a 9-month period) was probably too low to stay motivated to work on lifestyle changes. For the use of digital platforms for remote guiding during this phase, knowledge obtained during the COVID-19 pandemic might be helpful.[41] Another suggestion could be to use the activity tracker in a more standardized way, especially in the aftercare phase, since previous research has shown the benefits of activity trackers and apps in lifestyle outcomes after completion of CR.[42,43]

Strengths and Limitations

A major strength of the present randomized trial is the close collaboration between health professionals, patients, and scientists of Capri Cardiac Rehabilitation and Erasmus University Medical Centre in the design of the OPTICARE XL CR program. Another strength of our trial is the usage of accelerometers to objectively assess physical activity and SB, which is preferred over subjective measurement tools such as questionnaires.[44,45] A limitation of the study is the difference in percentage of successful measurements and average wear time of the accelerometer between study groups. The difference in wear time is not expected to have influenced the results since outcomes of intensity are expressed as a percentage of wear time, and patients of whom the wear time was unrepresentative (less than 4 days of 660 minutes per day) were excluded from analysis. The percentage of successful measurements was lower in the standard CR group on 2 time points. Since the number of patients who were lost to follow-up was equal between the 2 study groups, we do not expect that this difference in successful accelerometer measurements was due to allocated treatment. Another limitation of the current study might be the chosen study design. Since we recruited patients for an extensive RCT, focusing on obesity and with a relatively long follow-up period, we might have included a series of highly motivated patients. To avoid this and be able to draw conclusions from a group of patients that reflect patients with obesity better, we propose to perform prospective research outside the framework of a RCT, for example by means of a cohort study or by using a national registry. Lastly, we observed a drop-out of approximately 25% within both study groups. This drop-out rate was comparable to observed drop-out in a comparable trial investigating the effects of 2 advanced and extended CR programs.[28]

Conclusions

Although on the short-term, patients allocated to OPTICARE XL CR lost significantly more body weight and showed promising results with respect to physical activity, the OPTICARE XL CR program did not result in larger improvement than standard CR on the longer term. Finding the optimal CR program for patients with obesity remains a challenge. To further expand initial benefits, we would advise to redesign the after-care phase of the OPTICARE XL CR program.

Authors' Contributions

Concept/idea/research design: I. den Uijl, R.J.G. van den Berg-Emons, N. ter Hoeve
Writing: I. den Uijl, R.J.G. van den Berg-Emons, M. Sunamura, H.J. Stam, E. Boermsa, N. ter Hoeve
Data collection: I. den Uijl, M. Sunamura, N.C.C.W. Tenbült-van Limpt, N. ter Hoeve
Data analysis: I. den Uijl, R.J.G. van den Berg-Emons, N. ter Hoeve
Project management: I. den Uijl, R.J.G. van den Berg-Emons, M. Sunamura, N. ter Hoeve
Fund procurement: R.J.G. van den Berg-Emons, H.J. Stam
Providing participants: I. den Uijl, N.C.C.W. Tenbült-van Limpt, N. ter Hoeve
Providing facilities / equipment: M. Sunamura, H.M.C. Kemps
Consultation (including review of manuscript before submitting): I. den Uijl, R.J.G. van den Berg-Emons, M. Sunamura, M.J. Lenzen, H.J. Stam, E. Boersma, N.C.C.W. Tenbült-van Limpt, H.M.C. Kemps, M.L. Geleijnse, N. ter Hoeve

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Ethics Approval

The study protocol was approved by the Medical Ethics Committee of the Erasmus MC, University Medical Centre Rotterdam, the Netherlands (MEC-2016-622).

Clinical Trial Registration

This trial registration was prospectively registered in the International Clinical Trial Registry Platform (ICTRP), (https://trialsearch.who.int/. Main ID: NTR6181).

Data Availability

The dataset generated and analyzed during the current study is available in DANS, at https://easy.dans.knaw.nl/ui/datasets/id/easy-dataset:204552.

Disclosures

The authors completed the ICMJE Form for Disclosure of Potential Conflicts of Interest and reported no conflicts of interest.

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