Early physical training and psycho-educational intervention for patients undergoing coronary artery bypass grafting. The SheppHeart randomised 2x2 factorial clinical pilot trial

Ida Elisabeth Højskov, RN, MSN[1]

Philip Moons, RN, Ph.D.[2]

Niels Viggo Hansen, Ph.D.[4]

Helle Greve RN, MSN[1]

Dorte Bæk Olsen, RN, MCN[1]

Søren La Cour, MPH[4]

Christian Glud, MD, Dr.Med.Sci.[3]

Per Winkel, MD, Dr. Med. Sci.[3]

Jane Lindschou, MSc in Public Health[3]

Ingrid Egerod, RN, MSN, Ph.D.[5]

Anne Vinggaard Christensen, MSc in Public Health[1]

Selina Kikkenborg Berg, RN, MSN, Ph.D.[1]

1 Thoracic Clinic, the Heart Centre, Rigshospitalet, Copenhagen University Hospital, Copenhagen, Denmark.

2 KU Leuven – University of Leuven Department of Public Health and Primary Care, KU Leuven, Leuven, Belgium.

3 Copenhagen Trial Unit, Centre for Clinical Intervention Research, Rigshospitalet, Copenhagen University Hospital, DK-2100 Copenhagen, Denmark.

4 The Centre for Research in Existence and Society, University of Copenhagen.

5 Trauma Centre, Rigshospitalet, Copenhagen University Hospital, Copenhagen, Denmark.

Corresponding author:

Ida Elisabeth Højskov

Rigshospitalet, Copenhagen University Hospital

The Heart Center, Thoracic Clinic, Blegdamsvej 9, DK – 2100 Copenhagen, Denmark.

Mail: ida.elsiabeth.hoejskov@regionh.dk

Abstract

Background: Patients undergoing coronary artery bypass graft surgery often experience a range of problems and symptoms such as immobility, pain and interrupted insufficient sleep. Results from trials investigating testing either in-hospital physical exercise or psychological intervention in phase one rehabilitation; or in hospital 4-6 weeks following surgery for coronary artery bypass graft surgery patients have been promising. However, no randomised clinical trials have tested a comprehensive rehabilitation programme consisting of both physical plus, a psycho-educative component in this early rehabilitation phase. Before a large trial is mounted uncertainties regarding patient acceptance of the trial and feasibility of the interventions should be addressed in a pilot trial.

Aims: The aims of the present SheppHeart pilot randomised clinical trial were to evaluate the feasibility of patient recruitment, patient acceptance of the intervention, safety and tolerability of the intervention, and to provide outcome data for sample size calculations. SheppHeart is the acronym for "SHaping outcomes by Exercise training and Psycho-education in Phase 1 Hearts patients."

Methods/Design: In this 2x2 factorial pilot trial, 60 patients admitted for first time coronary artery bypass graft were randomised 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 4 week period after coronary artery bypass grafting.

Results: The acceptability of trial participation was 67% during the three month recruitment period. In the two physical exercise groups, patients complied with 59% (924/1565) of the total expected training sessions during hospitalisation. Nine patients (30%) complied with >75% (348/447) and nine patients (30%) complied with 50% of the planned exercise sessions (363/642). Eleven patients (42%) participated in ≥75% of the four consultations and six patients (23%) participated in 50% of the psycho-educational programme, 12 patients (46%) indicated that they had used mindfulness during the psycho-educational programme. The physical interventions and tests seemed safe and well tolerated by the participants.

Conclusion: Comprehensive phase one rehabilitation combining physical exercise and psycho-education in coronary artery bypass graft patients shows reasonably high inclusion, feasibility, and safety, but only moderate compliance with both interventions.

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

Trial registration: www.clinicaltrials.gov identifier; NCT101941355

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[1]. Surgery outcomes are generally good, but recovery can be complicated. Patients undergoing CABG often experience a range of physical and psychological problems and symptoms[2], 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 post-operative fatigue[2].

Cardiac rehabilitation is an important aspect of recovery after heart surgery. Cardiac rehabilitation programmes are generally divided into three main phases: phase one, which is inpatient cardiac rehabilitation; phase two, which is early outpatient cardiac rehabilitation; and phase three, 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[3] and for this reason phase one rehabilitation starting in hospital seems reasonable[4], but evidence regarding phase one rehabilitation is sparse in CABG populations.

