# UNIVERSITEIT TWENTE.

**Master assignment Health Sciences** 

# Early cardiac rehabilitation through eHealth

A Quasi-experimental study on the effect of early cardiac rehabilitation on postoperative recovery of patients after open heart surgery

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#### Preface

This master thesis is the result of my participation in a larger research project of Roessingh Research & Development, the paramedical department of Medisch Spectrum Twente hospital and Thoraxcentrum Twente. I have investigated the results of the effect of an online eHealth portal for patients after open heart surgery and wrote a research article in order to obtain my Master of Science degree at the Master Health Sciences of the University of Twente. The research was performed in the Thoraxcentrum Twente with cooperation of a dedicated team of physiotherapists, healthcare providers of the cardiac rehabilitation department and other students.

I have always been interested in how healthcare is changing, how patients and healthcare providers respond to those changes and what we, as Health Scientists, researchers or other healthcare specialists can do to create connections between those aspects. Care should, in my opinion, be accessible for everyone. Therefore I was very enthusiastic when Prof Job van der Palen and Dr Martine Veehof gave me the opportunity to take part on a research, investigating the effectiveness of early cardiac rehabilitation through an online eHealth portal on patients after open heart surgery. Giving patients access to an online eHealth portal at home could increase self-support and possible guidance by healthcare providers. I specified the research to my own area of interest, to see the effects of the technology on postoperative physical and psychological recovery.

A delay in the development of the online eHealth portal made it impossible to include all patients needed for the research, as for the initial third measurement moment after regular cardiac rehabilitation. The research project however still continues including patients until the needed sample size is reached.

I took part on the research from the moment we had to write the approval report for the METC, in which I contributed, so I was able to learn every step of research with the guidance of Prof. Job van der Palen and Dr Martine Veehof, the principal investigator of the main research. They helped me structure my research and visualize the final product.

Besides Prof. Job van der Palen and Dr. Martine Veehof I would like to thank Dr. Carine Doggen, for providing the needed feedback on my thesis. I also thank the patients who were willing to participate in this research. They gave an insight in their lives and eventually the results we needed. Last but not least, my family and friends, for their incredible patience and support on tough moments.

Performing research was very interesting and challenging. Therefore I'm very proud to mention that by the end of the year, we will write an article about the completed research project. Furthermore, I hope I can maintain and improve the things I've learned by participating in, or performing, other research in the future.

Lieneke Poppe

Almelo, August 24<sup>th</sup> 2017

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#### L. Poppe, Prof. Dr. J. van der Palen, Dr. C. Doggen and Dr. M. Veehof.

#### Abstract

Cardiac rehabilitation reduces the risk of having another cardiac incident, by improving physical exercise performance and help adopting or maintaining a healthy lifestyle. In the weeks prior to cardiac rehabilitation patients experience insufficient guidance, which makes them over active or less active than they are actually capable of. Research claims that cardiac rehabilitation starting within 6 weeks, allows for less complications and a decrease in readmissions. A directive about the best starting time is missing, as is the psychological recovery after a cardiac incident. The aim of this study is to investigate the effects of early cardiac rehabilitation on postoperative physical and psychological recovery through eHealth.

In this quasi experimental research, early cardiac rehabilitation started at discharge from the hospital until the start of the regular cardiac rehabilitation approximately 6 weeks later. An online eHealth portal was used with which patients could perform physical and relaxation exercises 3 times a week. Participants were Dutch patients who underwent a Coronary Artery Bypass Graft or a valve replacement through open heart surgery. Besides questionnaires to measure a patient's physical disability, activity and psychological status, a 6 minutes' walking test was used as a primary outcome measure for physical exercise capacity. A comparison group and intervention group were followed from the day before discharge from the hospital, until the start of regular cardiac rehabilitation. The intervention group used the online eHealth portal.

Fifty-seven patients (comparison group n=42, intervention group n=15) were included according to the intention-to-treat approach. Results of the baseline measurement directly after surgery and the second measurement in the week before regular cardiac rehabilitation showed a not statistically significant decrease in the 6 minutes' walking test with 38.6m (95%CI: -92.2-15.0) compared to the comparison group. The comparison group improves on physical activity with a relevant difference of 67 sitting minutes per day compared to the intervention group. Minimal improvement compared to the comparison group was seen on the GARS questionnaire (4.0), average steps per day (160) and the Borg score (1.0). All other outcome measures showed deteriorated results or no difference at all compared to the comparison group. None of the results were statistically significant.

Physical and psychological recovery does not seem to improve when early cardiac rehabilitation is offered in the current set-up.

Keywords: cardiac rehabilitation; early rehabilitation; open heart surgery

#### Introduction

Cardiac incidents cause 30% of all deaths worldwide and this percentage will increase over the next years, while secondary prevention reduces the risk of another incident and improves the health on physical and psychological level (1). After a Coronary Artery Bypass Grafting (CABG) as a treatment

for a cardiac incident, or a valve replacement, it is important to take time to recover while balancing physical activities and handle with the psychological impact.

To support patients and improve the quality of care after a cardiac incident and treatment, outpatient cardiac rehabilitation is offered approximately 6 weeks after hospital discharge, related to the healing of the sternum (2). Cardiac rehabilitation exists of several physical exercises accompanied by relaxation exercises and possible behavioural therapy, to increase physical recovery and to reduce stress, insecurity and symptoms of depression and anxiety (3).The chance of recurrence of a cardiac incident is in that way decreased versus patients who receive no cardiac rehabilitation (18.4% vs 34.7%) and postoperative recovery is stimulated with an increase of 25% on functional capacity (3, 4).

Before the start of cardiac rehabilitation, patients are facing 6 weeks in which they try to pick up their daily activities and find a way to handle the psychological aspect of diagnoses and treatment of the cardiac disorder. Based on global physical exercise advises of the physiotherapists or other caregivers, patients are hoping to recover from surgery as quickly as possible. A survey among 50 Dutch patients who completed the regular cardiac rehabilitation program in Medisch Spectrum Twente (MST), recorded the experiences of patients concerning the period before cardiac rehabilitation (5). It showed that patients experienced insufficient structure and inadequate guidance. They felt insecure and did not know what they were allowed to do and what they were capable of in terms of physical strain. Patients found this period stressful and unstructured, and they reported several symptoms like fatigue, sleeping disturbance and pain (6). This resulted in patients being possibly over active or less active than they are actually capable of.

Maximum benefits of cardiac rehabilitation can only be accomplished if patients already try to be as active as possible in the 6 weeks before cardiac rehabilitation. This could also have a positive impact on their psychological state and stimulate their self-confidence (7). The attention to the psychological impact of a cardiac incident and treatment seems important, since three quarters of all patients that experience a cardiac incident develop symptoms of depression or anxiety (3). The prevalence of depression and anxiety among patients after CABG surgery is respectively 17.5% and 24.7% (8). It could give a possible partial explanation of a patient's activity pattern and need for guidance.

Research showed that with early cardiac rehabilitation (start exercises after surgery within 6 weeks), there were less readmissions compared to regular cardiac rehabilitation (19.0% vs 35.1%) (9). The risks on postoperative complications like wound infections was not increased if early cardiac rehabilitation started, at the earliest, 1 week after surgery (9, 10). Patients accomplished a physical exercise improvement of 37m on the 6 minutes' walking test (11). This resulted in a higher level of daily activities (7). If patients started with cardiac rehabilitation within 28 days they even avoided further physical deterioration (12).

In every study, early cardiac rehabilitation was supported by frequent telephone contact or online eHealth portals (1, 13). Patients were asked to do physical exercises and attention was payed to potential risk factors. In this way, sufficient guidance was provided to (out)patients and apart from that, telephone and online support showed a positive effect on risk reduction and behavioural outcomes concerning the chance of recurrence of a cardiac incident (1, 13).

However, one cannot adopt these study results without further investigation. The studies have different starting times concerning early cardiac rehabilitation and different outcome measures were used to assess the impact of early cardiac rehabilitation. Most studies used the 6 minutes' walking distance test, incremental shuttle walk test or the fitness related Quality of Life. Apart from that, the

researchers do not seem to pay much attention to both the physical and psychological recovery of the patient (Table1).

Author Scalvini et al	Patient group	Inclusion period 2003-2005	Country Italy	Start after discharge 3 or 4 days	Primary outcome Measure 6 min test	Results ↑ of 97m
(10)	replacement	2003 2003	italy	5 01 4 ddy5	o min test	1 01 5711
Pack et al (9)	CABG+ valve replacement	2009-2012	US	Within 2 weeks	Adverse events	Normal CR: 17% Early CR: 17% Wound infections: Similar
Fell et al (12)	CABG+PCI+ post myocardial infarction	2012-2015	UK	Within 28 days (early) Between 29-365 days (late)	Incremental Shuttle walk test Fitness related Qol	Late CR: 个 of 90m Early CR: 个 of 120m Late CR 个 by 29% Early CR 个 by 36%
Eder et al (7)	Cardiac surgery	2010	unknown	Normal CR with supplement of walking or cycling training	6 min test	Control: 个 of 86m Intervention: 个 of 138m
Macchi et al (11)	Cardiac surgery	unknown	Italy	In the second week after surgery	6 min test	Late CR: 个 of 69m Early CR: 个 of 106m

 Table 1: results of studies in early cardiac rehabilitation

This study aims to measure the effects of early cardiac rehabilitation on postoperative physical and psychological recovery directly after discharge from the hospital, and responds to the demand of patients for more influence and guidance in the period prior to the regular cardiac rehabilitation. The main question of the study is: "What is the effect of early cardiac rehabilitation through eHealth, relative to regular cardiac rehabilitation on the postoperative physical and psychological recovery of a patient after open heart surgery in the six weeks after discharge from the hospital?"

### Methods

#### Study design

The study had a quantitative controlled quasi-experimental design, comparing a regular outpatient cardiac rehabilitation exercise group (comparison group) with an early cardiac rehabilitation group (intervention group) in Medisch Spectrum Twente hospital. The study consisted of 2 phases. In the first phase, from June 25<sup>th</sup> 2016 until February 28<sup>th</sup> 2017, focus groups were held to collect the needed content for the online eHealth portal (June 25<sup>th</sup>-November 1<sup>st</sup>) and data of the comparison group was collected (November 1<sup>st</sup> -February 28<sup>th</sup>). In the second phase, from April 1<sup>st</sup> until May 15<sup>th</sup> 2017, data was collected of the intervention group and early cardiac rehabilitation was introduced by using an online eHealth portal.

