

# Early physical training and psycho-educational intervention for patients undergoing coronary artery bypass grafting. The SheppHeart randomized 2 × 2 factorial clinical pilot trial

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## Abstract

**Background:** Patients undergoing coronary artery bypass graft surgery often experience a range of problems and symptoms such as immobility, pain and insufficient sleep. Results from trials investigating testing in-hospital physical exercise or psychological intervention have been promising. However, no randomized clinical trials have tested a comprehensive rehabilitation programme consisting of both physical exercise and psycho-education in the early rehabilitation phase.

**Aims:** The aims of the present SheppHeart pilot randomized clinical trial were to evaluate the feasibility of patient recruitment, patient acceptance of the intervention, safety and tolerability of the intervention.

**Methods and design:** Sixty patients admitted for coronary artery bypass graft were randomized 1:1:1:1 to: 1) physical exercise plus usual care, or 2) psycho-educational intervention plus usual care, or 3) physical exercise and psycho-educational plus usual care, or 4) usual care alone during a four week period after surgery.

**Results:** The acceptability of trial participation was 67% during the three month recruitment period. In the physical exercise groups, patients complied with 59% of the total expected training sessions during hospitalization. Nine patients (30%) complied with >75% and nine patients (30%) complied with 50% of the planned exercise sessions. Eleven patients (42%) participated in ≥75% of the four consultations and six patients (23%) participated in 50% of the psycho-educational programme.

**Conclusion:** Comprehensive phase one rehabilitation combining physical exercise and psycho-education in coronary artery bypass graft patients shows reasonably high inclusion, feasibility and safety.

## Keywords

Phase one rehabilitation, coronary artery bypass grafting, physical exercise, psycho-education.

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## Introduction

Coronary artery bypass grafting (CABG) is one of the most frequent types of open heart surgery in the western world. The average yearly CABG rate in Europe is 490 per million inhabitants. In Denmark, this figure is 740 per million.<sup>1</sup> Surgery outcomes are generally good, but recovery can be complicated. Patients undergoing CABG often experience a range of physical and psychological problems and symptoms<sup>2</sup> which are related to the procedure and the underlying heart disease. These problems include anxiety and depressive symptoms, immobility issues, complications such as neck and shoulder pains, respiratory complications, insufficient sleep and postoperative fatigue.<sup>2</sup>

Cardiac rehabilitation is an important aspect of recovery after heart surgery. Cardiac rehabilitation programmes are generally divided into three main phases: phase 1, which is inpatient cardiac rehabilitation; phase 2, which is early outpatient cardiac rehabilitation; and phase 3, which is long-term outpatient cardiac rehabilitation. It has been established that exercise training in cardiac rehabilitation after hospital discharge in phase 2 has a positive effect in patients after CABG<sup>3</sup> and for this reason phase 1 rehabilitation starting in hospital seems reasonable,<sup>4</sup> but evidence regarding phase 1 rehabilitation is sparse in CABG populations.

Exercise interventions such as respiratory physiotherapy or aerobic training in phase 1 rehabilitation after CABG have demonstrated improvements in patient outcomes measured by pulmonary complications and physical functional capacity.<sup>5,6</sup> Also psycho-educative interventions have a positive influence on anxiety and depression in the post-hospital recovery period.<sup>7</sup> A combined rehabilitation approach consisting of physical exercise and psycho-education has been found to improve various patient outcomes such as physical and psychological functioning.<sup>8</sup> Trials targeting psychological interventions in the early postoperative period after CABG have shown improvements in depression and anxiety symptoms; however, no randomized clinical trials with sufficient power have been published.<sup>9</sup> Mindfulness-based interventions have been found effective in reducing anxiety and other types of psychological distress in a wide range of contexts, including a few promising results in patients with cardiovascular disease. But more scientific knowledge about the implementation, acceptability and effects of mindfulness during a cardiovascular hospitalization is needed.

Accordingly, there is a need for trials to investigate the effectiveness of physical rehabilitation and psycho-education in the early postoperative phase after CABG. Before a large trial is mounted, uncertainties regarding patient recruitment and feasibility of the interventions should be addressed in a pilot trial. Therefore, the aims of the present pilot trial are: (i) to evaluate the feasibility of

patient recruitment and interventions; (ii) to test the safety and tolerability of the interventions; and (iii) to provide outcome data that can be used for sample size calculations in a comprehensive randomized clinical trial.