Exercise interventions such as respiratory physiotherapy or aerobic training in phase one rehabilitation after CABG have demonstrated improvements in patient outcomes measured by pulmonary complications and physical functional capacity[5,6]. Also psycho-

educative interventions have a positive influence on anxiety and depression in the post-hospital recovery period[7]. 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[8]. Trials targeting psychological interventions in the early postoperative period after CABG have shown improvements in depression and anxiety symptoms; however, no randomised clinical trials with sufficient power have been published[9]. 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 post-operative 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 randomised clinical trial.

Materials and methods

Trial design, population

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 x 2 factorial randomised 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 randomisation. The allocation sequence was computer-generated in varying block sizes of 8 and 12 and kept unknown for 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. Three days a week, group training for patients who had undergone heart surgery was offered in the gym and ready to discharge. Furthermore, the physiotherapist at hospital discharge gave directions on how to manage daily activities with sternotomy after hospital discharge and being physical active daily plus make shoulder and neck exercises.

The main features of pre-operative care were: admission interview, preoperative screening (falls, nutrition), 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 hospitalisation 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, e.g., 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 administrated by physiotherapists and consisted of exercise programmes that started at admission and continued to four weeks following 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 and to hospital discharge. From 8 am to 10 pm, participants performed 7-10 deep breaths four times. Incentive spirometry was performed from postoperative day 1 to 4 by deep breathing with positive expiratory pressure for 3-5 minutes 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 semicircle in front of the body to the opposite shoulder. Each exercise was repeated ten times and done twice daily from postoperative day one until hospital discharge.

The aerobic training was on a stationary bicycle with moderate intensity. Patients were familiarised with the RPE (Ratings of Perceived Exertion) Borg scale® [10] 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 6-20. At the three first cycling sessions, heart rate

and saturation were measured and patients used pulse watches during cycle training. Cycling interventions were 10 minute sessions preceded by five minute warm-ups and followed by five minutes of cool-down to achieve cardiovascular adjustment and reduce the risk of ischemia and arrhythmia. The intensity at warm-up and cool-down was ≤10RPE Borg and the cycling sessions were performed from postoperative day 3 until discharge twice daily, morning and afternoon.

After hospital discharge, until four weeks following 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 following 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 were 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 ‘Human

Becoming Practice Methodologies'[11]. 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, which 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 contribute with knowledge and to 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 hospitalisation and after hospital discharge.

Outcomes

All participants were assessed three times: at admission (T1), at hospital discharge (T2), and four weeks following 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 [12] at hospital discharge and four weeks post-CABG. The cardiopulmonary testing protocol consisted of a four minute 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 [13].

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 following surgery. For the six minute walk test, the participants walked up and down a 30 meter hallway for six minutes according to the guidelines for the test[14]. For the sit-to-stand test, the participants repeatedly sat in a chair and got up to a full standing position as many times as possible in 30 seconds to test leg strength and endurance. The test was performed in accordance to guidelines[15]. Physical tests were not done at baseline due to the risk of complications pre-CABG.

Psychological and physical health was measured by the Short Form 36 (SF-36) at admission, at discharge, and four weeks following surgery[16]. Furthermore, a set of patient self-reported outcomes were assessed: anxiety and depression using the Hospital Anxiety and Depression Scale[17] health related quality of life using The HeartQoL questionnaire[18] fatigue was measured using Multidimensional Fatigue Inventory[19] and illness-related knowledge was measured using the Brief Illness Perception Questionnaire[20]. Physical activity was measured using the International Physical Activity Questionnaire[21] and finally, sleep and pain were measured using The Pittsburgh Sleep Quality Index and The Örebro Musculoskeletal Screening Questionnaire[22,23]. 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 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[24] 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 4.*

Feasibility The feasibility of the SheppHeartCABG pilot was evaluated in terms of acceptability, adherence, and attrition[25]. 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 session prescribed. Adherence calculations only include 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 program 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 per minute; temperature >38° C., or finger saturation <90%. In terms of safety and tolerability, we assessed the number of days the patient was off the program.