#### **Online eHealth portal**

The choice of the online eHealth portal is based on earlier research about the effect of an online exercise programme (telecare) on activity level and health status of patients after a Cerebrovascular Accident (CVA), patients with Chronic Obstructive Pulmonary Disease (COPD) and patients with chronic pain (14-16). Those studies were performed by the Roessingh Research and Development (RRD), who were also responsible for the development of the online exercise programme used in the studies. Patients who were using the online exercise programme showed a significantly improved

health status compared to the ones receiving only usual care and they experienced more structure in their training at home (14, 16). Validation of the online exercise programme was hereby proven, although the programmes did differ in exercises and online communication, dependent on the target group (14-16).

The actual use of the online eHealth portal for patients after open heart surgery, implies that patients were asked to log in on a computer, tablet or smartphone and perform physical exercises 3 times a week on Monday, Wednesday and Friday, staged by the treating physiotherapist of MST. In addition, the physiotherapist sets a step goal for every week, based on previous average steps per day measured with a pedometer. Patients manually enter these steps in the online eHealth portal. The portal mainly focuses on physical exercises based on individual capacity, but is supplemented with relaxation exercises and common information about a healthy lifestyle and postoperative recovery. Patients and physiotherapist are able to communicate through messages within the online portal. In order to align the content of the application as much as possible with the wishes of the patient, three focus groups were organized with a maximum of five patients each. The goal of these 45 minutes during focus groups was to collect information about the need for guidance and support of the patients and to gather remarks about the content and first set up of the online eHealth portal.

The development of the online eHealth portal for patients after open heart surgery was performed by technicians of the investigator institute MIRA (University of Twente) in cooperation with the Roessingh Research & Development (RRD) and healthcare professionals of MST.

#### Study population and procedure

Patients were included in the study if they met the following criteria:

- CABG or valve surgery (through open heart surgery)
- Clinically stable and capable of performing an exercise program;
- Intending to participate in the regular cardiac rehabilitation;
- Access to the internet;
- Mastery of the Dutch language;
- Age >18 years;
- Live in the adherence area of the MST.

Cardiothoracic surgeons and nurse practitioners screened the patients carefully whether it was safe for them to participate in (early) cardiac rehabilitation. For example, if a patient suffered from severe cardiac arrhythmias like ventricular tachycardia, he or she could not participate in the study. No explicit exclusion criteria were determined.

The study protocol was approved by the METC of Medisch Spectrum Twente hospital (NTR6274, Appendix 1). An informed consent was obtained from all participants. Patients who were eligible for the study, were informed by the researcher and if necessary, their physical therapist. The data was collected by the researcher or physical therapist.

#### **Outcome measures**

To assess physical and psychological recovery, several outcome measures were used. For physical exercise capacity, the 6 minutes' walking distance test was used as the primary outcome measure (17). This test was proven to be reliable and valid (18). As part of regular care, this test was performed under supervision of a physical therapist. Patients could indicate the level of perceived exertion of the test with the use of the BORG scale (19). The physical disability of patients was measured with the Groninger Activity Restriction Scale (GARS), indicating self-care capacity and performance of daily activities (20, 21). All outcome measures were proven to be reliable and valid

(18, 21). A pedometer objectively assessed the patient's physical activity level by the average number of steps per day. As a supplement to the pedometer the International Physical Activity Questionnaire (IPAQ) was used. This questionnaire of 7 items subjectively describes a patient's activity level during the past week (22). The psychological recovery was measured with the use of the Hospital Anxiety and Depression Scale (HADS), to assess symptoms of depression and anxiety (23, 24). For the BORG, GARS, pedometer, IPAQ and HADS, validity and reliability was not unanimously proven but their functionality was recognised in the above-mentioned studies.

To assess the effects of early cardiac rehabilitation, all measurements were conducted at baseline (in the clinical phase, before discharge) and at the start of the regular cardiac rehabilitation exercise program (6 weeks after discharge).

All patients who completed the baseline measurements: IPAQ, GARS, HADS, pedometer and the 6 minutes' walking distance test, were included in the analysis according to the intention-to-treat approach. To calculate the needed sample size for the study, the 6 minutes' walking distance test was used as the primary outcome. Eight studies out of 22 from a meta-analysis of Bellet et al. (18), showed the mean distance walked of patients with Coronary Artery Disease before and after exercise based cardiac rehabilitation. A between group difference of 60m with a standard deviation of 89 was found. Based on these results in combination with a power of 80% and a significance level of 5%, 2x35 participants were needed for this study.

#### Statistical analysis

Since the study was quasi-experimental, all background characteristics were analysed to check for differences between groups. The same goes for the baseline measurement (first measurement directly after surgery) moment of the outcome measures. An independent samples t-test was used for all normally distributed continuous variables, as the Chi-Squared test was used for the categorical variables. In case of non-normally distributed continuous background characteristics a Mann-Whitney U-test would have been used. Normal distribution of all variables was tested with the use of histograms.

Apart from the six minutes' walking test and the IPAQ sitting variable (as a separate part of the IPAQ), all outcome variables were non-normally distributed. After a log transformation on the 6 nonnormally distributed variables, there were still 5 outcome variables positively skewed. For the outcome measures that stayed non-normally distributed, a Wilcoxon signed rank test was used to assess differences over time within groups and a Mann-Whitney U-test to assess differences over time between groups. This applied for the GARS, HADS anxiety, HADS depression, IPAQ and Borg score. For the Mann-Whitney U-test, difference variables were computed in preparation for this analysis. However, if these difference variables were normally distributed, an independent sample ttest would have been performed instead of a Mann-Whitney U-test, but non-normally distribution stayed intact.

A repeated measurement analysis (linear mixed models in SPSS) with fixed effects was performed to determine the progress and differences over time between the comparison and intervention group for normally distributed outcome measures. This applied for the 6 minutes' walking test, de IPAQ sitting variable in minutes per day and the log transformed 'average steps per day'.

Potential confounders were, if present, included in both the repeated measurement analysis as in a linear regression. In that way, it was possible to correct for these confounders on both the

normally distributed outcome measures and the non-normally distributed outcome measures, since the Mann-Whitney U-test does not allow for correction on potential confounders.

All non-normally distributed variables are expressed as medians and interquartile ranges, all normally distributed variables are expressed as means and standard deviations. The level of statistical significance was, for all analysis, set at p<0,05. All statistical analysis was performed with SPSS (version 24).

## Results

#### Participants

Between November 7<sup>th</sup> 2016 and May 15<sup>th</sup> 2017, 104 patients were eligible for the study. Sixtyfive patients were eventually enrolled in the study, 39 patients were excluded due to several causes as for example complications after surgery (n=7), no access to the internet (n=4), illiterate or unable to speak the Dutch language (n=3), or death (n=2). Eleven patients refused to participate. Of the included 65 patients, 49 underwent a CABG, 12 had a valve replacement and 4 patients underwent both a CABG and valve replacement. The comparison group included 48 patients, the intervention group 17. There were 8 drop outs (quit before the baseline measurement was completed) and 4 patients quit the study after the baseline measurement was completed (Figure 1).

#### Figure 1 flowchart participants



Of all patients in the comparison group, 83.3% were men. For the intervention group this number was 73.3%. The average age (in years) of all patients of the comparison group was 66.2±8.6 vs 64.7±9.2 of the intervention group. Four to 6 weeks after surgery, when most of the second measurements were performed, 16.7% of the comparison group and 50% of the intervention group were bothered in their daily activities due to complications like heart rhythm disorders, painful ankles/legs, or shortness of breath. Of all the participants in the comparison group 73.8% actually joined the regular cardiac rehabilitation of the MST vs 53.3% of the intervention group. Due to drop outs or patients that quit the study early, it is in 2.4% (comparison group) vs 6.7% (intervention group) of the times unknown whether patients started regular cardiac rehabilitation. Reasons for not taking part of the rehabilitation differed. Some patients already started their fulltime job (5.3%), others preferred training individually or at physical therapists near their home (12.5%), or they simply suffered long-term complications like heart failure or heart rhythm disorders (3.5%). If patients did join the regular cardiac rehabilitation, the waiting time (since open heart surgery), was 7.2 weeks for the comparison group vs 6.9 weeks for the intervention group (Table 2).

Results of the Chi-squared test and the independent sample t-test showed that there were no statistical significant differences in background characteristics between the comparison and intervention group (Table 2). Results of the Mann-Whitney U-test and the independent sample t-test showed that there were no statistical significant differences in outcome measures at the first measurement moment directly after surgery (Table 3).

Gender	men women	Control group 83,3% 16,7%	Intervention group 73,3% 26,7%	Pearson Chi-Square 0,40	Independent Sample t- test (sign)
Age (yrs.)	mean (SD)	66,2 ± 8.6	64,7 ± 9.2		0,57
Limited by other	no	69%	66,7%	0,80	
diseases	partly	28,6%	33,3%		
	yes	2,4%	0%		
BMI	mean (SD)	27,9 ± 4,33	30,4 ± 4,7		0,07
Marital status	married or living together	83,3%	86,7%	0,38	
	single	16,7%	6,7%		
	missing		6,7%		
Working status	working	28,6%	40,0%	0,41	
	not working	71,4%	60,0%		
Highest education	primary education (none or LBO)	23,8%	40,0%	0,90	
	secondary education (high school, MBO)	50%	33,3%		
	Higher education (HBO, WO)	23,8%	26,7%		
	missing	2,4%			
Cardiac rehabilitation	yes	73,8%	53,3%	0,19	
	no	23,8%	40,0%		
	unknown	2.4%	6.7%		
Time until cardiac rehabilitation (weeks)	mean (SD)	7,2± 1,83	6,9 ± 0,86		0,64

Table 2 Baseline Characteristics and between group difference

#### Table 3 Between group difference at the first measurement moment

		Control group	Intervention group	Mann Whitney U- test	Independent Sample t-test (sign)
SIXMIN	Mean (SD)	305±80	306±110		0,99
IPAQ	Median (IQR)	369 (107-693)	685 (248-1136)	0,19	
IPAQ sitting	Mean (SD)	494±314	407±330		0,44
Steps per day	Median (IQR)*	1797 (539-3077)	2379 (1008-5004)		0,27
Borg	Median (IQR)	12.0 (11.0-13.0)	13.0 (11.0-15.0)	0,20	
GARS	Median (IQR)	36.5 (31-42)	37.0 (34-46.6)	0,42	
HADS anxiety	Median (IQR)	4.0 (2.0-7.0)	5.0 (2.0-8.0)	0,47	
HADS depression	Median (IQR)	4.0 (1.0-6.0)	6.0 (1.0-8.0)	0,56	

\*Steps per day are log transformed in order to act as normally distributed variables. The actual medians are used in the table to make the values more interpretive. SIXMIN: 6 minutes' walking distance test; IPAQ: International Physical Activity Questionnaire; Borg: perceived exertion scale; GARS: Groninger Activity Restriction Scale; HADS: Hospital Anxiety and Depression Scale; IQR: interquartilerange (25<sup>th</sup> and 75<sup>th</sup> percentile); SD:standard deviation.