## Materials and methods

### *Trial design, population*

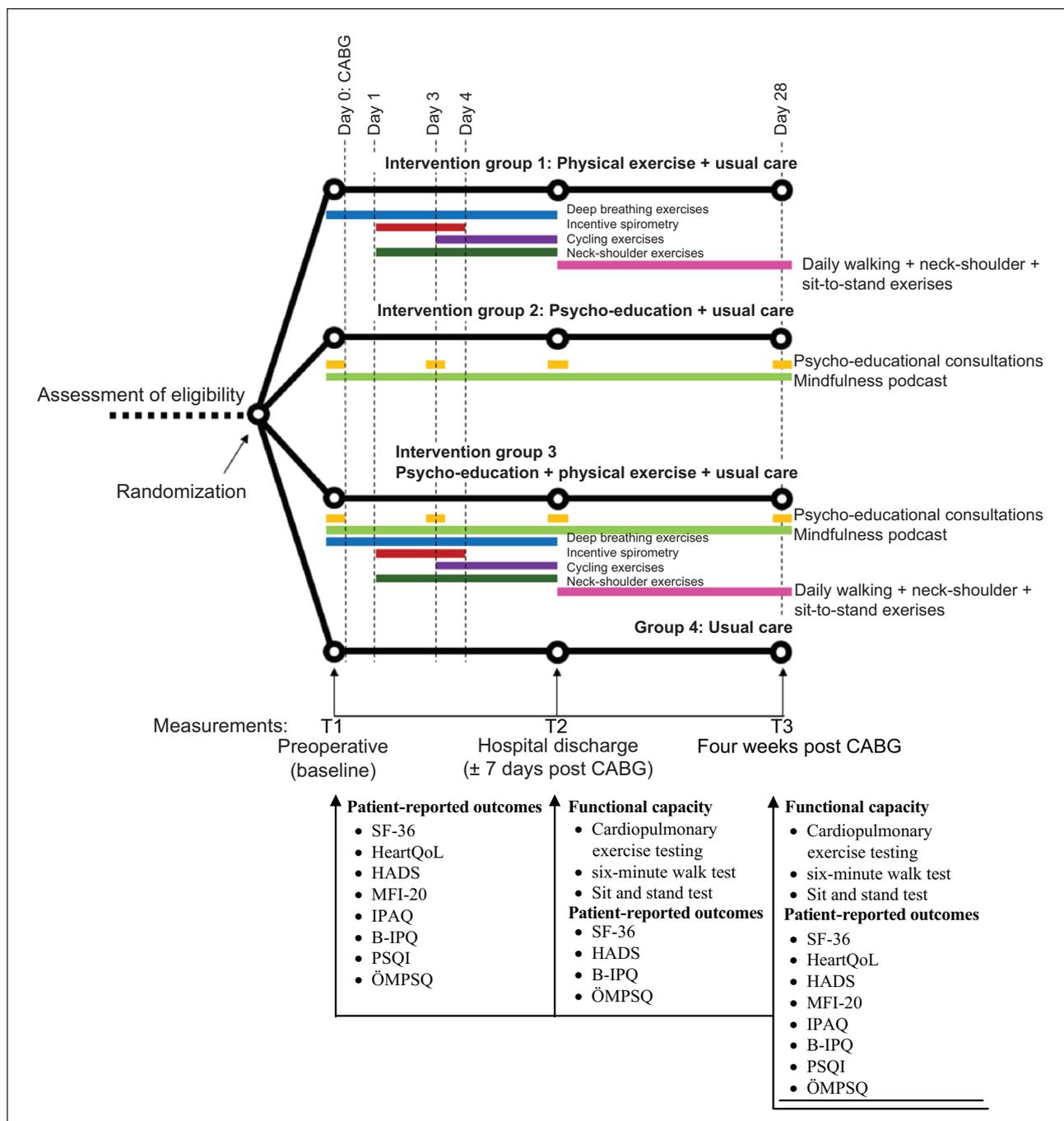
The SheppHeartCABG (SheppHeart is the acronym for 'SHaping outcomes by Exercise training and Psycho-education in Phase 1 for Heart patients') pilot was designed as an investigator-initiated 2 × 2 factorial randomized clinical pilot trial with blinded outcome assessment. The setting was a thoracic clinic at a large university hospital in Denmark. Included were patients who were going to receive first time elective CABG, who gave informed consent. Excluded were patients younger than 18 years of age, diagnosed with a musculoskeletal or neurological disease precluding exercise testing and training, who were non-Danish speaking and who did not consent. The four intervention groups were: 1) physical exercise plus usual care; 2) psycho-educative intervention plus usual care; 3) physical exercise plus psycho-educative intervention plus usual care; and 4) usual care alone. Recruitment was undertaken at one site, with a 1:1:1:1 central randomization. The allocation sequence was computer-generated in varying block sizes of 8 and 12 and kept unknown to the investigators.

### *Interventions*

Figure 1 details the intervention components and their timing for the four intervention groups.

**Usual care.** All patients followed the usual care procedure. The patients were admitted the day before surgery and discharged on postoperative day 6–8. The usual care programme included medical follow-up as well as standard treatment according to disease specific guidelines. The physiotherapist instructed patients at admission how to cough, protect their sternum, sit down and get up from a chair, get out of bed and take daily walks after surgery and answered patients' questions. There was no respiratory physiotherapy in usual care but, if needed, it could be prescribed by the physician. Group training for patients who had undergone heart surgery and were ready to discharge was offered in the gym three days a week. Furthermore, at hospital discharge the physiotherapist gave directions on how to manage daily activities with sternotomy, advice on being physically active daily and shoulder and neck exercises after hospital discharge.

The main features of preoperative care were: admission interview, preoperative screening (falls, nutrition),



**Figure 1.** Trial design.

SF-36: Medical Outcome Study Short Form 36; HeartQoL: HeartQoL questionnaire; HADS: Hospital Anxiety and Depression Scale; MFI-20: Multidimensional Fatigue Inventory-20; IPAQ: International Physical Activity Questionnaire; B-IPQ: Brief Illness Perception Questionnaire; PSQI: Pittsburgh Sleep Quality Index; ÖMPSQ: Örebro Musculoskeletal Screening Questionnaire

introduction to postoperative pain and nausea medication, pain assessment and postoperative activities. Furthermore, patients were prepared for surgery by an introduction to fasting procedures, epilation and a disinfecting bath. The early postoperative care was focused on observation of vital signs. The remaining hospitalization included recovery and preparation for hospital discharge. Psychological

issues were discussed with a nurse as needed. At hospital discharge, the patient was informed of long-term care issues, for example, care of scar tissue; identification, prevention and care of infection; pain management; and driving, swimming, and lifting restrictions. Usual care did not include systematic psycho-educational follow-up, mindfulness or systematic physical exercise.