Results

Demographic data

The demographic data and preoperative clinical characteristics of the four groups are presented in *Table 3*.

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

A flowchart indicating the progress of patients through the pilot trial is shown in *Figure 2.* 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 hospitalisation. One patient (3%) performed all training sessions (52/52). Nine patients (30%) carried out >75% (348/447) and 18 patients (63 %) carried out ≥ 50% of the planned sessions (363/642).

Regarding the psycho-educational intervention, 11 patients (42%) participated in ≥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 randomised to the combined group died three weeks following CABG. No other adverse reactions or events were observed as a result of the testing, consultations, or the 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 one rehabilitation intervention in patients undergoing CABG. The intervention was a comprehensive rehabilitation programme from admission to four weeks following surgery that involved physical exercise with moderate to high intensity and a psycho-educational programme, including mindfulness. A comprehensive rehabilitation programme consists of both a physical and 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 one 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 ten 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 two have shown significant improvements in adherence to cardiac rehabilitation, e.g., the use of a simple diary had a positive influence to adherence with physical exercise[26]. 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 hospitalisation and the last one was held four weeks following 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[8]. During the pilot trial, we encountered some organisational challenges. First, it was difficult to integrate the consultations and physical test (T1) in

the already busy schedule for patients on the day of admission. However, the greatest number of organisational 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 decide which are going to become secondary outcomes (e.g., outcomes with ≥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; e.g., 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 organisational, 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 one rehabilitation after CABG surgery.

Contributions. IEH in collaboration with PM, NVH, HG, DBO, SLC, CG, PW, JL, IE, and SKB designed the trial. PW, PM, IEH and AVC conducted the statistical analyses. IEH drafted the manuscript. All authors revised the manuscript critically. All have given their final approval of the version to be published. All authors meet the criteria in the ICMJE Authorship guidelines.

Acknowledgements

We thank all patients for participating in this pilot trial. The authors would like to thank Camilla Larsen, Rikke Jensen and the Department of Occupational Therapy and Physiotherapy for their professional contribution to the physical intervention. We would

also like to thank Lone Cramer Johnson and Inge Seerup Frandsen for secretarial assistance.

Funding

This work was supported by the Lundbeck Foundation; Metropolitan University College; and Copenhagen University Hospital, Rigshospitalet.

Conflict of interest

The authors declare that there are no conflicts of interest.