#### **Physical recovery**

For the primary outcome, the 6 minutes' walking test, the comparison group improved with 132m were the intervention group improves with 93m. This is a between group difference in mean change of 38.6m (95%CI: -92-15.0) (Figure 2a). When it comes to the physical activity expressed in sitting minutes per day (IPAQsitting), the comparison group improved with 83 minutes compared to 16 minutes of the intervention group. This is a between group difference in mean change of 68 minutes (95%CI: -119-254). The IPAQ showed a deterioration in results for the intervention group compared to the comparison group with 192 MET minutes.

Minimal between group differences in favour of the intervention group were seen for the GARS, Borg and steps per day. All within group differences based on the Wilcoxon signed rank test were statistically significant, apart from the Borg score of the intervention group. None of the between group differences were significant (Table 4).

#### **Psychological recovery**

Although the progress of the HADS score on depression for the intervention group seems increased compared to the comparison group (Figure 2c), the HADS score for depression and anxiety showed no statistical within or between group difference for the intervention group compared to the comparison group (Table 4, Figure 2b, 2c).

	Baseline	Second	Within group	Significance	Between group	Significance
	measurement	measurement	difference		difference (mean)	(p)
SIXMINCG	305±80	437 ± 90	132		20.6 (059) (01.02.45.0)	0.45
SIXMINIG	306±110	399±154	93		-38.6 (95%CI:-92-15.0)	0.15
IPAQ CG	369 (107-693)	1986 (739-3994)	1473 (437-3152)	0.001		0.47
IPAQ IG	685 (248-1136)	2635 (1386-3857)	1281 (1050-2982)	0.003		0.47
IPAQ sitting CG	494±314	411±240	83		67 (95%Cl:-119-254)	0.47
IPAQ sitting IG	407±330	391±253	16			
Steps per day CG*	1797 (539-3077)	4019 (2716-6377)	2608 (1129-4120)			
Steps per day IG*	2379 (1008-5004)	6285 (3609-8607)	2768 (825-4352)		-0.19 (95%Cl:-0.42-0.04)*	0.10
Borg CG	12.0 (11.0-13.0)	11.0 (10.0-11.0)	1.0 (0.0-3.0)	0.001		
Borg IG	13.0 (11.0-15.0)	11.0 (8.0-12.0)	2.0 (0.0-4.0)	0.06		0.50
GARS CG	36.5 (31-42)	21.0 (18-25.8)	13.0 (7.6-19.5)	0.001		
GARS IG	37.0 (34-46.6)	19.0 (18-24.5)	17.0 (9.0-20.3)	0.002		0.46
HADS anxiety CG	4.0 (2.0-7.0)	1.0 (0.0-4.0)	2.5 (1.0-4.0)	0.001		
HADS anxiety IG	5.0 (2.0-8.0)	2.0 (0.0-4.5)	3.0 (-1.0-5.0)	0.04		0.83
HADS depression CG	4.0 (1.0-6.0)	1.0 (0.0-2.8)	1.0 (0.0-4.0)	0.001		
HADS depression IG	6.0 (1.0-8.0)	1.0 (0.0-5.0)	1.0 (0.0-4.5)	0.05		0.60

All normally distributed variables are displayed in means and standarddeviations. All non-normally distributed variables are displayed in medians and interquartileranges (25<sup>th</sup> and 75<sup>th</sup> percentile) \*Steps per day are log transformed in order to act as normally distributed variables. The actual medians are used in the table to make the values more interpretive. CI: Confidence Interval.; CG: control group; IG: intervention group; SIXMIN: 6 minutes' walking distance test; IPAQ: International Physical Activity Questionnaire; Borg: perceived exertion scale; GARS: Groninger Activity Restriction Scale; HADS: Hospital Anxiety and Depression Scale;









Figure 2c



#### Discussion

This study investigated the effect of early cardiac rehabilitation through eHealth, relative to regular cardiac rehabilitation on the postoperative physical and psychological recovery of the patient after open heart surgery in the 6 weeks after discharge from the hospital. Early cardiac rehabilitation through an online eHealth portal is not in all outcomes in favour of the intervention group. The main outcome measure, the 6 minutes' walking test, showed a not statistically significant decrease in exercise capacity compared to the comparison group, but the intervention group assesses this second measurement of the 6 minutes' walking test as less exhausting. They also did not improve on IPAQ sitting in minutes per day and HADS anxiety and depression. On the decreased IPAQ questionnaire patients stated they were less active on severe and mild activities. Minimal improvement compared to the comparison group was seen on physical disability and physical activity, measured with the GARS questionnaire and pedometer.

Although previous studies were promising, this quasi experimental study showed that with early cardiac rehabilitation through the current online eHealth portal, physical and psychological recovery do not significantly improve on every aspect and even decreases on some outcomes.

#### **Physical recovery**

The outcomes of this study were not as expected and differ compared to the earlier described studies on early cardiac rehabilitation (7, 11, 12). In these studies the intervention group improved on the primary outcome, the 6 minutes' walking test, with 30-50m compared to the control group. In the current research, the intervention group decreases on the 6 minutes' walking test but they also perceived the test as less exhausting compared to the comparison group. This arises questions about the right intensity level and the way in which patients possibly need to be stimulated to increase their physical capacity level.

An important difference in earlier studies compared to the current research is that patients participating in early cardiac rehabilitation were immediately transferred to the inpatient cardiac rehabilitation centre, whereas patients in the current research followed early cardiac rehabilitation at home (11). Inpatient rehabilitation makes it possible for healthcare providers to adjust early cardiac rehabilitation to a patient's specific needs and identify possible physical or psychological problems in an earlier stage. Also, early cardiac rehabilitation started between 2-4 weeks after surgery instead of directly after surgery. Patients seemed sufficiently recovered since those starting times did not cause an increase in complications.

Exercises of the current research could be too heavy. Instead of performing physical upper and lower body exercises 2 or 3 times a week, previous studies offered lower extremity exercises as stationary cycling or walking. In another study walking and cycling was offered as a supplement to regular cardiac rehabilitation (7). On the other hand, the intervention group of the current research showed cautious signs of improvement on the distance walked in steps per day and the ability to be self-sufficient (GARS).

Nevertheless, physical exercises of previous studies seem better adjusted to a patient's physical capacity since the results of those studies were promising. A tele monitoring module with which video contact was initiated and blood pressure, heart rate and body weight were measured, made it possible for healthcare providers to respond to clues for physical stress and possible complications after surgery (13). This could be a valuable addition to the current online eHealth portal to increase self-confidence and to make sure the exercises are well fitted to the patients.

Training shortly after surgery with the current frequency could be too much for patients after a CABG or valve replacement. Fifty percent of the intervention group vs 16.7% of the comparison group was bothered with physical problems related to the surgery in the 6 weeks after the procedure (see results section). Eder et al. (7) already mentioned that in the first weeks after surgery the incidence of symptoms related to that surgery is the highest. Some patients in the current research literally mentioned their physical problems as a reason for their relatively poor performance on the 6 minutes' walking test. This is in contradiction with earlier mentioned studies were early cardiac rehabilitation should be safe for patients to participate in, and the risk on postoperative complications should not be increased (9, 10). Nevertheless, the perceived exertion of the intervention group is less on the second measurement before the start of the regular cardiac rehabilitation compared to the comparison group, which could indicate that the effort with which the patients fulfilled these test is questionable. The reasons for this possible decrease in effort are not investigated in this research but it could have to do with a possibly higher anxiety level for physical effort compared to the comparison group. Although communication with the physical therapist is possible, the lack of face to face contact during early cardiac rehabilitation at home in combination with what might be intense online exercises, could have resulted in patients being more careful.

#### **Psychological recovery**

An important note on the results of psychological recovery, is that it was only measured with the HADS-score on anxiety and depression. With the use of extra outcome measures, as in physical recovery, a more complete image about psychological recovery could have been given.

No statistically significant differences were found in perceived anxiety or depression between the comparison and intervention group, but patients reactions on the online eHealth portal were promising. The motivation of patients and the need for guidance was already seen during the inclusion of patients in the research. Patients that were approached for the intervention group were more eager to participate than patients who were asked for the comparison group. This confirms the study of Fokkens (5). At measuring moments in the MST or in the contact with the physical therapists, patients mentioned the benefits of structured guidance. The online eHealth portal seems to give patients the guidance and support they need, but it is not enough to decrease anxiety or depression. Involvement in group training and the ability to share experiences is one of the key-factors which makes early cardiac rehabilitation a success (7). It leads to an increase in self-confidence and less fear for physical activities. However, early cardiac rehabilitation started 4 weeks after surgery, where the current research started directly after discharge form the hospital. Immediate group training could be too much for patients directly after surgery and makes them less motivated.

#### Limitations and recommendations

The current online eHealth portal did not give the results that were hoped for, but potential success could be accomplished as long as some remarks will be taken into consideration.

The first and most important fact is that only 17 participants could be included in the intervention group, were these numbers should be at least 35 according to the sample size calculations. Secondly, attention must be payed to patients that are not familiar with a computer or the internet. Less or no knowledge of a computer or the internet, results in patients being dependent of friends and family for technical support, which makes it harder for them to take part on the online eHealth portal (1). This was noticed by the researchers and mentioned by the patients during the inclusion. Patients in this research claimed to be flooded with information in the days after surgery

while they were still in the hospital. Once at home, they seemed to be forgotten a lot of information, including dealing with the online portal. Although all patients received a manual, the investigators where contacted a lot with questions about the online eHealth portal. For those patients, its imaginable that the physiotherapist visits the patient at home in the first week after discharge from the hospital, in order to go through and to practice the online eHealth portal together.