**Physical exercise component.** The physical interventions were administered by physiotherapists and consisted of exercise programmes that started at admission and continued to four weeks after CABG. The physical intervention was divided into two parts: respiratory physiotherapy and aerobic training. Respiratory physiotherapy consisted of deep breathing exercises and incentive spirometry with positive expiratory pressure airway. Deep breathing exercises extended from admission to hospital discharge. Between 08:00 and 22:00, participants performed 7–10 deep breaths four times. Incentive spirometry was performed from postoperative day 1 to day 4 by deep breathing with positive expiratory pressure for 3–5 min twice daily. Related to the respiratory physiotherapy, patients performed neck and shoulder exercises consisting of rolling and lifting the shoulders, looking over one shoulder and then moving the head in a semicircle in front of the body to the opposite shoulder. Each exercise was repeated 10 times and done twice daily from postoperative day 1 until hospital discharge.

The aerobic training was on a stationary bicycle with moderate intensity. Patients were familiarized with the RPE (Ratings of Perceived Exertion) Borg scale®<sup>10</sup> prior to the first three sessions and were instructed to exercise at an RPE of 13–15 ('moderate' to 'somewhat strong') on a scale from 6 to 20. At the three first cycling sessions, heart rate and saturation were measured and patients used pulse watches during cycle training. Cycling interventions were 10-min sessions preceded by 5-min warm-ups and followed by 5 min of cool-down to achieve cardiovascular adjustment and reduce the risk of ischaemia and arrhythmia. The intensity at warm-up and cool-down was  $\leq 10$  RPE Borg and the cycling sessions were performed from postoperative day 3 until discharge twice daily, morning and afternoon.

After hospital discharge, until four weeks after CABG, physical exercise consisted of daily walking with increasing duration, and muscle and endurance exercises consisted of sit-to-stand and heel lifting exercises with increasing number of repetitions. The physiotherapist introduced the exercises, enabling patients to perform the exercise sessions independently at home (Figure 1).

**Psycho-educational component.** The psycho-educative intervention consisted of four individual consultations with a nurse: at admission, postoperative day 3, day of hospital discharge, and four weeks after surgery. The intervention had a theoretical basis of the patient-centred approach where the emphasis was on support and education. The method was based on a holistic patient view and focus on the handling of life and managing time post CABG. The topics dealt with initially covered life before admission and CABG surgery, present life, and visions of future short- and long-term life. Subsequently, events and opportunities were explored and discussed and imagined possibilities were pursued, inspired by three dimensions of RR Parse's

*The Human Becoming School of Thought: A Perspective for Nurses and Other Health Professionals.*<sup>11</sup> According to this theory, three ways of changing health are possible: (i) creative imaging; that is, to see, hear and feel what a situation might be like if lived in a different way; (ii) affirming personal patterns and value priorities; and (iii) shedding light on paradoxes, that is, looking at the incongruence in a situation and changing existing views. The emphasis was on openness in the interviews and on the nurse's ability to be silently present while the patient talked, asking questions that encouraged reflection, letting the patient find answers and solutions, and to contribute with knowledge and provide advice and guidance when it was requested and relevant. An inspirational guide formed the basis for the consultations. The guide (Table 1) consisted of several elements and issues (medical, psychosocial and educational) as inspiration.

Finally, elements of mindfulness were integrated into the psycho-educational component, as support for stress reduction, capacity for intimacy, and self-care through meditation-based exercises. The delivery of the elements of mindfulness was adapted to fit into the clinical situation where standardized group-based courses of mindfulness exercises would not have been feasible. Instead, nurses were trained in introducing mindfulness exercises, and in mindfulness supported communication skills. During the first session with a patient, the nurse would give a brief introduction to mindfulness followed by an exercise. Depending on the patient's needs, this was briefly repeated at the following sessions. In addition, the mindfulness intervention included three guided meditation sessions on an mp3 player (recorded with the voice of the patient's own consulting nurse). Participants were encouraged to incorporate the mindfulness exercises into their daily lives during hospitalization and after hospital discharge.

## Outcomes

All participants were assessed three times: at admission (T1), at hospital discharge (T2) and four weeks post CABG (T3) (Figure 1). The following explorative outcomes were used. Physical capacity was measured by  $VO_2$  using a standardized protocol in accordance with guidelines<sup>12</sup> at hospital discharge and four weeks post CABG. The cardiopulmonary testing protocol consisted of a 4-min rest period followed by an increase every minute until exhaustion. Blood pressure and electrocardiogram were continuously monitored.  $VO_2$  was estimated from maximal wattage achieved. The tests follow current standards for cardiopulmonary exercise testing.<sup>13</sup>

Functional capacity was also measured by a six-minute walk test, leg strength and endurance measured by a sit-to-stand test performed at hospital discharge and four weeks post surgery. For the six-minute walk test, the participants walked up and down a 30 m hallway for 6 min according to the guidelines for the test.<sup>14</sup> For the sit-to-stand test, the participants repeatedly sat in a chair and got up to a full

**Table 1.** Inspiration guide for nursing consultation.

	C <sub>1</sub>	C <sub>2</sub>	C <sub>3</sub>	C <sub>4</sub>
Discuss the events leading up to the CABG surgery and experiences before admission	✓			
Address present thoughts and questions	✓	✓	✓	✓
How have the heart disease and the CABG pending affected daily living? Are specific activities avoided?	✓			
How has the CABG affected daily life? Are specific activities avoided?				✓
Status of mobilization and activities				✓
Discuss pain, sleep, fatigue and mobility		✓	✓	✓
Discuss family; how do they tackle changing patterns in the family?	✓		✓	✓
Impact of CABG surgery on working conditions				✓
Education about preparation and precaution following CABG surgery	✓	✓	✓	✓

C<sub>1</sub>: consultation at admission; C<sub>2</sub>: consultation postoperative day 3; C<sub>3</sub>: consultation at hospital discharge; C<sub>4</sub>: consultation four weeks post coronary artery bypass grafting (CABG)

standing position as many times as possible in 30 s to test leg strength and endurance. The test was performed in accordance with guidelines.<sup>15</sup> Physical tests were not done at baseline due to the risk of complications pre-CABG.