Figure 1: Trial design

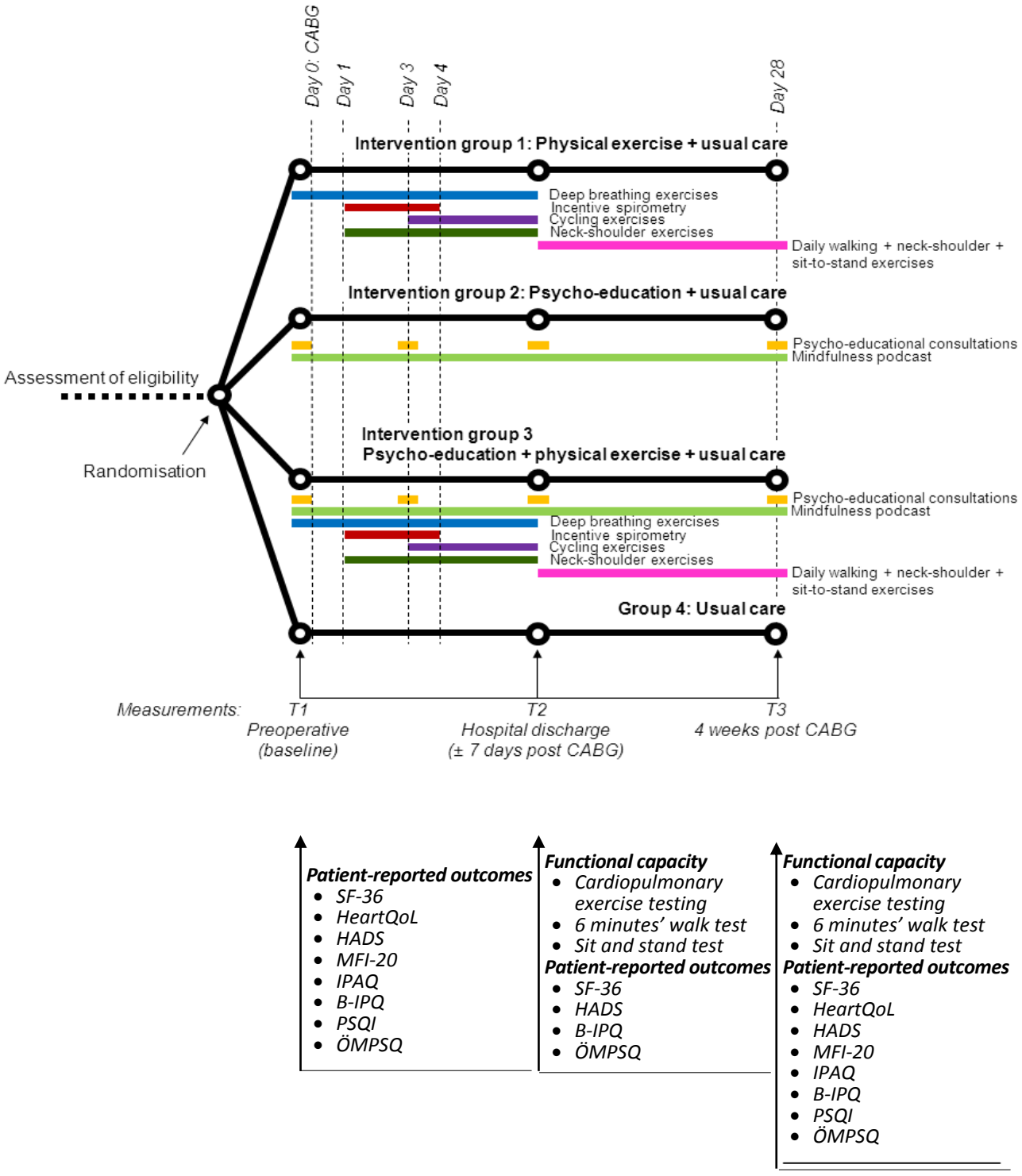

Figure 2: CONSORT flow chart – SheppHeartCABGpilot

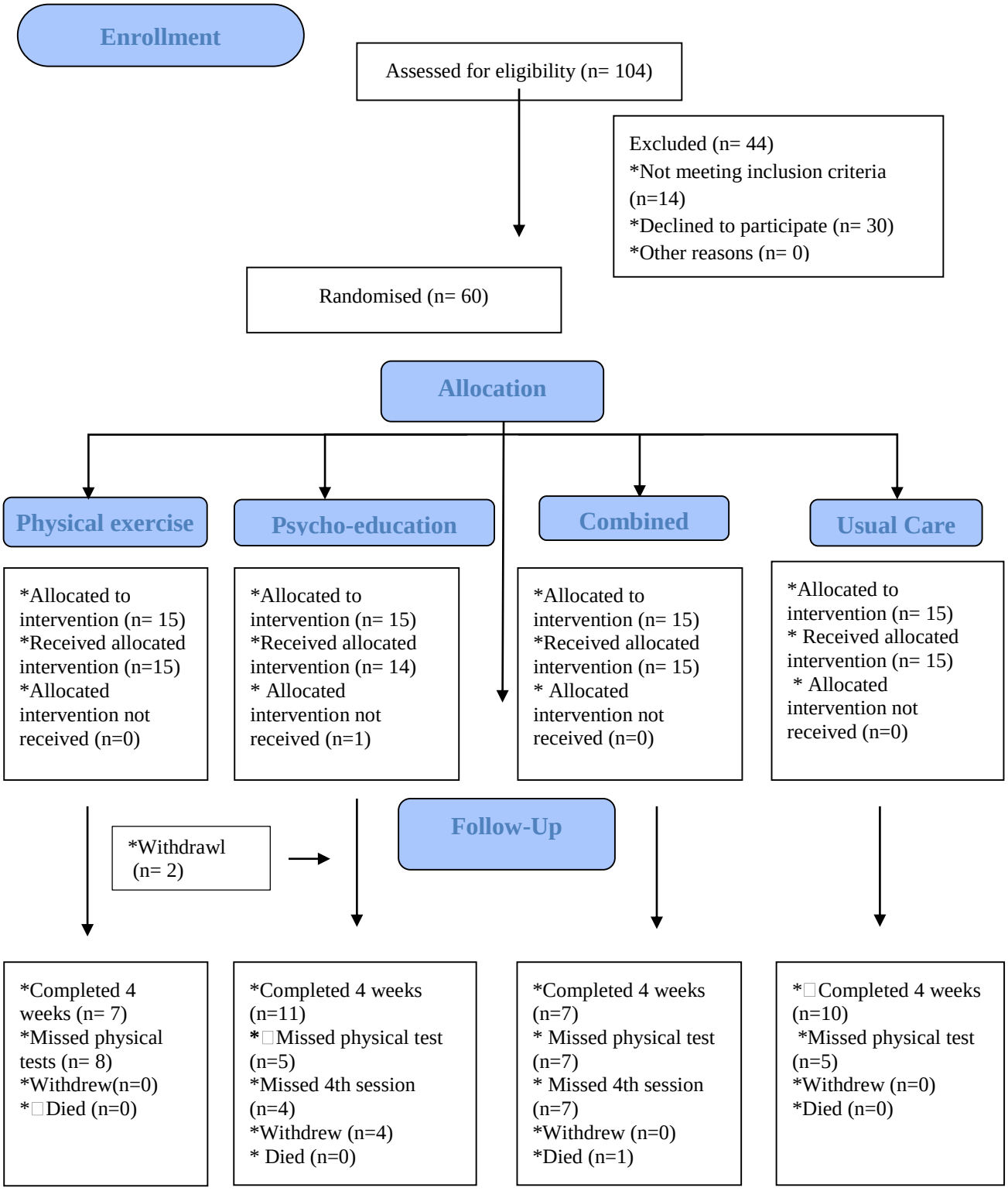

Table 1 Inspiration Guide for Nursing Consultation

	C_1	C_2	C_3	C_4
Discuss the events leading up to the CABG surgery and experiences before admission	x			
Address present thoughts and questions.	x	x	x	x
How have the heart disease and the CABG pending affected daily living? Are specific activities avoided?	x			
How has the CABG affected daily life? Are specific activities avoided?				x
Status of mobilisation and activities.				x
Discuss pain, sleep, fatigue and mobility.		x	x	x
Discuss family; how do they tackle changing patterns in the family?	x		x	x
Impact of CABG surgery on working conditions.				x
Education about preparation and precaution following CABG surgery	x	x	x	x

C1: consultation at admission, C_2: consultation postoperative day 3, **C_3:** consultation at hospital discharge, C_4**:** consultation 4 weeks post-CABG

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 T2 T3	36	Construct and content validity confirmed [16]	The minimum standard of α= 0.70 recommended for measures used in group comparisons in more than 25 studies and most have exceeded α=0.80 (41) Reliability estimates for physical and mental summary scores usually exceed α=0.90 (42)	NR	Scores range 0-100. Higher scores indicate better perceived health
Anxiety and depression	The Hospital Anxiety and Depression Scale (HADS).	T1 T2 T3	14	Content validity confirmed [17]	Internal consistency confirmed. Adolescents' self-report scores: HADS-A α=0.83 HADS-D α=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
Health-related quality of life in cardiac patients	The HeartQoL questionnaire (HeartQol)	T1 T3	14	Content validity confirmed [18]	Proven as a reliable instrument with α= 0.80-0.91 for the global score (40)	Responsiveness confirmed (36)	NR
Fatigue	The Measurement of Fatigue Instrument	T1 T3	20	Construct validity confirmed [19]	Internal consistency confirmed: General fatigue α=0.82 Physical fatigue α=0.81	Responsiveness confirmed (37)	Scores from 4 -20 Higher scores indicate a higher degree of fatigue
Cognitive and emotional representations of illness	The Brief Illness Perception Questionnaire	T1 T2 T3	8	Content validity confirmed [20]	Good test-retest reliability (38)	Responsiveness confirmed (38)	Scores from 0 -10 A higher score reflects a more threatening view of the illness.