Some parts of this research are not further investigated to avoid the research becoming too extended and complex for the time period in which it was performed. This includes, among others, research at the frequency of exercises in combination with physical capacity and communication with health care providers. Performance could progress if adherence with the online eHealth portal will be investigated and can be increased. Does every patient practice at their maximum, or way beneath that? What are the reasons for their current performance level or adherence? Log data is necessary to gain an insight in the actual performance, perceived exertion (through online Borg scores) and frequency of exercises. With the same data, the communication frequency and kind of questions and remarks near exercises could be analysed. In-depth interviews could be a valuable addition to this part of research to explore the rationale behind the current performance level.

An in-depth interview could also provide a clearer picture about the psychological impact of an online eHealth portal in relation to physical performance. The intervention group scores higher at baseline on steps per day, physical activity and the IPAQ sitting in minutes per day, but deteriorates in the following weeks compared to the comparison group. An increase in physical exercises could also increase possible fear of those exercises, although the results of the HADS anxiety and depression showed no difference. Yet the Multidisciplinaire Richtlijn Hartrevalidatie (3) mentioned three quarters of all patients after a cardiac incident develops anxiety or depression. Therefore, the fear of performing exercises is plausible.

Further research could investigate if patients with a higher physical condition after surgery also have a higher physical condition before surgery compared to the comparison group. A measurement moment before surgery could possibly explain the not statistically, but relevant difference in physical condition at baseline between the intervention and comparison group. It could be a coincidence, but it's also possible that patients of the intervention group are more motivated and in physical better shape before and directly after surgery.

#### Conclusion

The success of the online eHealth portal is dependent on several factors, among which the physical and psychological bearing strength of patients, their social network and the level of support offered by healthcare providers. Future research should aim at an online eHealth portal alternated with face to face contact, video contact and tele monitoring (measuring vital signs). The measurement of blood pressure, heart rate and body weight could detect physical stress and signs of possible complications, but it also creates a feeling of being watched and therefore less anxious to perform exercises. Face to face contact and video contact increases motivation and adherence. Group training would not be the first recommendation since patients do not look forward to the visits they have to make in the first weeks after surgery due to fatigue and pain.

This study showed that early cardiac rehabilitation through the current online eHealth portal under these circumstances did not give the results that were hoped for, but the set-up has the potential to contribute to a faster physical and psychological recovery. By combining personal and digitally contact, healthcare providers could be able to motivate, stimulate and support patients in their path to full recovery.

#### Acknowledgement

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Appendix 1: Approval protocol METC

# **RESEARCH PROTOCOL**

# The effectiveness of an online exercise program in early cardiac rehabilitation after cardiac surgery

Title	The effectiveness of an online exercise program
	in early cardiac rehabilitation after cardiac surgery
Short title	E-health in early cardiac rehabilitation
EudraCT number	Not applicable
Version	3
Date	20-02-2017
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Laboratory sites < <i>if applicable</i> >	Not applicable
Pharmacy <if applicable=""></if>	Not applicable

# **PROTOCOL SIGNATURE SHEET**

|

E-health in early cardiac rehabilitation

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# LIST OF ABBREVIATIONS AND RELEVANT DEFINITIONS

ABR	ABR form, General Assessment and Registration form, is the application form that is required for submission to the accredited Ethics Committee (In Dutch, ABR = Algemene Beoordeling en Registratie)
AE	Adverse Event
AR	Adverse Reaction
CA	Competent Authority
CABG	Coronary Artery Bypass Grafting
CAD	Coronary Artery Disease
CHD	Coronary Heart Disease
ССМО	Central Committee on Research Involving Human Subjects; in Dutch:
	Centrale Commissie Mensgebonden Onderzoek
CR	Cardiac Rehabilitation
CV	Curriculum Vitae
CVD	Cardiovascular Disease
DSMB	Data Safety Monitoring Board
EU	European Union
EudraCT	European drug regulatory affairs Clinical Trials
GCP	Good Clinical Practice
IB	Investigator's Brochure
IC	Informed Consent
IMP	Investigational Medicinal Product
IMPD	Investigational Medicinal Product Dossier
METC	Medical research ethics committee (MREC); in Dutch: medisch ethische
	toetsing commissie (METC)
MI	Myocardial Infarction
(S)AE	(Serious) Adverse Event
RCT	Randomized Controlled Trial
SPC	Summary of Product Characteristics (in Dutch: officiële productinformatie
	IB1-tekst)
Sponsor	The sponsor is the party that commissions the organisation or performance
	of the research, for example a pharmaceutical
	company, academic hospital, scientific organisation or investigator. A party
	that provides funding for a study but does not commission it is not
	regarded as the sponsor, but referred to as a subsidising party.
SUSAR	Suspected Unexpected Serious Adverse Reaction
Wbp	Personal Data Protection Act (in Dutch: Wet Bescherming Persoonsgevens)
WMO	Medical Research Involving Human Subjects Act (in Dutch: Wet Medisch-
	wetenschappelijk Onderzoek met Mensen

#### SUMMARY

**Rationale:** Cardiac rehabilitation (CR) has shown to be an effective treatment to reduce mortality and morbidity among cardiac patients who underwent cardiac surgery. Exercise training is a major component of CR. It usually starts in the hospital and continues in an outpatient setting six weeks after discharge from the hospital. In the intervening period patients continue rehabilitation by themselves with the advices they received in the hospital. Research has shown that patients experience this intervening period as stressful. They feel insufficiently supported and are in need of more information and advice. No general consensus exists concerning the best timing of exercise-based CR. However, there seems to be a positive relation between the timing of the start of an exercise program and physical functioning.

**Objective**: This study aims to investigate the effects of an early online exercise-based CR program among patients after cardiac surgery.

**Study design:** A quasi-experimental study will be conducted comparing patients who completed a traditional outpatient exercise-based CR program (control group) with patients who completed an early (home-based) online exercise CR program (in the first 6 weeks after discharge from the hospital) as adjuvant to the traditional outpatient exercise-based CR program (intervention group).

**Study population:** Patients who underwent CABG or valve surgery in the MST and are intended to participate in exercise-based CR offered by the MST.

**Intervention (if applicable)**: Online exercise program which consists of three modules: exercises, monitoring health status and communication (with physical therapist).

Main study parameters/endpoints: Main outcome measure is exercise capacity, measured with the 6 min walk test. Secondary outcomes measures are physical activity, quality of life, disability, anxiety, depression and satisfaction with treatment.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: By starting the exercise program in an earlier phase, we respond to the needs of patients to get more (tailored) support in the first weeks after discharge from the hospital. Furthermore, we expect that patients will start the traditional outpatient CR in better physical condition and gain better health outcomes. From literature, we know that there are no indications that early enrollment in exercise-based CR after MI or cardiac surgery is harmful to patients. Moreover, only low to moderate strenuous exercises will be conducted. Exercises will be tailored and the intensity will be build, dependent on the performance and willing of the patient. So, we don't expect extra risks for the patients, related to participation in this study.

There are three measurement points: at baseline (clinical phase) and at the start and end of the traditional outpatient exercise-based CR program. The outcome measures mostly exist of questionnaires, which take maximally 20 minutes at a time to complete. The six minutes' walk test is usual care. Finally, patients are asked to wear an accelerometer for three (control group) or seven (intervention group) weeks. This is a small device that can be worn without

hindrance of daily activities. So, the burden for the patients seems acceptable and in proportion to the benefits.

# INTRODUCTION AND RATIONALE

#### Introduction

Cardiovascular disease (CVD) remains a major cause of death throughout the world (Nichols et al., 2014). In the Netherlands, 28% of all deaths were caused by CVD, particularly by coronary heart diseases (CHDs) and stroke (Hartstichting, 2015). In addition to death, CVD cause many serious non-fatal events which are major causes of disability (Vos et al., 2012). The aging population, obesity, lack of physical activity, unhealthy diet, smoking and stress are all risk factors that contribute to the mortality and morbid burden of CVD, especially CHD. Management of these factors is important to reduce the burden of CVD.

Cardiac rehabilitation (CR) has shown to be an effective treatment to reduce mortality and morbidity. It involves multiple interventions designed to optimize a cardiac patient's physical and psychological health and to adopt a healthy lifestyle in order to reduce risk factors and to prevent future cardiac problems. Exercise training is a major component of CR. It usually starts in the hospital (phase 1) and continues in an outpatient setting after discharge (phase 2). Other components of CR include psychosocial support and education / counselling to adopt a healthy lifestyle.

A recent systematic review and meta-analysis of Anderson et al. (2016) has shown the beneficial effects of exercise-based CR among patients with CHD. In this meta-analysis 63 randomized controlled trials (RCTs) were included (14.486 patients). Compared with a no exercise control condition, exercise-based CR reduces the risk of cardiovascular mortality and hospital admissions and improves health-related quality of life. Furthermore, several studies have shown that exercise-based CR improves exercise capacity and fitness (Hsu et al., 2011; Giallauria et al., 2011; Eder et al., 2010, Lavie et al., 2009). Despite these positive effects of exercise-based CR, a critical comment to the timing of CR has to be made.

### Timing of CR

Most exercise programs start at least four to six weeks after discharge from the hospital. This is especially applied to patients who underwent cardiac surgery like Coronary Artery Bypass Grafting (CABG) surgery of valve surgery (Clark et al., 2005). In Medisch Spectrum Twente (MST) the wait time for an exercise program after cardiac surgery is six weeks, which is related to the healing time of the sternum after sternotomy. In this period, patients continue rehabilitation by themselves with the advices they received in the hospital during admission. In 2014 an improvement project concerning cardiac rehabilitation was conducted in MST. A survey was performed among 50 patients to evaluate their experiences with cardiac rehabilitation. The results of this project has shown that patients experience the usual wait time as too long. The current advices given in the clinical phase offer insufficient structure in

the period prior to the start of the outpatient exercise program. Patients experience lack of guidance, are uncertain in the first weeks after discharge, and do not know what they're allowed to do in terms of physical load (Fokkens, 2014). A qualitative study of Lie et al. (2012) among 93 CABG patients confirmed the stressfulness of the first four weeks after discharge from the hospital. Patients feel insufficiently supported and are in need of more information and advice. Uncertainties exist with regard to postoperative pain, physical activity and medications. Furthermore, feelings of anxiety and/or depression might occur (Lamb et al., 2012). Next to psychological consequences, insufficient support and guidance may result in a lower activity level than a patient physically might be able to. This may lead to loss of muscle mass and physical condition, instead of building up condition and developing a healthy lifestyle. Too much activity or overload is also a risk, which may cause delay of recovery of the sternum.