Psychological and physical health was measured by the Medical Outcome Study Short Form 36 (SF-36) at admission, at discharge and four weeks post surgery.<sup>16</sup> Furthermore, a set of patient self-reported outcomes were assessed: anxiety and depression using the Hospital Anxiety and Depression Scale,<sup>17</sup> health related quality of life using The HeartQoL questionnaire,<sup>18</sup> fatigue was measured using the Multidimensional Fatigue Inventory<sup>19</sup> and illness-related knowledge was measured using the Brief Illness Perception Questionnaire.<sup>20</sup> Physical activity was measured using the International Physical Activity Questionnaire<sup>21</sup> and, finally, sleep and pain were measured using The Pittsburgh Sleep Quality Index and The Örebro Musculoskeletal Screening Questionnaire.<sup>22,23</sup> Detailed information about the instruments used to assess the clinical impact of the rehabilitation programme and timing of assessments is shown in Table 2.

### Sample size

As this was a pilot trial, we arbitrarily decided to include 60 participants, corresponding to 15 participants in each of the four intervention groups.

### Blinding

Because of the conditions for rehabilitation, it was not possible to blind the staff and patients. The statistical analysis of outcomes and conclusions was blinded.

### Ethical considerations

Patients gave their written informed consent after receiving verbal and written information about the trial. Data were handled confidentially and patients were assured

anonymity. The pilot trial followed the recommendations of the updated Declaration of Helsinki<sup>24</sup> and was approved by the Regional Ethics Committee in the Capital Region of Denmark (H-3-2013-112) and the Danish Data Protection Agency (2007-58-0015). The pilot trial was registered at ClinicalTrials.gov (NCT01941355).

### Data analysis

**Outcomes.** The estimates of the mean and the standard deviations of patient-reported outcomes were calculated (Table 3).

**Feasibility.** The feasibility of the SheppHeartCABG pilot was evaluated in terms of acceptability, adherence and attrition.<sup>25</sup> Acceptability was measured by the percentage of eligible patients who agreed to participate in the trial. For each individual component in the programme, adherence to the intervention was measured by calculating the percentage of recommended exercise sessions performed by the patient versus the number of sessions/number of sessions prescribed. Adherence calculations include only the prescribed sessions. Attrition was calculated by the percentage of patients who did not complete the trial.

**Safety and tolerability.** Patients were taken off the intervention programme in cases of high or low blood pressure (diastolic <50 or >120 mmHg and systolic <90 or >200 mmHg), fast or slow heart rate <50 or >100 beats/min; temperature >38°C, or finger saturation <90%. In terms of safety and tolerability, we assessed the number of days the patient was off the programme.

## Results

### Demographic data

The demographic data and preoperative clinical characteristics of the four groups are presented in Table 4.

**Table 2.** Overview of variables and measurements in the quantitative study.

Variable	Measurement	Time	Items	Validity	Reliability	Responsiveness	Interpretation
Psychological and physical health	The Medical Outcome Study Short Form 36 (SF-36)	T1	36	Construct and content validity confirmed <sup>16</sup>	The minimum standard of $\alpha=0.70$ recommended for measures used in group comparisons in more than 25 studies and most have exceeded $\alpha=0.80$ (41) Reliability estimates for physical and mental summary scores usually exceed $\alpha=0.90$ (42)	NR	Scores range 0–10 Higher scores indicate better perceived health
		T2					
		T3					
Anxiety and depression	The Hospital Anxiety and Depression Scale (HADS)	T1	14	Content validity confirmed <sup>17</sup>	Internal consistency confirmed Adolescents' self-report scores: HADS-A $\alpha=0.83$ ; HADS-D $\alpha=0.82$	Responsiveness confirmed	Scores of 7 for either subscale are regarded as normal 8–10 suggests the presence of a mood disorder 11 and above suggests probable presence of a mood disorder NR
		T2					
		T3					
Health-related quality of life in cardiac patients	The HeartQoL questionnaire (HeartQoL)	T1	14	Content validity confirmed <sup>18</sup>	Proven as a reliable instrument with $\alpha=0.80-0.91$ for the global score (40)	Responsiveness confirmed (36)	NR
		T2					
		T3					
Fatigue	The Measurement of Fatigue Instrument (MFI)	T1	20	Construct validity confirmed <sup>19</sup>	Internal consistency confirmed: general fatigue $\alpha=0.82$ physical fatigue $\alpha=0.81$	Responsiveness confirmed (37)	Scores range 4–20 Higher scores indicate a higher degree of fatigue
		T2					
		T3					
Cognitive and emotional representations of illness	The Brief Illness Perception Questionnaire (B-IPQ)	T1	8	Content validity confirmed <sup>20</sup>	Good test–retest reliability (38)	Responsiveness confirmed (38)	Scores range 0–10 A higher score reflects a more threatening view of the illness
		T2					
		T3					
Health-related physical activity	The International Physical Activity Questionnaire (IPAQ)	T1	4	Content validity confirmed <sup>21</sup>	NR	NR	Three levels of physical activity proposed to classify populations: low, moderate and high
		T2					
		T3					
Sleep	The Pittsburgh Sleep Quality Index (PSQI)	T1	19	Content validity confirmed <sup>22</sup>	$\alpha=0.83$ obtained indicates a high degree of internal homogeneity (40)	NR	PSQI total: minimum score = 0 (better); maximum score = 21 (worse) Interpretation: total < 5 associated with good sleep quality; total > 5 associated with poor sleep quality
		T2					
		T3					
Musculoskeletal pain	The Örebro Musculoskeletal Screening Questionnaire (OMPSQ)	T1	25	Construct validity confirmed <sup>23</sup>	High reliability (41)	NR	Scores from 1 to 200. Higher scores are associated with increased risk of long-term disability
		T2					
		T3					