Health-related physical activity	The International Physical Activity Questionnaire	T1 T3	4	Content validity confirmed [21]	NR	NR	Three levels of physical activity proposed to classify populations: low, moderate and high.
Sleep	The Pittsburgh Sleep Quality Index (PSQI)	T1 T3	19	Content validity confirmed [22]	α= 0.83 obtained indicates a high degree of internal homogeneity (40)	NR	PSQII TOTAL: minimum Score = 0 (better); maximum Score = 21 (worse) Interpretation: TOTAL < 5 associated with good sleep quality TOTAL > 5 associated with poor sleep quality.
Musculoskeletal pain	The Örebro Musculoskeletal Screening Questionnaire	T1 T2 T3	25	Construct validity confirmed [23]	High reliability (41)	NR	Scores from 1 to 200. Higher scores are associated with increased risk of long-term disability

T1, baseline, T2, hospital discharge, T3, 4 weeks follows surgery. NR, not reported

Table 3: 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 (±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/cm^2)	0	0	0	0
> 25 < 30 (kg/cm^2), *n (%)*	6 (40)	5 (33)	3 (20)	7 (47)
> 30 (kg/cm^2), *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 (±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

Table 4: 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
MCS[1]												
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
4 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
PCS[2]												
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
4 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
HADS-A[3]												
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
4 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
HADS-D[4]												
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
4 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
PSQI total[5]												
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
4 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

[1] Mental health measured by The MOS 36 Item Short Form Health Survey
[2] Physical health measured by The MOS 36 Item Short Form Health Survey
[3] Anxiety measured by The Hospital Anxiety and Depression Scale
[4] Depression measured by The Hospital Anxiety and Depression Scale - Depression
[5] Sleep measured by The Pittsburgh Sleep Quality Index

MET total[6]												
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
4 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
HeartQol physical[7]												
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
4 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
HeartQol emotional[8]												
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
4 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
HeartQol global[9]												
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
4 weeks	7 (47)	1.95	060	6 (40)	1.50	0.97	10 (67)	1.62	0.52	13 (87)	1.41	0.74
OMPQ[10]												
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
4 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
General fatique[11]												
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
4 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
Max watt[12]												
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
4 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

[6] Physical activity measured by The International Physical Activity Questionnaire
[7] Physical health-related quality of life measured by The HeartQoL questionnaire
[8] Emotional health-related quality of life measured by The HeartQoL questionnaire
[9] Health-related quality of life The HeartQoL questionnaire
[10] Pain measured by The Örebro Musculoskeletal Screening Questionnaire
[11]Fatigue measured by The Measurement of Fatigue Instrument
[12] Maximal watt performed at cardiopulmonary test

Peak VO_2 [13]												
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
4 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
6MWT[14]												
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
4 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
Sit to stand[15]												
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
4 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

[13] Peak VO2 estimated from maximal wattage achieved in cardiopulmonary test
[14] Distance in meters achieved in six minute walking test
[15] Number of times the participant stood up and sat down in a chair measured by the sit to stand test

References

1. Lafortune, G.,Balestat,G., Durand A. Comparing activites and performance of the hospital sector in Europe:how many surgical procedures perdormed as inpatient and day cases? *OECD, Directorate for Employment, Labour and Social Affaris.*; 2012.

2. Lie I, Bunch EH, Smeby NA, et al. Patients' experiences with symptoms and needs in the early rehabilitation phase after coronary artery bypass grafting. *Eur J Cardiovasc Nurs*; 2012: 11:14-24.

3. Balady GJ, Ades PA, Comoss P, et al. Core components of cardiac rehabilitation/secondary prevention programs: A statement for healthcare professionals from the American Heart Association and the American Association of Cardiovascular and Pulmonary Rehabilitation Writing Group. *Circulation*; 2000: 102:1069-73.

4. Piepoli MF, Corra U, Adamopoulos S, et al. Secondary prevention in the clinical management of patients with cardiovascular diseases. Core components, standards and outcome measures for referral and delivery. *Eur J Prev Cardiol*; 2012.

5. Westerdahl E,Olsén MF. Chest physiotherapy and breathing exercises for cardiac surgery patients in Sweden - a national survey of practice. ; 2011: Juni; 75(2):112-119.

6. Hirschhorn AD, Richards DA, Mungovan SF, et al. Does the mode of exercise influence recovery of functional capacity in the early postoperative period after coronary artery bypass graft surgery? A randomized controlled trial. *Interact Cardiovasc Thorac Surg*; 2012: 15:995-1003.