Although most exercise-based CR programs start at least four to six weeks after discharge from the hospital, no general consensus exists concerning the best timing of exercise-based CR (Dafoe et al., 2006). Some researchers and physicians recommend to start earlier. Dubach et al. (1998) stated that phase II rehabilitation after cardiac surgery can start as early as one week after surgery without having a negative influence on infections, mortality or readmission. Early rehabilitation can even improve graft patency after CABG. Carrel et al. (1998) analyzed the impact of fast tract protocols after cardiac surgery and concluded that phase II of CR can start after 2-4 weeks following CABG and valvular procedures in patients with normal and slightly reduced left ventricular function. Because wound healing usually takes six weeks, certain activities, such as uncontrolled and asymmetrical movements of the shoulders and arms, should be avoided in this period.

The number of studies on the effects of early exercise-based CR is limited. To the best of our knowledge, no study has compared the effects of early CR with traditional CR (starting at least four to six weeks after hospital discharge). However, there seems to be a positive effect between the timing of the start of an exercise program and physical functioning. Fell et al. (2015) conducted an observational study among 32.899 patients with acute coronary syndrome and showed that delayed CR significantly impacts fitness outcomes. For every 1day increase in CR wait time, patients were 1% less likely to improve across all fitnessrelated measures. These results were in line with the results of a study of Johnson et al. (2015) among 1.241 patients. They concluded that patients who enrolled in CR within 15 days after treatment had greater changes in exercise capacity compared with patients who enrolled > 30 days after treatment. Finally, Haykowsky et al. (2011) performed a metaanalysis to assess the overall effects of exercise training on left ventricular remodeling in clinically stable post Myocardial Infarction (MI) patients. They found the greatest benefits when training starts earlier following MI (from one week). Delayed exercise training by one week after MI would require an additional month of training to attain the same changes. In conclusion, early enrollment in CR seems to lead to greater health benefits than late enrollment. There are no indications that early enrollment in exercise-based CR after MI or

cardiac surgery is harmful to patients (Hawkowsy et al., 2011; Pack et al., 2015; Macchi et al., 2007). There were no differences in complications between early and late enrollees. More controlled studies are necessary to investigate the effects of early exercise-based CR compared to traditional CR.

The current study aims to investigate the effects of early exercise-based CR among patients after cardiac surgery. By starting the exercise program in an earlier phase, immediately after discharge from the hospital, we respond to the needs of patients to get more (tailored) support in the first weeks after discharge from the hospital. Furthermore, patients might gain greater health benefits. Early exercise-based CR will be offered complementary to the traditional outpatient exercise program. Because the current organization and financing of cardiac rehabilitation does not allow an increase of face-to-face treatment, early CR will be home-based with the use of the internet.

#### Home-based CR

Home-based CR has been introduced in the late 1980s in an attempt to widen access and participation. It may include a combination of home visits, telephone or mail support or self-education materials (Clark et al., 2011). Several studies comparing home-based with centre-based CR have been published. Dalal et al. (2010) conducted a systematic review and meta-analysis and included 12 randomized controlled studies (1938 participants). They concluded that home-based CR is equally effective as centre-based CR in improving exercise capacity, health related quality of life, modifiable risk factors and cardiac events (including mortality, revascularization, and readmission to hospital). Given the widespread and easy access to web services and telecommunications devices (mobile phones, smartphones, tablets, etc.), home-based CR is increasingly being supported by these tools (Clark et al., 2015). Several internet-based CR programs have been developed and investigated in recent years (Clark et al., 2015). Compared to usual care, they improve exercise performance, physical activity, quality of life and cardiovascular risk profile (Reid et al., 2011; Lear et al, 2014; Maddison et al., 2014; Zutz et al., 2007). These positive effects seem to be maintained at 12-month follow-up (Reid et al., 2011; Lear et al., 2014).

### OBJECTIVES

This study aims to investigate the effects of a home-based online exercise program, that will be used by patients after cardiac surgery in the early rehabilitation phase (immediately after discharge from the hospital) before they start with the traditional outpatient exercise program (6 weeks after discharge from the hospital).

### Primary research question:

What is the effect of the use of an (adjuvant) online exercise program in the early rehabilitation phase by patients who underwent cardiac surgery on physical exercise capacity?

### Secondary research questions:

What is the effect of the use of an (adjuvant) online exercise program in the early rehabilitation phase by patients who underwent cardiac surgery on physical activity?

What is the effect of the use of an (adjuvant) online exercise program in the early rehabilitation phase by patients who underwent cardiac surgery on functional status?

What is the effect of the use of an (adjuvant) online exercise program in the early rehabilitation phase by patients who underwent cardiac surgery on anxiety and depression?

What is the effect of the use of an (adjuvant) online exercise program in the early rehabilitation phase by patients who underwent cardiac surgery on satisfaction with treatment?

### STUDY DESIGN

A quasi-experimental study will be conducted comparing MST patients who completed the traditional outpatient exercise-based CR program (control group) with MST patients who completed an early home-based online exercise CR program (in the first 6 weeks after discharge from the hospital) as adjuvant to the traditional outpatient exercise-based CR program (intervention group). Both groups will be matched (mean age, mobility) in order to reduce bias due to group differences.

The study consists of two phases:

Phase 1) June - March

In this phase, the requirements for the online exercise program are defined by means of focus groups with health care professionals and patients. These requirements will be used to adapt the existing program to the needs of this specific target population. In addition, data collection of the control group will be conducted (from November till March).

Phase 2) April - July

In this phase, the online exercise program will be implemented and data collection of the intervention group will be conducted.

# STUDY POPULATION

## Population (base)

Patients who underwent CABG or valve surgery in the MST and are intended to participate in exercise-based CR offered by the MST, are asked to participate.

## Inclusion criteria

In order to be eligible to participate in this study, a patient must meet all of the following criteria:

- CABG or valve surgery
- Clinically stabile and capable of performing an exercise program (judgement cardiologist)
  - Intended to participate in the regular outpatient exercise program
  - Access to the internet
  - Master of Dutch language (reading and writing)
  - Live in adherence area of MST
  - Age >18 years

These criteria are applied for both the experimental group and the control group.

# **Exclusion criteria**

No exclusion criteria are defined.

### Sample size calculation

The experimental group will be compared to the control group before the start of the traditional outpatient exercise program and after completion of this program. The primary outcome measure is physical exercise capacity, measured with the 6 minutes' walk test. Data from a meta-analysis of 22 studies (Bellet et al., 2012) among patients with CAD has shown that the mean score on the 6 minutes' walk test before the start of an exercise-based CR program is 357 meters (SD 98). Mean improvement over the trainings period (range 6 weeks - 6 months) is 60 meters. Fiorina et al. (2007) conducted a 6 minutes' walk test among cardiac surgery patients in an earlier phase (within 15 days after OK). They found a mean score of 281 meter (SD 90). After a short trainings period of 15 days this score improved to 411 meters (SD 107).

We used the data of upper mentioned studies to calculate the number of subjects required for our study. For this calculation, an online program of ClinCalc was used <u>http://clincalc.com/stats/samplesize.aspx</u>). Assuming a mean score of 357 meter (SD 98 meter) in the control group before the start of the regular exercise-based CR program and a mean score of 417 meter in the intervention group (this is an improvement of 60 meter compared to the control group), in combination with a power of 80% and a significance level of 0.05 leads to a sample size of 2x42 patients. Adjusting for drop outs and non-compliance, a total of 2 x 50 patients will be included.

In the period 1 January 2016 – 15 September 2016 152 patients fulfilled the inclusion criteria and were included in traditional outpatient exercise-based CR. Therefore, we expect it is feasible to include 100 patients in six months.

# TREATMENT OF SUBJECTS

# Investigational product/treatment

The starting point for this study is an existing home-based exercise program which has been developed and evaluated for other diagnosis groups (chronic pain, COPD, oncology etc). This program will be adapted to the needs of CR and the definite content of these modules will be established by means of focus groups with patients and health professionals (physiotherapists) (phase 1 of the study). The content is in line with the guidelines of the Royal Dutch Society for Physical Therapy for CR (Vogels et al., 2011).

The online exercise program consists of three different modules, each with their own functionalities. Through a secure login, the patient and physiotherapist log into a web portal to gain access to these modules (see figure 1).





# Module 1: Online exercise program

This module has the goal to support the patient in his reconditioning at home. The module has a database of 60 exercise videos of different exercises, composed and recorded by physiotherapists. Exercises are clustered into five main categories: strength (arms/shoulders, legs, butt), thoracal mobility, breathing, relaxation and balance (see supplement 1). Relaxation and balance exercises are only included on indication. Patients are asked to log in three times a week and to perform about 6 exercises each session. These exercises are weekly selected by the treating physiotherapist according to a predefined schedule (see supplement 2). Next to these exercises, patients are recommended to achieve their walking goal (amount of steps) every day.

For each exercise there is a video with a written and spoken description available for both the physiotherapist and the patient (see figure 2). On the professional's portal, the

physiotherapist gets feedback on what exercises are performed by the patient and during which moment of the day.



Figure 2: Example of an exercise in the online exercise program

#### Tailoring of exercise program

The exercise program will be tailored to the needs of patients and the rehabilitation progress. A tailored exercise program means that (1) the program contains exercise categories that fit the patient profile (with regard to balance, relaxation and stairs exercises) and (2) the level of intensity / difficulty of strength and balance exercises and walking goal are in line with the performance of the patients. To support the physiotherapist in this process of tailoring, a decision tree has been developed. The main components of this decision tree will be summarized.

### Ad 1) Tailoring exercise categories:

One day before discharge from the hospital, the following data is collected:

- Hospital Anxiety and Depression Scale (HADS) scores. Relaxation exercises will be included if anxiety and/or depression score is ≥ 5, meaning that the patient is experiencing symptoms of anxiety and/or depression (Nederlandse Vereniging voor Cardiologie, 2012).
- Timed up and go-test (TUG) score. Balance exercises will be included if this score is > 10, meaning that the level of balance is insufficient (Mathias et al., 1986).
- Presence of stairs in home of patient. Stairs exercises will only be included if the patient has a stair at home.

If relaxation and / or balance exercises are indicated, some exercises from the category 'interchangeable exercises' (see supplement 2) will be deleted.