T1: baseline; T2: hospital discharge; T3: four weeks post surgery; NR: not reported

**Table 3.** Patient-reported outcomes.

Quantity	Physical exercise			Psycho-education			Psycho-education/physical exercise			Usual care		
	N (%)	Mean	SD	N (%)	Mean	SD	N (%)	Mean	SD	N (%)	Mean	SD
<b>MCS<sup>a</sup></b>												
Baseline	11 (73)	48.01	14.86	11 (73)	51.40	10.58	9 (60)	50.95	11.26	8 (53)	55.17	7.53
Discharge	6 (40)	53.74	13.08	6 (40)	43.74	12.61	11 (73)	41.15	12.74	11 (73)	45.48	10.80
Four weeks	7 (47)	53.24	10.04	6 (40)	49.94	15.22	9 (60)	51.82	10.04	10 (66)	43.61	12.99
<b>PCS<sup>b</sup></b>												
Baseline	11 (73)	39.09	8.87	11 (73)	46.00	8.47	9 (60)	41.28	8.73	8 (53)	45.62	8.78
Discharge	6 (40)	37.22	9.36	6 (40)	41.73	4.10	11 (73)	34.90	8.23	11 (73)	35.07	8.20
Four weeks	7 (47)	42.72	5.96	6 (40)	38.31	6.80	9 (60)	34.15	6.43	10 (67)	36.85	3.25
<b>HADS-A<sup>c</sup></b>												
Baseline	11 (73)	4.91	4.11	11 (73)	4.91	3.14	12 (80)	5.25	3.31	10 (67)	4.30	2.54
Discharge	7 (47)	7.00	0.58	7 (47)	7.43	1.72	11 (73)	6.45	2.55	11 (73)	6.82	1.48
Four weeks	7 (47)	2.29	0.49	6 (40)	5.67	3.01	10 (67)	4.70	3.71	12 (80)	3.92	3.23
<b>HADS-D<sup>d</sup></b>												
Baseline	11 (73)	6.18	2.93	11 (73)	6.18	2.75	12 (80)	6.92	2.97	10 (67)	5.90	2.69
Discharge	7 (11)	5.86	1.57	7 (47)	6.57	2.44	11 (73)	8.72	3.04	11 (73)	7.54	3.42
Four weeks	7 (11)	5.86	1.77	6 (40)	6.50	2.17	10 (67)	8.20	3.71	12 (80)	3.92	3.23
<b>PSQI total<sup>e</sup></b>												
Baseline	10 (67)	6.70	4.23	8 (53)	8.00	3.42	9 (60)	4.78	2.39	10 (67)	6.70	3.56
Four weeks	5 (33)	7.20	3.84	4 (27)	11.25	4.92	7 (47)	9.29	5.41	10 (67)	7.10	4.31
<b>MET total<sup>f</sup></b>												
Baseline	10 (67)	5448.5	13979.25	11 (73)	3096.81	3283.37	11 (73)	1729.63	1775.76	10 (67)	5160.70	7641.28
Four weeks	6 (40)	5145.0	2016.66	5 (33)	5608.80	6499.59	9 (60)	3799.00	3655.47	11 (73)	4786.36	3967.53
<b>HeartQoL physical<sup>g</sup></b>												
Baseline	13 (87)	1.43	1.00	11 (73)	1.81	0.74	12 (80)	1.42	0.80	11 (73)	1.55	0.73
Four weeks	7 (47)	2.03	0.73	6 (40)	1.46	0.77	10 (67)	1.46	0.77	13 (87)	1.27	0.68
<b>HeartQoL emotional<sup>h</sup></b>												
Baseline	13 (87)	1.81	1.13	11 (73)	2.00	0.81	12 (80)	2.23	0.85	13 (87)	1.89	0.90
Four weeks	7 (47)	2.71	0.47	6 (40)	1.58	1.23	10 (67)	2.00	0.96	13 (87)	1.92	1.00
<b>HeartQoL global<sup>i</sup></b>												
Baseline	13 (87)	1.34	0.91	11 (73)	1.86	0.67	80 (12)	1.60	0.81	13 (87)	1.64	0.71
Four weeks	7 (47)	1.95	0.60	6 (40)	1.50	0.97	10 (67)	1.62	0.52	13 (87)	1.41	0.74
<b>OMPSQ<sup>j</sup></b>												
Baseline	10 (67)	54.00	28.95	7 (47)	46.29	25.51	11 (73)	49.55	27.62	5 (33)	41.20	23.48
Discharge	7 (47)	57.57	24.40	7 (47)	64.00	15.04	11 (73)	79.00	25.48	8 (53)	76.75	30.87

(Continued)

Table 3. (Continued)

