Abdominal Aneurysm in Motion

Physical therapy for patients with an indication for AAA repair; a pilot, correlation study

AAiMo

Physical therapy for patients with an indication for AAA repair, a correlation study

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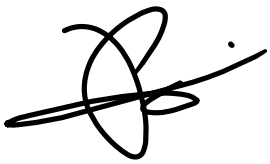
Head of Department: ***Prof. Dr. J.P.P.M de Vries*** ***Vascular surgeon, UMCG***		-21-07-2024
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LIST OF ABBREVIATIONS AND RELEVANT DEFINITIONS

AAA	**Aneurysm of the abdominal aorta**
ABR	**General Assessment and Registration form (ABR form), the application form that is required for submission to the accredited Ethics Committee; in Dutch: Algemeen Beoordelings- en Registratieformulier (ABR-formulier)**
AE	**Adverse Event**
CoF	**Change of aerobic Fitness**
CPET	**Cardiopulmonary exercise test**
CRF	**Case report form**
DSMB	**Data Safety Monitoring Board**
EU	**European Union**
GCP	**Good Clinical Practice**
GDPR	**General Data Protection Regulation; in Dutch: Algemene Verordening Gegevensbescherming (AVG)**
IB	**Investigator's Brochure**
IC	**Informed Consent**
HLOS	**Hospital length of stay**
HR	**Heart rate**
MACE	**Major adverse cardiac event**
MALE	**Major adverse limb event**
METC	**Medical research ethics committee (MREC); in Dutch: medisch-ethische toetsingscommissie (METC)**
nS	**Number of steps (pedometer)**
PRO	**Patient related outcome**
(S)AE	**(Serious) Adverse Event**
SES	**Socio-Economic Status**

SMM	**Sphygmomanometer (blood pressure measurement)**
SRT	**Steep Ramp Test**
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.**
UAVG	**Dutch Act on Implementation of the General Data Protection Regulation; in Dutch: Uitvoeringswet AVG**
VAT	**Ventilatory Anaerobic Threshold**
WMO	**Medical Research Involving Human Subjects Act; in Dutch: Wet Medisch-wetenschappelijk Onderzoek met Mensen**

SUMMARY

Rationale: An aneurysm of the abdominal aorta (AAA) is a potentially life-threatening condition. Growth control and preventive surgery are important. It is proven safe to train patients with an AAA aiming to enhance aerobic fitness and improve surgical outcomes. Hypothesis: Training of patients awaiting their surgery for an AAA improves preoperative aerobic fitness. However, not all patients will improve their aerobic fitness following these training sessions.

Objective: The main objective is to separate patients who benefit from training from patients who do not benefit from training in terms of the change in CoF. The secondary objective is to study if training leads to change of aerobic fitness (CoF) in AAA patients after supervised training with a patient-specific training program. Feasibility of the study will be evaluated as well.

Study design: This is a single-arm intervention study. Patients, elected for AAA surgery, are invited to participate in this study. After inclusion, patients' socio-economic and personal characteristics are collected in a questionnaire, as well as their comorbidities (frailty-score, daily activities, ASA-score, dietary habits). All included patients will train at home under the responsibility of the principal investigator and the remote supervision of a specialist in sports medicine and a physical therapist, using home monitoring by means of the Luscii app.

Study population: Patients with an indication for elective AAA surgery (endovascular and open surgery). Excluded are patients with AAA and an urgent (within less than 3 weeks) repair of the aneurysm and ruptured or symptomatic patients. Patients with genetic connective tissue disorders (e.g., Marfan) and patients unable to train will be excluded as well.

Intervention: Patients who signed informed consent (IC) for this study must fill out a questionnaire, with the assistance of a research nurse and perform a cardiopulmonary exercise test (CPET). Patients rejected from training will be excluded. This is evaluated by the cardiologist and the specialist in sports medicine. Subjects fit for training start with home monitoring (pulse oximeter and sphygmomanometer) under the remote supervision of a physical therapist. All patients will be supported with dietary substitution to avoid a catabolic condition preceding the operation. Before and after three-to-nine-week (on average six weeks) training program, subjects are evaluated by a specialist in sports medicine, to evaluate CoF with a CPET. All patients will be followed until three months postoperative.

Main study parameters/endpoints: The main endpoint is the analysis of patients who improve from training compared to patients who do not improve from training. Secondary endpoints are:

- change in oxygen uptake (VO2) at the ventilatory anaerobic threshold (VAT) after the training program.
- program feasibility (recruitment rate, adherence, completion rate, drop-out rate, attrition rate, and adverse events).
- the (preliminary) effect of the program on other cardiopulmonary exercise testing (CPET) values, e.g., VO2 at peak exercise, oxygen uptake efficiency slope, and response profiles, as well as strength improvement.
- Postoperative events will be compared in relation to the subgroup analysis of patients benefiting from training or not.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Patients will be asked to fill out a questionnaire with a research nurse and visit a cardiologist and a specialist in sports medicine preceding their training. During their three-to-nine weeks preoperative period, patients will be asked to train. This will be tiresome but rewarding; we expect to accomplish an increase in physical fitness. The elderly seem capable of performing home monitoring. The extra energy and proteins necessary for the training will be substituted with extra FortiFit®. These substitutes help patients to get into an anabolic condition, preoperatively. Apart from the extra consultations and the training the patient will not undergo extra laboratory tests other than necessary for regular AAA surgery. The risks are minor, for it has been proven safe to train patients indicated for elective AAA surgery in advance. Still, we wish to monitor at home, and training is prohibited outside office hours. This enables the research team to educate patients in health-related issues (heart rate recovery) and virtual hospital contact, earlier described as a Surgery School. Furthermore, it is expected that patients are encouraged by the virtual feedback.
Risk benefit analysis: the risks of causing harm are small, because patients will be physically evaluated before training starts and will be monitored for safety throughout the program. The benefits may be substantial for improving surgical outcome, patients have been taught to train in their living context, and home monitoring improves extramural communication and ease hospital capacity issues.

INTRODUCTION AND RATIONALE

Abdominal aneurysms (AAAs) affect a range of 1.9-18.5% of men and less than a quarter in women (1). In recent years the mortality rate is declining (2-4) and thirty-day mortality rate of an elective repair remains at 2-3% and higher for women (5).
Cardiopulmonary evaluation assesses operative risks in patients undergoing AAA surgery (6, 7). The decrease of operative mortality was mainly due to technical innovations (4), but no attention has been paid to fitness of patients. Preoperative exercise training improves aerobic fitness (e.g., the oxygen uptake (VO_2) at the ventilatory anaerobic threshold (VAT)) (7).
Several trials have established exercise training to be safe in people with AAA and training does not seem to influence aneurysm growth (8-11). Professional supervision (e.g., physical therapy and in-hospital aerobic exercise training) is expensive. Home-based monitoring of exercising patients with AAA is less expensive, and device handling by patients has been positively evaluated before (12).
This study is designed to investigate whether patients with AAA can improve their preoperative aerobic fitness during 3- to 9-week (6 weeks on average) training program. It is primarily designed to evaluate which patients benefit most from this program, based on three outcome measures: initial fitness (CPET), BMI and age. Home training will be performed with home-monitoring and weekly support by a physical therapist.
A successful six-week training program is a true investment, and some patients will not be able to benefit from it. At this point we are unable to select patients who will benefit most. Improvement of aerobic fitness probably depends on a combination of patient specific factors, e.g., age and sex, comorbidity, aerobic fitness at the start of the training, dietary habits, comorbidity, SES, frailty index, ASA-score, physical strength, and the available social support. Training specific factors play a role as well, such as the number of prescribed training sessions, intensity, and the duration. This study is designed to select patients who will benefit most from training, based upon their initial fitness, their BMI and their age.
Patients with an AAA and an indication for operative repair were often male smokers, with high blood pressure, and lipid profiles (1). Depending on their diligence, recruitment rate, adherence, completion, drop-out, and attrition rate, will be important. These rates will be evaluated in relation to SES and other characteristics. During training, patients will be supported with dietary substitutes, in order to maintain an anabolic condition (13).
Due to the training at home, the Luscii app (CE-certificate 0476) enables patients to ask questions and this might stimulate them to start training, under the suggestion to be observed by the call center.

OBJECTIVES

Primary Objective: To compare patient characteristics between patients with clear improvement (more than 1.5 ml/kg/min improvement in the VO2 at VAT) after a three-to-nine-week training program, with patient characteristics of those who do not improve after training We aim to identify three factors that predict responsiveness to improve preoperative aerobic fitness following the training program.

Secondary objective: To evaluate the preliminary effectiveness of an, on average, six-week home-monitored training program, in patients with AAA scheduled for elective AAA-repair to improve the preoperative VO2 at the ventilatory anaerobic threshold (VAT).

Other Secondary Objective(s):
Other secondary aims are to evaluate the feasibility of this three-to-nine-week home-monitored training program. A fall-out of some patients is expected because physical exercise requires perseverance and endeavor. This feasibility is evaluated with:

- recruitment rate (how many patients will consent to participate in relation to the patients refusing participation).
- adherence rate (how many patients will endure participation in relation to the patients who give up participation, a.k.a. dropout rate) (Appendix 1).
- completion rate (how many patients will complete participation in relation to the number of patients ending participation).
- drop-out rate (how many patients will drop out of participation in relation to the number of patients completing participation).
- Attrition rate (how many patients will ask if a transfer to another treatment facility is possible, a.k.a. churn rate).

Additionally, the individual (preliminary) effect of prehabilitation on other CPET variables will be evaluated, such as VO_2 at peak exercise (VO_{2peak}) and the oxygen uptake efficiency slope, individual response profiles on the progression in aerobic fitness, improvement of the steep ramp test throughout the program. (Appendix 2).
The postoperative course in patients after AAA repair will be described as well, by collecting data on the surgical intervention and postoperative outcomes (e.g., hospital length of stay (HLOS), number of complications, mortality rate, readmission rate).