7. Lie I, Arnesen H, Sandvik L, et al. Effects of a home-based intervention program on anxiety and depression 6 months after coronary artery bypass grafting: a randomized controlled trial. *J Psychosom Res*; 2007: 62:411-8.

8. Berg S,Kikkenborg. *Comprehensive rehabilitaotn for patients with ICD.* Phd ed. : Aarhus University, 2011.

9. Stroobant N and Vingerhoets G. Depression, anxiety, and neuropsychological performance in coronary artery bypass graft patients: a follow-up study. *Psychosomatics*; 2008: 49:326-31.

10. Borg GA. Psychophysical bases of perceived exertion. *Med Sci Sports Exerc*; 1982: 14:377-81.

11. Parse R. The human becoming school of though: a perspective for nurses and other health professionals. ; 1998: Thousand Oaks, Calif.:Stage.

12. Gibbons L, Blair SN, Kohl HW, et al. The safety of maximal exercise testing. *Circulation*; 1989: 80:846-52.

13. Mezzani A, Agostoni P, Cohen-Solal A, et al. Standards for the use of cardiopulmonary exercise testing for the functional evaluation of cardiac patients: a report from the Exercise Physiology Section of the European Association for Cardiovascular Prevention and Rehabilitation. *Eur J Cardiovasc Prev Rehabil*; 2009: 16:249-67.

14. ATS Committee on Proficiency Standards for Clinical Pulmonary Function Laboratories. ATS statement: guidelines for the six-minute walk test. *Am J Respir Crit Care Med*; 2002: 166:111-7.

15. Ada L, Mackey F, Heard R, et al. Stroke rehabilitation: Does the therapy area provide a physical challenge? *Aust J Physiother*; 1999: 45:33-8.

16. Tsai C, Bayliss MS, Ware JE (ed) *SF-36® Health Survey Annotated Bibliography. Second Edition (1988-1996).* Boston, MA: Health Assessment Lab, New England Medical Center, 1997 ed. , 1997.

17. Bjelland I, Dahl AA, Haug TT, et al. The validity of the Hospital Anxiety and Depression Scale. An updated literature review. *J Psychosom Res*; 2002: 52:69-77.

18. Oldridge N, Hofer S, McGee H, et al. The HeartQoL: Part II. Validation of a new core health-related quality of life questionnaire for patients with ischemic heart disease. *Eur J Prev Cardiol*; 2013.

19. Lin JM, Brimmer DJ, Maloney EM, et al. Further validation of the Multidimensional Fatigue Inventory in a US adult population sample. *Popul Health Metr*; 2009: 7:18,7954-7-18.

20. Broadbent E, Petrie KJ, Main J, et al. The brief illness perception questionnaire. *J Psychosom Res*; 2006: 60:631-7.

21. Hagstromer M, Oja P and Sjostrom M. The International Physical Activity Questionnaire (IPAQ): a study of concurrent and construct validity. *Public Health Nutr*; 2006: 9:755-62.

22. Buysse DJ, Reynolds CF,3rd, Monk TH, et al. The Pittsburgh Sleep Quality Index: a new instrument for psychiatric practice and research. *Psychiatry Res*; 1989: 28:193-213.

23. Gabel CP, Melloh M, Burkett B, et al. The Orebro Musculoskeletal Screening Questionnaire: validation of a modified primary care musculoskeletal screening tool in an acute work injured population. *Man Ther*; 2012: 17:554-65.

24. World Medical Association Inc. Declaration of Helsinki. Ethical principles for medical research involving human subjects. *J Indian Med Assoc*; 2009: 107:403-5.

25. Wilson RW, Jacobsen PB and Fields KK. Pilot study of a home-based aerobic exercise program for sedentary cancer survivors treated with hematopoietic stem cell transplantation. *Bone Marrow Transplant*; 2005: 35:721-7.

26. Arrigo I, Brunner-LaRocca H, Lefkovits M, et al. Comparative outcome one year after formal cardiac rehabilitation: the effects of a randomized intervention to improve exercise adherence. *Eur J Cardiovasc Prev Rehabil*; 2008: 15:306-11.