Quantity	Physical exercise			Psycho-education			Psycho-education/physical exercise			Usual care		
	N (%)	Mean	SD	N (%)	Mean	SD	N (%)	Mean	SD	N (%)	Mean	SD
Four weeks	5 (33)	56.60	12.87	5 (33)	62.00	34.91	8 (53)	66.88	23.24	6 (40)	56.67	37.95
<b>General fatigue<sup>k</sup></b>												
Baseline	11 (73)	11.73	4.98	11 (73)	10.55	5.92	10 (73)	13.36	4.23	10 (67)	10.60	4.97
Four weeks	7 (47)	10.29	5.47	5 (33)	12.20	4.32	10 (67)	11.30	4.11	12 (80)	12.25	4.00
<b>Max watt<sup>l</sup></b>												
Discharge	5 (33)	75.00	25.00	2 (13)	75.00	0.00	3 (20)	53.33	37.53	3 (20)	83.33	14.43
Four weeks	6 (40)	101.67	58.02	4 (27)	106.25	23.94	7 (47)	117.86	35.36	9 (60)	108.33	35.36
<b>Peak VO<sub>2</sub><sup>m</sup></b>												
Discharge	5 (33)	16.36	3.19	2 (13)	19.45	2.19	3 (20)	14.97	5.82	3 (20)	16.83	0.74
Four weeks	5 (33)	22.32	4.53	4 (27)	22.35	1.65	7 (47)	23.40	4.14	9 (60)	21.99	5.24
<b>6MWT<sup>n</sup></b>												
Discharge	5 (33)	264.20	103.70	6 (40)	410.67	29.81	5 (33)	433.00	93.15	5 (33)	331.00	147.49
Four weeks	7 (47)	459.71	94.49	6 (40)	504.00	39.01	9 (60)	548.11	104.66	9 (60)	450.89	74.53
<b>Sit-to-stand<sup>o</sup></b>												
Discharge	6 (40)	10.33	3.14	6 (40)	11.50	1.95	6 (40)	11.83	4.07	6 (40)	8.83	1.72
Four weeks	7 (47)	15.00	3.41	6 (40)	14.00	1.67	9 (60)	15.33	6.30	10 (67)	11.70	2.86

<sup>a</sup>Mental health measured by the Medical Outcome Study 36-item Short Form health survey.

<sup>b</sup>Physical health measured by the Medical Outcome Study 36-item Short Form health survey.

<sup>c</sup>Anxiety measured by the Hospital Anxiety and Depression Scale.

<sup>d</sup>Depression measured by the Hospital Anxiety and Depression Scale – Depression.

<sup>e</sup>Sleep measured by the Pittsburgh Sleep Quality Index.

<sup>f</sup>Physical activity measured by the International Physical Activity Questionnaire.

<sup>g</sup>Physical health-related quality of life measured by the HeartQoL questionnaire.

<sup>h</sup>Emotional health-related quality of life measured by the HeartQoL questionnaire.

<sup>i</sup>Health-related quality of life measured by the HeartQoL questionnaire.

<sup>j</sup>Pain measured by the Orebro Musculoskeletal Screening Questionnaire.

<sup>k</sup>Fatigue measured by the Measurement of Fatigue Instrument.

<sup>l</sup>Maximal watt performed at cardiopulmonary test.

<sup>m</sup>Peak VO<sub>2</sub> estimated from maximal wattage achieved in cardiopulmonary test.

<sup>n</sup>Distance in metres achieved in six minute walking test (6MWT).

<sup>o</sup>Number of times the participant stood up and sat down in a chair measured by the sit-to-stand test.