### Ad 2) Tailoring exercise level of intensity:

The strength exercises contain upper and lower extremity exercises. Both categories can be divided into several subcategories (see supplement 1). Each subcategory (e.g. squat, lunge) contains several exercises of different intensity. One day before discharge from the hospital, the physiotherapist determines one start level for all lower extremity exercises (range 1-6)

and one start level for all upper extremity exercises (range 1-4), except for the heels-butt exercises which always start at level 1. These two start levels are based on a subjective judgement of the physiotherapist (based on TUG test and 6 minutes' walk test). The Borg Scale of Perceived Exertion will be used to change the level of intensity of the strength exercises in time. After completion of each exercise patients are asked to rate perceived level of exertion, ranging from 6 ('least amount of effort') to 20 ('most effort'). The Borg scale has shown to be a useful tool to build a training program and to recognize physical limits (Vogels et al, 2011; Jongert et al., 2004; Borg, 1982). When the patient reports a mean Borg score  $\leq$  11, this implies that the patient perceives the exercise intensity as low. The level of intensity will then go up one (score 9 or 10) or two (score 6, 7, or 8) level(s) the next training week. When the patient scores 12 or 13 the exercise intensity is moderate and thus adequate. No changes will be made. When the patient reports a score of 14 or higher this implies that the patient perceives the level of intensity of the exercises as too high. Trainings intensity will be kept constant and the physiotherapist will contact the patient to explore the reason for this high level. If necessary, adaptations will be made (e.g. level down of intensity, deletion of exercise).

The balance exercises start at level 1 and can be build up to level 3. After completion of an exercise, the performance (amount of effort) is evaluated with a 4-point Likert scale, ranging from 'no effort' (score 1) to 'impossible to complete' (score 4). Exercises are build up in level of difficulty if patients score 1 ('no effort') or 2 ('a bit effort'). If patients score 3 or 4, no adaptations will be made.

The walking goal will be tailored and build up by calculating the mean amount of daily steps each week (registered with Fitbit). The step goal for the next week is the mean amount of daily steps in previous week + 10% (Kaminsky et al., 2013).

### Module 2: Telemonitoring; monitoring of health status and disabilities

This module makes it possible to identify health problems or to gain insight in the rehabilitation progress of the patient and can be used for optimal treatment (e.g. by modifying the exercise program). As mentioned above, different standardized questions are asked at fixed time intervals to gain insight into the rehabilitation progress (e.g., Borg scale of perceived exertion). The answers to these questions are presented in a clear overview on the portal of the health care professional. Answers are also made visible to the patient to give them insight into his health status and progress in rehabilitation.

### Module 3: Telecommunication

This module makes it possible for the patient and professional to have contact with each other. The physiotherapist and patients are notified of new messages when they log in to the portal and the new messages are shown in a clear overview. Professionals are explained that patients have the option to use telecommunication. It is up to the professional how often they view these messages and whether they respond. Patients know that there is an option

to contact the professional, but the professional may not respond immediately. In case of emergency issues, they need to make contact by telephone.

There are two possibilities for telecommunication:

1) Messages linked to exercises

Both patients and professionals are able to put messages linked to specific exercises in the personal training program that can be used for example to indicate whether or not the exercise went well, was too difficult etc. When the patient or the professional logs onto the portal, this message is visible and a response to the message is possible (for example feedback in the form of instruction relating to the exercise, or from the patient's point of view a note that the exercise caused pain).

2) Other messages

Direct messages between patient and professional that are not linked to specific exercises, for example about the patient's functioning or rehabilitation progress.

Nieuv	v bericht			×
		Aan*	Selecteer gebruiker(s)	
		Titel*	Titel	
	6			

Figure 3: Example of communication option

### Use of co-intervention (if applicable)

Not applicable. All patients receive usual care and will start traditional outpatient exercisebased CR.

### **Escape medication (if applicable)**

Not applicable.

### **INVESTIGATIONAL PRODUCT**

Not applicable.

### NON-INVESTIGATIONAL PRODUCT

Not applicable.

## METHODS

## Study parameters/endpoints

#### Main study parameter/endpoint

The primary outcome measure is exercise capacity, measured with the 6 minutes' walk test (Butland et al., 1982; Reybrouck, 2003; Fiorina et al., 2008).

### Secondary study parameters/endpoints (if applicable)

Secondary outcome measures are:

- Physical activity, objectively measured with an accelerometer, subjectively measured with the International Physical Activity Questionnaire (IPAQ) short form (Craig et al., 2003; Vandelanotte et al., 2005).
- Quality of life, measured with the Quality of Life after Myocardial Infarction (QLMI) questionnaire (Hillers et al., 1994)'
- Disability, measured with the Groningen Activiteiten Restrictie Schaal (GARS) (Kempen et al., 1990).
- Anxiety and depression, measured with the Hospital Anxiety and Depression Scale (HADS) (Zigmond and Snaith, 1983; Spinhoven et al., 1997).
- Satisfaction with treatment (Client Satisfaction Questionnaire) (Attkisson and Zwick, 1982; de Brey, 1983).

### Other study parameters (if applicable)

At baseline, sociodemographic variables (sex, age, education, marital status, occupation) and disease-related variables (diagnosis, co-morbidity, complications after surgery, medication, mobility) will be collected.

### Randomisation, blinding and treatment allocation

Not applicable.

### **Study procedures**

All interventions and assessments are summarized in table 1. Measurements will be performed at baseline (end clinical phase), before the start of the traditional exercise program (outpatient phase) and after completion of the traditional exercise program (outpatient phase). Only quality of life will be measured twice: in the second/third week after discharge from the hospital and at the end of the total cardiac rehabilitation (as part of usual care).

#### Clinical phase

One day before discharge from the hospital patients (in both groups) complete a questionnaire including sociodemographic variables, the GARS (18 items) and the HADS (14 items). The physical therapist will complete the 6 minutes' walk test. The latter is part of usual care.

All patients receive an accelerometer and get instructions on how to use it. They receive a questionnaire (IPAQ) with answer envelope to be completed at home (at the end of the first week). Patients in the intervention group get instructions on the use of the online exercise program.

Home phase (after discharge hospital, before start traditional outpatient exercise program) In the period between discharge from the hospital and the start of the traditional outpatient exercise program, patients in the intervention group have access to the online exercise program (see 5.1) and are asked to complete the exercises. Patients in the control group receive no treatment. They continue rehabilitation by themselves with the advices they received in the hospital during admission.

In the first week at home, patients (in both groups) are asked to wear the accelerometer (to assess physical activity. At the end of this week, they are asked to complete the IPAQ to subjectively assess physical activity. Patients in the intervention group are asked to continue wearing the accelerometer until they start outpatient exercise-based CR (in order to establish a weekly step goal  $\rightarrow$  see 5.1).

In the week before the start of the traditional outpatient exercise program, measurements (6 min walk test, GARS, HADS, IPAQ) in both groups will be repeated. Patients are asked to visit the hospital to complete the measurements. In the week before these measurements, patients in the control group are asked to wear the accelerometer (for 1 week) to assess physical activity. The patient will be reminded to wear the accelerometer by means of a text message in the exercise program (intervention group) and by SMS (both groups).

As part of usual care, both groups receive and complete the CARDDS questionnaire in the second week after discharge from the hospital. Several variables are measured in this questionnaire among which quality of life, anxiety, depression, risk behaviour, etc. Only the data of the QLMI (quality of life), will be used in this study.

#### Outpatient phase

Approximately six weeks after discharge from the hospital both groups will start the traditional outpatient exercise program (as part of usual care), which takes six weeks. In the week after completion of this program, measurements (6 min walk test, GARS, HADS, IPAQ, CSQ) will be repeated (in both groups). Measurements will be completed in the hospital. The
6 minutes' walk test is part of usual care, so the patients have to visit the hospital anyway. In the week before these measurements, patients in both groups will be asked to wear the accelerometer for one final week. They will be reminded by means of a text message in the exercise program (intervention group) and by SMS (both groups).

At the end of the total cardiac rehabilitation (as patients has completed all rehabilitation modules) all patients receive the CARDSS questionnaire for a second time (= part usual care). Only the data of the QLMI will be used in this study.

Timing	Part of study (= additional)	Part of usual care
Clinical phase		
1 day before	Assessments:	Assessments:
discharge	- GARS	6 min walk test
	- HADS	
	Instructions:	
	- Use of accelerometer	
	- Use of online exercise program	
	(only intervention group)	
Home phase		
Week 1	Exercises:	
	Access to online exercise program	
	(only intervention group)	
	Assessments:	
	- Accelerometer (both groups) IPAQ	
	short form (end of week)	
Week 2	Exercises:	Assessments:
	Access to online exercise program	QLMI (included in CARDDS)
	(only intervention group)	
	Assessments:	
	- Accelerometer (only intervention	
	group	
Week 3	<u>Exercises:</u>	
	Access to online exercise program	
	(only intervention group)	
	Assessments:	
	- Accelerometer (only intervention	
	group)	
Week 4	<u>Exercises:</u>	
Week I	Access to online exercise program	
	(only intervention group)	
	Assessments:	
	- Accelerometer (only intervention	
Week 5	group Exercises:	
Week 5		
	Access to online exercise program	
	(only intervention group)	
	Assessments:	
Maak	- Accelerometer (both groups)	
Week 6	Exercises:	
	Access to online exercise program	
	(only intervention group)	
	Assessments:	
	- GARS	
	- HADS	
	-	
	- IPAQ short form - 6 min walk test	

Outpatient phas	5e	
Week 1		Exercises:
		Traditional outpatient exercise program
Week 2		Exercises:
		Traditional outpatient exercise program
Week 3		Exercises:
		Traditional outpatient exercise program
Week 4		Exercises:
		Traditional outpatient exercise program
Week 5		Exercises:
		Traditional outpatient exercise program
Week 6	Assessments:	Exercises:
	<ul> <li>Accelerometer (both groups)</li> </ul>	Traditional outpatient exercise program
Week 7	Assessments:	Assessments:
	- GARS	6 min walk test
	- HADS	
	- CSQ	
	- IPAQ short form	
End cardiac		Assessments:
rehabilitation		QLMI (included in CARDDS)

Table 1: Summary of interventions and assessments in both intervention group and control group

#### Withdrawal of individual subjects

Subjects can leave the study at any time for any reason if they wish to do so without any consequences. The investigator can decide to withdraw a subject from the study for urgent medical reasons.

#### Specific criteria for withdrawal (if applicable)

Not applicable.