**Table 4.** Demographic and clinical characteristics of the sample by group.

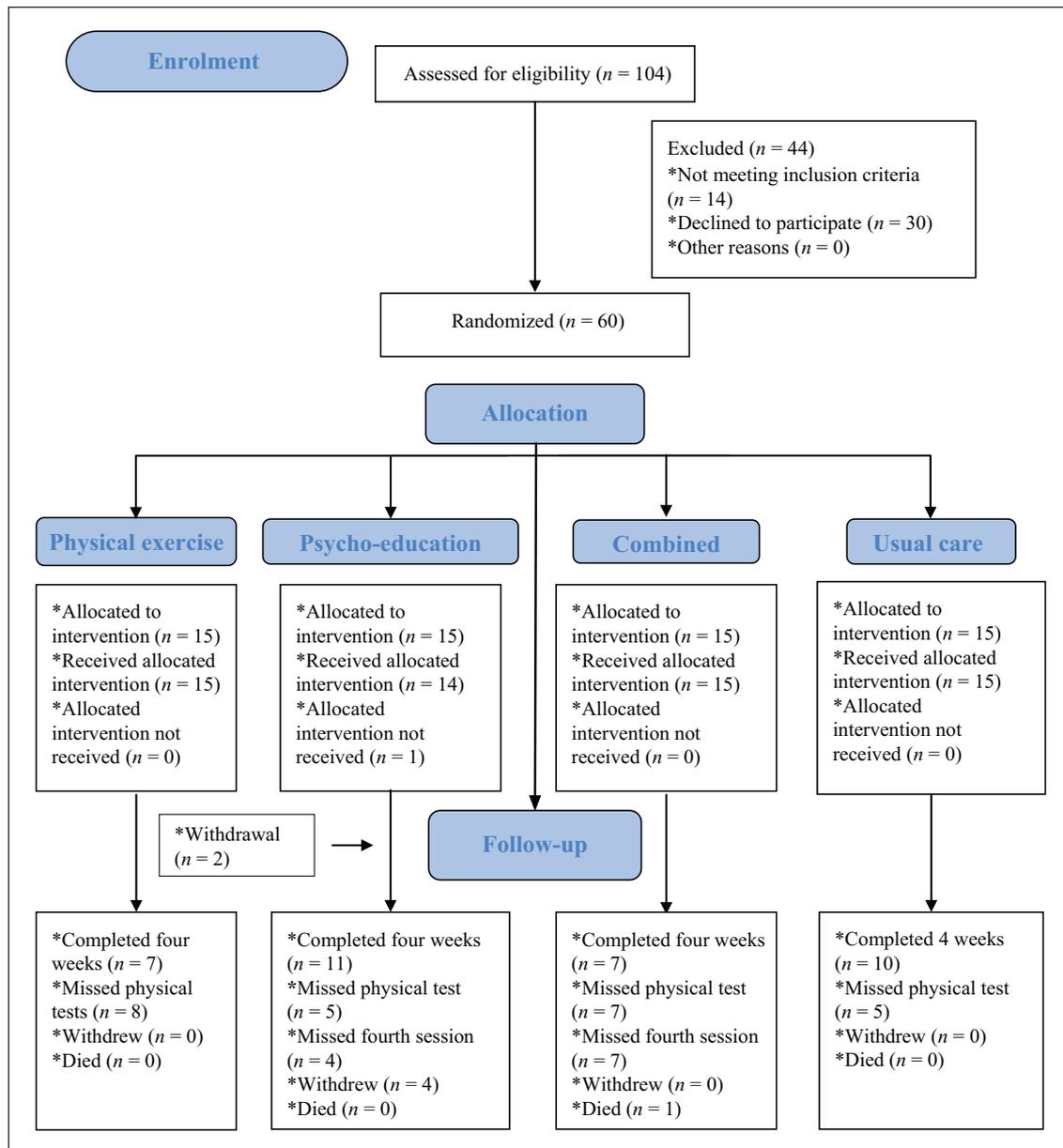
	Physical exercise group (n=15)	Psycho-educational group (n=15)	Combined psycho-educational/ physical exercise group (n=15)	Usual care group (n=15)
Age, years, mean ( $\pm$ SD)	61.3 (12.3)	68.3 (11.9)	62.3 (10.2)	67.2 (8.0)
Sex, n (%)				
Male	11 (73)	12 (80)	13 (87)	11 (73)
Female	4 (27)	3 (20)	2 (13)	4 (27)
Marital status, n (%)				
Single/divorced/widowed	4 (27)	6 (33)	3 (20)	8 (53)
Married/domestic partner	11 (73)	9 (60)	12 (80)	7 (47)
Occupational status, n (%)				
Active employment, n (%)	8 (53)	3 (20)	6 (40)	6 (40)
Pensioner, n (%)	4 (27)	11 (73)	5 (33)	5 (33)
Early retirement, n (%)	2 (13)	1 (7)	2 (13)	2 (13)
Person on job release scheme, n (%)	1 (7)			1 (7)
Undisclosed, n (%)				1 (7)
Educational level, n (%)				
Vocational education, n (%)	6 (33)	8 (53)	7 (47)	7 (47)
College, n (%)	1 (7)	2 (13)	2 (13)	
University, n (%)	3 (20)	1 (7)	3 (20)	5 (33)
None, n (%)	3 (20)			
Other, n (%)				
Undisclosed, n (%)	2 (13)	4 (27)	3 (20)	6 (40)
Body mass index, n (%)				
< 18.5 (kg/m <sup>2</sup> )	0	0	0	0
> 25 < 30 (kg/m <sup>2</sup> ), n (%)	6 (40)	5 (33)	3 (20)	7 (47)
> 30 (kg/m <sup>2</sup> ), n (%)	3 (20)	5 (33)	5 (33)	4 (27)
Type of heart disease, n				
Ischaemic heart disease	15	15	15	15
Heart failure	0	0	0	0
NYHA class I, n (%)				
NYHA class II, n (%)	5 (33)	7 (47)	4 (27)	5 (33)
NYHA class III, n (%)	5 (33)	7 (47)	11 (73)	9 (60)
NYHA class IV, n (%)	5 (33)	1 (7)		1 (7)
LVEF mean ( $\pm$ SD)	48.0 (12.8)	50.0 (9.4)	53.2 (11.6)	52.1 (12.4)
Current smoker, n (%)	3 (20)	2 (13)	1 (7)	1 (1)
Previous smoker, n (%)	6 (40)	8 (53)	9 (60)	7 (47)
Prescribed medication, n (%)				
Blood pressure-lowering drugs	3 (20)	5 (33)	4 (27)	3 (20)
ACE inhibitor	3 (20)	1 (7)	2 (13)	2 (13)
Beta-blocker	13 (87)	9 (60)	12 (80)	10 (67)
Calcium antagonist	3 (20)	3 (20)	4 (27)	1 (1)
Antiplatelet drugs	15 (100)	13 (87)	14 (93)	14 (93)
Diuretic	2 (13)	4 (27)	4 (27)	4 (27)
Anti-diabetic	3 (20)	2 (13)	5 (33)	3 (20)
Statin	14 (93)	12 (80)	13 (87)	14 (93)
Antidepressant	1 (7)	2 (13)	1 (7)	1 (7)
Pain reliever			1 (7)	3 (20)
Sleeping medicine	None	None	None	None

NYHA: New York Heart Association; LVEF: left ventricular ejection fraction; ACE: angiotensin-converting enzyme

### Feasibility

**Acceptance.** During the inclusion period September–December 2013, 104 patients were admitted for elective

CABG surgery and 90 were found eligible to participate (87%). Sixty patients provided informed consent to participate in the trial, corresponding to 58% of all patients admitted and 67% of all eligible patients (Figure 2). Reasons for



**Figure 2.** CONSORT flow chart – SheppHeartCABG pilot.

refusal to participate included a lack of interest in participation (40%; 12/30), fatigue (47%; 14/30) and apprehension regarding surgery (7%; 2/30).

A flowchart indicating the progress of patients through the pilot trial is shown in Figure 2 as a CONSORT flow chart (CONsolidated Standards Of Reporting Trials).<sup>26</sup> Four patients, all of whom were assigned to the psycho-educational group, dropped out of the pilot trial: one during the first session; one before and two after hospital discharge. The reasons were a refusal to participate further due to the distance to the hospital; two participants did not want to give an explanation, and one patient died.

**Adherence.** In the two intervention groups that included physical exercise, the patients carried out 59% (924/1565)

of the total expected training sessions during hospitalization. One patient (3%) performed all training sessions (52/52). Nine patients (30%) carried out >75% (348/447) and 18 patients (63%) carried out  $\geq$  50% of the planned sessions (363/642).

Regarding the psycho-educational intervention, 11 patients (42%) participated in  $\geq$ 75% of the four consultations and 17 patients (65%) in >50% of the four consultations. Twelve patients (46%) indicated that they had used mindfulness during the psycho-educational programme.