#### Replacement of individual subjects after withdrawal

Subjects who withdraw form study participation, will not be replaced.

#### Follow-up of subjects withdrawn from treatment

Subjects who withdraw from study participation, will receive usual care. They will not be asked to complete specific follow-up measurements.

#### Premature termination of the study

There are no established criteria for premature termination of the study. It is our expectation that the subject can use the home exercise program without much effort.

## SAFETY REPORTING

#### Temporary halt for reasons of subject safety

In accordance to section 10, subsection 4, of the WMO, the sponsor will suspend the study if there is sufficient ground that continuation of the study will jeopardise subject health or safety. The sponsor will notify the accredited METC without undue delay of a temporary halt including the reason for such an action. The study will be suspended pending a further positive decision by the accredited METC. The investigator will take care that all subjects are kept informed.

# AEs, SAEs and SUSARs

## Adverse events (AEs)

Adverse events are defined as any undesirable experience occurring to a subject during the study, whether or not considered related to the intervention. All adverse events reported spontaneously by the subject or observed by the investigator or his staff will be recorded.

## Serious adverse events (SAEs)

A serious adverse event is any untoward medical occurrence or effect that

- results in death;
- is life threatening (at the time of the event);
- requires hospitalisation or prolongation of existing inpatients' hospitalisation;
- results in persistent or significant disability or incapacity;
- is a congenital anomaly or birth defect; or
- any other important medical event that did not result in any of the outcomes listed above due to medical or surgical intervention but could have been based upon appropriate judgement by the investigator.

An elective hospital admission will not be considered as a serious adverse event.

The investigator will report all SAEs to the sponsor without undue delay after obtaining knowledge of the events.

The sponsor will report the SAEs through the web portal *ToetsingOnline* to the accredited METC that approved the protocol, within 7 days of first knowledge for SAEs that result in death or are life threatening followed by a period of maximum of 8 days to complete the initial preliminary report. All other SAEs will be reported within a period of maximum 15 days after the sponsor has first knowledge of the serious adverse events.

#### Suspected unexpected serious adverse reactions (SUSARs)

Not applicable.

# Annual safety report

Not applicable.

#### Follow-up of adverse events

All AEs will be followed until they have abated, or until a stable situation has been reached. Depending on the event, follow up may require additional tests or medical procedures as indicated, and/or referral to the general physician or a medical specialist. SAEs need to be reported till end of study within the Netherlands, as defined in the protocol

### [Data Safety Monitoring Board (DSMB) / Safety Committee]

Not applicable.

## STATISTICAL ANALYSIS

All outcome variables (6 min walk test, IPAQ, GARS, HADS, CSF) are continuous variables. Descriptive statistics (mean, standard deviation) will be used to summarize the outcome scores at baseline (clinical phase), t1 (start of traditional outpatient exercise program) and t2 (end of traditional outpatient exercise program).

Data will be analysed on an intention-to-treat basis. Differences in scores between and within both groups (intervention and control) at t1 and t2 will be analysed for each outcome variable with repeated measures analyses (if scores are normally distributed), controlling for baseline values. If case of not normally distributed outcomes scores, differences between the groups will be analysed with a Wilcoxon signed rank test. Differences between the groups will be analysed with a Mann Whitney U test.

In both groups, we expect significant improvements from baseline to t1 and from t1 to t2. A significant greater improvement from baseline to t1 and from baseline to t2 is expected in the intervention group (compared to the control group).

#### **ETHICAL CONSIDERATIONS**

#### **Regulation statement**

The study will be conducted according to the principles of the Declaration of Helsinki (version October 2013) and in accordance with the Medical Research Involving Human Subjects Act (WMO).

#### Recruitment and consent (both groups)

Potential eligible patients are referred by the cardiologist for inclusion in the study. If they fulfil the inclusion criteria, they are asked by the investigator to participate in the study (4 days after operation). They receive an information letter with informed consent. They get minimally 24 hours to consider their decision. After obtaining informed consent, baseline

measurements will be conducted by the investigator (questionnaires) and physical therapist (6 minutes' walk test).

# Objection by minors or incapacitated subjects (if applicable)

Not applicable

## Benefits and risks assessment, group relatedness

By starting the exercise program in an earlier phase, immediately after discharge from the hospital, we respond to the needs of patients to get more (tailored) support in the first weeks after discharge from the hospital. Furthermore, we expect that patients will start the traditional outpatient rehabilitation in better physical condition and will gain better health outcomes (improved exercise capacity and physical activity, reduced disability, depression and anxiety). Finally, an online exercise program increases the possibilities of self-management and might increase efficiency of future cardiac rehabilitation (by reducing (phase-to-phase) contact moments).

From literature, we know that there are no indications that early enrollment in exercise-based CR after MI or cardiac surgery is harmful to patients. Moreover, only low to moderate strenuous exercises will be conducted like walking, functional activities, mobility, respiratory, relaxing and strength exercises. Exercises will be tailored and the intensity will be build, dependent on the performance and willing of the patient. So, we don't expect extra risks for the patients, related to participation in this study.

The control group has no direct benefits or risks related to participation in the study.

There are three measurement points: at baseline (clinical phase) and at the start and end of the traditional outpatient exercise-based CR program. The outcome measures mostly exist of questionnaires, which take maximally 20 minutes at a time to complete. The six minutes' walk test is usual care (except the second measurement). Finally, patients are asked to wear an accelerometer for two weeks. This is a small device that can be worn without hindrance of daily activities. So, the burden for the patients seems acceptable and in proportion to the benefits.

# **Compensation for injury**

The sponsor has a liability insurance which is in accordance with article 7 of the WMO.

#### **Incentives (if applicable)**

Patients have to visit the hospital for one extra time. Travelling costs will be reimbursed.

# ADMINISTRATIVE ASPECTS, MONITORING AND PUBLICATION

## Handling and storage of data and documents

All personal data will be handled confidentially and anonymously in compliance with the Dutch Personal Data Protection Act. Only the investigators will have access to the data. Data will be digitally saved, both in Medisch Spectrum Twente and at Roessingh Research and Development. In case of loss of data, a backup will be available (in MST during 3 months after loss of data). A patient identification list will be used (not based on patient initials, birth-date or patient number) to link the data to the patient (both for the digital data and the written data). Each patient gets a code, existing of the I (intervention group) or the C (control group), followed by a unique number that ranges from 1 to 50. This number is based on the order of inclusion. The patient identification list will be safeguarded by the investigators. The written data will be kept for 15 years and will be destroyed afterwards. The data will only be used for research purposes. No data will be published that can be traced to patients.

## **Monitoring and Quality Assurance**

Not applicable

## Amendments

Amendments are changes made to the research after a favourable opinion by the accredited METC has been given. All amendments will be notified to the METC that gave a favourable opinion.

# Annual progress report

The investigator will submit a summary of the progress of the trial to the accredited METC once a year. Information will be provided on the date of inclusion of the first subject, numbers of subjects included and numbers of subjects that have completed the trial, serious adverse events/ serious adverse reactions, other problems, and amendments.

# Temporary halt and (prematurely) end of study report

The investigator will notify the accredited METC of the end of the study within a period of 8 weeks. The end of the study is defined as the last patient's last visit.

The sponsor will notify the METC immediately of a temporary halt of the study, including the reason of such an action.

In case the study is ended prematurely, the investigator will notify the accredited METC within 15 days, including the reasons for the premature termination.

Within one year after the end of the study, the investigator will submit a final study report with the results of the study, including any publications/abstracts of the study, to the accredited

METC.

# Public disclosure and publication policy

The protocol will be registered in a public trial register (www.trialregister.nl), after ethical approval. The number that will be allocated by the 'Nederlands Trial Register' (NTR) will meet the registration requirements of the editors to be eligible for publication. The results of the study will be disclosed in the trial register and will be published in scientific papers and conference proceedings.

# STRUCTURED RISK ANALYSIS

Not applicable.

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Supplement 1:	Exercises	online p	rogram
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Soort	Code	Niveau	Oefening	Herhalingen	Aantal
	0.0			per serie*	series
Beenspieren: Quadriceps	SQ	1	Met handen op tafel opstaan uit stoel	10	3
	LU	1	Grote stap naar voren + door knieën zakken (om en om)	20 (10 links + 10 rechts)	3
	SQ	2	Met handen op knieën opstaan uit stoel	10	3
	LU	2	Grote stap naar voren, telkens hetzelfde been	20 (10 links + 10 rechts)	3
	SQ	3	Met handen op schouders opstaan uit stoel	10	3
	LU	3	Grote stap naar voren, telkens hetzelfde been	30 (15 links + 15 rechts)	3
	SQ	4	Zonder steunen opstaan uit stoel, bij gaan zitten alleen stoel aantikken met billen	10	3
	LU	4	Grote stap naar voren, telkens hetzelfde been. Bij teruggaan blijft voet van de grond af	20 (10 links + 10 rechts)	3
	SQ	5	Met rug tegen deur of muur naar beneden glijden	5	3
	LU	5	Grote stap naar voren, telkens hetzelfde been. Bij teruggaan blijft voet van de grond af	30 (15 links + 15 rechts)	3
	SQ	6	Met rug tegen deur 'zitten zonder stoel'	30 sec	3
Beenspieren:	HS	1	Bruggetjes maken	10	3
Hamstrings	HS	2	Bruggetjes maken	15	
	HS	3	Bruggetje vasthouden en om en om knie strekken	10 (5 links + 5 rechts)	3
	HS	4	Bruggetje vasthouden en om en om knie strekken	20 (10 links + 10 rechts)	3
	HS	5	Eén been gestrekt houden, dan bruggetjes maken	10	3
Bilspieren	BL	1	Eén been voor- en achterwaarts	20	3

			zwaaien	(10 links + 10	
				rechts)	
	BL	2	Eén been voor- en achterwaarts	40	3
			zwaaien	(20 links + 20	
				rechts)	
	BL	3	Eén been zijwaarts heffen en	20	3
			laten zakken	(10 links + 10	
				rechts)	
	BL	4	Eén been zijwaarts heffen en	40	3
			laten zakken	(20 links + 20	
				rechts)	
	BL	5	Eén been vlot zijwaarts heffen,	20	3
			afremmen bij het zakken	(10 links + 10	
				rechts)	
	BL	6	Eén been vlot zijwaarts heffen,	40	3
			afremmen bij het zakken	(20 links + 20	
				rechts)	
Trap	TR	1	Opstappen en terugstappen	20	2
		I	Opstappen en terugstappen		2
(kracht/conditie)				(10 links eerst	
				+ 10 rechts	
				eerst)	_
	KU	1	Met alleen voorvoet op	10	3
			traptrede staan. Op tenen staan		
			en naar beneden zakken		
			(kuitspieren)		
	TR	2	Opstappen en terugstappen	40	2
				(20 links eerst	
				+ 20 rechts	
				eerst)	
	κυ	2	Met alleen voorvoet op	20	3
			traptrede staan. Op tenen staan		
			en naar beneden zakken		
			(kuitspieren)		
	TR	3	Eén been blijft op trede, op en	20	2
					-
			afstannen met andere been	(10  links + 10)	
			afstappen met andere been	(10 links + 10 rechts)	
	тр	1		rechts)	2
	TR	4	Eén been blijft op trede, op en	rechts) 40	2
	TR	4		rechts) 40 (20 links + 20	2
			Eén been blijft op trede, op en afstappen met andere been	rechts) 40 (20 links + 20 rechts)	
	TR	4	Eén been blijft op trede, op en afstappen met andere been Eén been blijft op trede, op en	rechts) 40 (20 links + 20 rechts) 20	2
			Eén been blijft op trede, op en afstappen met andere been Eén been blijft op trede, op en afstappen met andere been. Bij	rechts) 40 (20 links + 20 rechts) 20 (10 links + 10	
			Eén been blijft op trede, op en afstappen met andere been Eén been blijft op trede, op en	rechts) 40 (20 links + 20 rechts) 20	

/schouderspieren			deur/muur staan → opdrukken		
	SE	1	Op <u>gehele</u> armlengte van deur/muur staan → met gestrekte armen schouderbladen naar elkaar toe/van elkaar af bewegen	10	3
	DE	2	Op <u>onderarmlengte</u> van deur/muur staan → opdrukken	20	3
	SE	2	Op <u>gehele</u> armlengte van deur/muur staan → met gestrekte armen schouderbladen naar elkaar toe/van elkaar af bewegen	20	3
	DE	3	Op <u>gehele</u> armlengte van deur/muur staan → opdrukken	10	3
	DE	4	Op <u>gehele</u> armlengte van deur/muur staan → opdrukken	20	3
Arm- /schouderspieren met waterflesje	FL	1	Elleboog buigen en strekken	20 (10 links + 10 rechts)	3
(500g)	AB	1	Arm gestrekt zijwaarts optillen tot schouderhoogte	20 (10 links + 10 rechts)	3
	FL	2	Elleboog buigen en strekken	40 (20 links + 20 rechts)	3
	AB	2	Arm gestrekt zijwaarts optillen tot schouderhoogte	40 (20 links + 20 rechts)	3
	FL	3	Naar voren en naar boven boksen vanaf schouder	20 (5 links + 5 rechts voorwaarts 5 links + 5 rechts omhoog)	3
	AB	3	Arm gestrekt zijwaarts optillen tot schouderhoogte, deze positie vasthouden	15 sec (15sec links + rechts gelijktijdig)	3
	FL	4	Naar voren en naar boven boksen vanaf schouder	40 (10 links + 10 rechts	3

				voorwaarts	
				10 links + 10	
				rechts	
				omhoog)	
	AB	4	Arm gestrekt zijwaarts optillen	30 sec	3
			tot schouderhoogte, deze	(15sec links +	
			positie vasthouden	rechts	
				gelijktijdig)	
Thoracale	THL 1	1	Ruglig, opgetrokken knieën	10	3
mobiliteit: Liggend			naar links en rechts laten vallen		
	THL 2	1	Ruglig, opgetrokken knieën.	10	3
			Holle en bolle onderrug maken		
Thoracale	THS 1	1	Handen in elkaar, bij inademing	5	3
mobiliteit:			armen naar boven strekken, bij		·
Op stoel			uitademing laten zakken		
	THS 2	1	Handen in elkaar, met gestrekte	5	3
	1110 2	1	armen draaien met romp	5	5
	THS 3	1	Schouders pro- en retractie	5	3
	THS 4	1	Schouders draaien	5	3
		-		5	
	THS 5	1	Onderkin maken		3
	THS 6	1	Lateroflexie CWK	5	3
	THS 7	1	Rotaties CWK	5	3
Oefeningen op	HK	1	Zwaartepunt van tussen handen	10	3
handen en knieën			naar tussen voeten brengen		
	НК	2	Diagonaal arm-been	20	3
			uitstrekken. Om en om	(10 links + 10	
				rechts)	
	HK	3	Diagonaal arm-been	20	3
			uitstrekken. Zelfde kant	(10 links + 10	
				rechts)	
	(HK 4)	(4) is	Diagonaal arm-been	20	3
		deze	uitstrekken. Zelfde kant + 3	(10 links + 10	
		gefilmd?	tellen vasthouden	rechts)	
Ontspanning	ON	1	Losdraaien		
	ON2a	1	Progressieve relaxatie zit		
			(volgens Jacobson)		
	ON2b	1	Progressieve relaxatie lig		
			(volgens Jacobson)		
	ON3	1	Hartritmevariabiliteit		
			biofeedback		
	ON4	1	3 minuten ademruimte		
	ON5	1	Bodyscan		
	AH1a	1	Ademhalingsoefening (in:		

	AH1b	1	armen naar buiten; uit: armen naar binnen) Ademhalingsoefening (in: armen omhoog; uit: handen kruis)		
Balans	BAL	1	Staan met voeten aan elkaar	10 seconden	3
	BAL	2	Staan met hak ene voet voor de tenen van de andere voet	20 seconden (10sec ene houding + 10sec andere houding)	3
	BAL	3	Op één been staan	20 seconden (10sec ene houding + 10sec andere houding)	3

AB=abductie; AH=ademhaling; BAL=balans; BL=bilspieren; DE= deltoideus; FL=flexie; HS=hamstrings; HK= hakken-knieen; KU=kuit; LU=lunge (quadriceps) ON= ontspanning; SE=seratus; SQ=squat (quadriceps); THL=thoracale mobiliteit lig; THS=thoracale mobiliteit stoel; TR = trap

# Supplement 2: Week schedule exercises

Week	Soort	Maandag	Woensdag	Vrijdag
	oefeningen			
	Ontspanning	AH1a		AH1b
	Thoraxmobiliteit	THS 1 – THS 2 – THS 4	THS 5 – THS 6 – THS 7	THS 1 – THS 2 – THS 4
1	Uitwisselbare oefeningen	THS 3	THL 1 – THL 2	THS 3
	Indicatie oefeningen	BAL - ON3	BAL - ON4	BAL - ON3
	Ontspanning	AH1a		AH1b
	Thoraxmobiliteit	THS 1 – THS 2 – THS 4	THS 6 – THS 7	THS 1 – THS 2 – THS 4
2	Uitwisselbare oefeningen	THL 1 – HS 1	BL – SQ – DE	THL 1 – HS 1
	Indicatie oefeningen	BAL - ON3	BAL - ON4	BAL - ON3 Evaluatie ON3
	Thoraxmobiliteit	THS 1 – THS 2		THS 1 – THS 2
	Armspieren	FL – AB	DE – SE	FL – AB
	Beenspieren	LU	HS – SQ	LU
2	Uitwisselbare oefeningen	BL – TR	THS 4 – THS 5	BL – TR
3	Indicatie oefeningen	BAL – ON3 of ON2a Indien geen baat ON3 of andere oefening willen uitproberen→ ON2	BAL - ON4 Evaluatie ON4	BAL – ON3 of ON2a Indien geen baat ON3 → ON2
	Thoraxmobiliteit	1 oefening naar keuze		1 oefening naar keuze
	Armspieren	DE	FL – AB	DE
	Beenspieren	LU – SQ	HS	LU – SQ
	Uitwisselbare oefeningen	TR – KU	HK – TR – BL	TR – KU
4	Indicatie oefeningen	BAL – ON3 of ON2a Indien geen baat ON3 (of andere oefening willen uitproberen)→ ON2	BAL - ON4 of ON2a of AH1b Indien geen baat ON4 (of andere oefening willen uitproberen)→ ON 2a Indien ON2a al ingezet is → AH1b	BAL – ON3 of ON2a Indien geen baat ON3 (of andere oefening willen uitproberen)→ ON2 Evaluatie ON 3 of ON2a

	Thoraxmobiliteit	1 oefening naar keuze		1 oefening naar keuze
	Armspieren	DE	FL – AB	DE
	Beenspieren	SQ - HS	LU	SQ - HS
	Uitwisselbare oefeningen	TR – SE – HK	KU – BL	TR – SE – HK
	Indicatie	BAL - ON3 of ON2a of	BAL - ON4 of ON2a of	BAL - ON3 of ON2a of
	oefeningen	ON5	AH1b	ON5
5		Indien geen baat bij ON3 of ON2a (of	Indien geen baat ON4 (of andere oefeningen	Indien geen baat bij ON3 of ON2a (of
		andere oefening willen	willen uitproberen→	andere oefening willen
		uitproberen → ON5	ON 2	uitproberen→ ON5
			Indien ON2a al ingezet	
			is → AH1b	
			Evaluatie ON4, ON2a	
			of AH1b	
	Thoraxmobiliteit	1 oefening naar keuze		1 oefening naar keuze
	Armspieren	FL – AB	DE –SE	FL – AB
	Beenspieren	SQ – LU	HS	SQ – LU
	Uitwisselbare oefeningen	TR – HK	TR – KU – BL	TR – HK
6	Indicatie	BAL - ON3 of ON2a of	BAL - ON4 of ON2a of	BAL - ON3 of ON2a of
0	oefeningen	ON5	AH1b	ON5
		Indien geen baat bij	Mits nog niet ingezet	Indien geen baat bij
		ON3 of ON2a (of	die week. Niet inzetten	ON3 of ON2a (of
		andere oefening willen	als pt aangegeven	andere oefening willen
		uitproberen→ ON5	heeft er geen baat bij	uitproberen→ ON5
			te hebben.	

AB=abductie; AH=ademhaling; BAL=balans; BL=bilspieren; DE= deltoideus; FL=flexie; HS=hamstrings; HK= hakken-knieen; KU=kuit; LU=lunge (quadriceps) ON= ontspanning; SE=seratus; SQ=squat (quadriceps); THL=thoracale mobiliteit lig; THS=thoracale mobiliteit stoel; TR = trap