**Attrition.** Eight patients in the physical exercise group, four patients in the psycho-educational group, seven patients in the combined group, and five patients in the usual care group

failed to complete the physical tests at discharge because of sudden discharge or transfer to the cardiology department at their regional hospital. In the psycho-educational groups, four patients in the single group and seven in the combined group failed to complete the fourth session.

### *Safety and tolerability*

One patient randomized to the combined group died three weeks post CABG. No other adverse reactions or events were observed as a result of the testing, consultations or exercise programme.

### *Outcomes*

Table 3 shows the mean values and standard deviations over time of each of the patient-reported outcomes.

### **Discussion**

This pilot trial provides data concerning the feasibility of patient recruitment and intervention and the safety and tolerability of a phase 1 rehabilitation intervention in patients undergoing CABG. The intervention was a comprehensive rehabilitation programme from admission to four weeks post surgery that involved physical exercise with moderate to high intensity and a psycho-educational programme, including mindfulness. A comprehensive rehabilitation programme consisting of both a physical and a psycho-educative component is not routine after cardiac surgery.

We were uncertain as to whether it would be possible to recruit a sufficient number of participants for a phase 1 rehabilitation trial following CABG. The present pilot trial showed that 67% of all eligible patients admitted for CABG within the time frame could be included. However, inclusion of participants is not enough, adherence to the intervention components is also critical in order to achieve results. We found that only six per 10 of the expected exercise sessions were performed and only half of the patients used mindfulness. Obviously, this is suboptimal adherence to the intervention. In a future SheppHeart trial, we need to put more emphasis on 'why and how to do exercises' and motivate patients to perform the interventional components as prescribed. The most challenging task is to improve adherence to both programmes. Up until now no trials have investigated improvement to adherence in cardiac rehabilitation in the in-hospital phase. However, trials to increase adherence to cardiac rehabilitation phase 2 have shown significant improvements in adherence to cardiac rehabilitation, for example, the use of a simple diary had a positive influence on adherence to physical exercise.<sup>27</sup> Therefore in a future confirmatory SheppHeart trial, nurses and physiotherapist in daily contact with the participant have to be motivating and supporting regarding exercise and consultations.

Based on the experiences from this pilot trial, we suggest modifying certain aspects of the intervention. The first three sessions in the psycho-educational programme took place during hospitalization and the last one was held four weeks after surgery. We found that the last consultation should be scheduled before the last assessment four weeks after CABG and might be performed as a telephone call, which is common in cardiac rehabilitation.<sup>8</sup> During the pilot trial, we encountered some organizational challenges. First, it was difficult to integrate the consultations (T1) in the already busy schedule for patients on the day of admission. However, the greatest number of organizational issues arose at T2, the day of hospital discharge. Indeed, quite often hospital discharge was abrupt (to give way to new patients), and occurred when no intervention or testing personnel were available. Since hasty hospital discharge is common, we need a plan to accommodate this situation. Furthermore, we will give more attention to questionnaire response rates by closely monitoring patients' follow-up.

One of the aims of this pilot trial was to evaluate the tolerability of interventions for patients. Normally, physical tests are not performed in the days immediately following cardiac surgery. Hence, evidence is lacking regarding the safety of cardiopulmonary testing during the first week after CABG surgery. This pilot trial showed that the physical interventions and tests appear to be safe and tolerable for the participants. However, it would be useful to include the patient perspective of safety and tolerability by conducting in-depth interviews with patients. This type of information would have been applicable in the evaluation of this pilot trial. There was no data monitoring and safety committee established for the pilot trial, but such a committee should be established for a larger trial.

These pilot data provide a good basis for exploring the potential for improvement for the different outcomes. In addition, it may allow us to estimate the required sample size for a larger trial, relying on mean values and standard deviations of the primary outcome obtained from the present pilot trial. Furthermore, similar data from other outcomes may be used for calculating the power for these outcomes in a future trial and deciding which are going to become secondary outcomes (e.g. outcomes with  $\geq 80\%$  power) and which should become exploratory outcomes (e.g. outcomes with  $< 80\%$  power).

Some outcomes did not show sufficient sensitivity towards changes over time in this pilot trial. This was the case for some of the questionnaires as well as physical tests and might be due to a poor interventional effect or random variation or, alternatively, due to poor sensitivity of the outcome measures; for example, SF-36 with a four week recall obviously did not pick up differences between T1 and T2, as could have been anticipated. Furthermore, the cardiopulmonary test did not seem to be useful in testing a short to moderate intensity exercise intervention. A

main reason for CABG patients to participate in cardiac rehabilitation was to improve their functional capacity in daily life. Therefore, outcomes have to be related to the improvement of daily life and thus measures such as walking capacity, six minute walk test and muscle strength in legs (measured by the sit-to-stand test) reduced pain in neck and shoulder, and provided better sleep.

## Conclusions

The SheppHeartCABG pilot trial suggests potentials for further investigation. The SheppHeartCABG pilot trial demonstrates feasibility, with a sufficient inclusion rate but with low adherence. The pilot trial highlighted some organizational, interventional, and administrative challenges as well as challenges with regard to which outcomes to use in future trials. These are the challenges which will have to be dealt with in a large scale trial, which is required to determine the effects of comprehensive phase 1 rehabilitation after CABG surgery.

### Implications for practice

- The SheppHeartCABG pilot trial demonstrates feasibility, with a sufficient inclusion rate but with low adherence.
- The pilot trial highlighted some organizational, interventional and administrative challenges as well as challenges with regard to which outcomes to use in future trials.
- These are the challenges which will have to be dealt with in a large scale trial, which is required to determine the effects of comprehensive phase 1 rehabilitation after coronary artery bypass grafting surgery.

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## Conflict of interest

The authors declare that there is no conflict of interest.

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