1. STUDY DESIGN

Study design

This is a multicenter single-arm intervention study with a pre- and post-training test, supplemented with enriched nutrient intake. The study will be executed in accordance with the declaration of Helsinki and is registered in ISRCTN registry under reference number 10008907. Written informed consent (IC) will be obtained from all participants.

Participants

Patients >18 years with an indication for AAA-repair will be included in the Treant Hospital (Emmen, Hoogeveen, and Stadskanaal) and in the Wilhelmina Hospital in Assen. This study was designed in close cooperation with the University Medical Center Groningen (UMCG). Patients with an elective indication for operation will be included in this study. Patients will be excluded with an indication for operative intervention within three weeks (semi-elective), patients with connective tissue disorders (e.g., Marfan), patients evaluated unfit for training, and patients unable to understand the meanings of this research.

Recruitment

Consecutive patients with an indication for an aneurysm repair will be asked to participate by their treating physician. The investigator or one of the members of the research team will collect the IC. They will complete a questionnaire with the help of a research nurse and will be assessed for initial eligibility by means of a cardiopulmonary exercise test at the sports medicine office, under the responsibility of the principal investigator (Figure 1). Patients unable to train as indicated by the specialist in sports medicine and/or the cardiologist, will receive necessary medication, and will be excluded. After this judgement, subjects evaluated fit for training, receive the home monitor (pulse oximeter and sphygmomanometer (SMM)) and an explanation how to use the home monitoring app Luscii and FortiFit. The explanation concerning the use of the monitors and FortiFit will be given to the accompanying spouse and/or caregivers, as well. Subjects evaluated unfit for training will receive additional information and follow up by the cardiologist. If, during this follow up, patients medical condition improves, training will be promptly started.

Following the explanation, patients have their intake with a physical therapist. The patients able to perform training, will be prescribed a personalized exercise program and will be followed by a local physical therapist. This includes a training scheme for exercises at home (Appendix 2). They will be asked to train at home and once a week at the physical therapist, check their vital sings with the pulse oximeter and de SMM, and communicate these vital

signs with the Luscii app to a call center Altide. In case of previously set limitations, this call center will contact the hospital (Appendix 3).

Home-monitored training

All eligible patients will participate in a three-to-nine-week (average of six weeks), partly supervised, home-monitored training program prior to elective AAA-repair. The second CPET measurement is planned after the training program. Training frequency during the prehabilitation will be five sessions per week including a weekly evaluation by the physical therapist. Training sessions at home are prepared and should be able to be performed without extra adjuncts (see below). Before and after home-monitored training sessions without a physical therapist, subjects communicate oxygen saturation, heartrate, blood pressure, number of steps (nS), and number of smoked cigarettes through the Luscii app. According to these measurements, automatic advises will be given through the app (Appendix 3).

To evaluate a difference after the average of six weeks, subjects visit the specialist in sports medicine a second time to perform a CPET. Depending on the performance of patients in relation to the improvement in this second CPET, a subdivision of an improved and a stable (not improved) group will be made. It is expected that improved patients will show an increase of their VO2 at VAT of 1,5 ml/kg/min or more.

Three months after surgery, monitoring is complete, and preoperative patient characteristics of the groups will be compared.

Home-monitored exercises

Four times a week subjects perform exercises at home, preceded and followed by communication of preset parameters through the Luscii app. These exercises include stair-climbing and sit-to-stand exercises (high-intensity), as well as outdoor cycling, outdoor walking, and outdoor running (moderate intensity). The combination will be assembled in close collaboration between the physical therapist and the specialist in sports medicine, under the responsibility of the principal investigator. Through registration and monitoring activities by the patient, the physical therapist will be able to advise activities performed at home. The physical therapist will discuss these findings with the patient on a weekly base and adjust the scheme in relation to physical improvement.

Once a week subjects perform a steep ramp test performance to estimate aerobic fitness, under the supervision of the physical therapist. This test is used to optimize training intensity of the interval and endurance training sessions, as well as to monitor progression.

Nutritional supplementation

To support muscle protein synthesis, participants will be provided with protein supplementation immediately following exercise and (approximately 30 minutes) before sleep, providing a standard dosage of 30 g of a high-quality (whey and casein) protein that contains at least 10 g of essential amino acids, of which 2-3 g Leucine. Since vitamin D is associated with muscle mass and muscle strength. It will be supplemented daily according to guidelines of the Health Council of the Netherlands (10 µg for woman aged 50-69 years, for men <70 years and women <50 years with colored skin and/or little sun exposure, and 20 µg for women and men aged 70 years or older)(14, 15). To prevent patients from having a deficiency of vitamins and minerals below recommended doses before surgery, all other vitamins and minerals are supplied in a multivitamin/mineral supplement containing 50% of the recommended daily allowance (13).

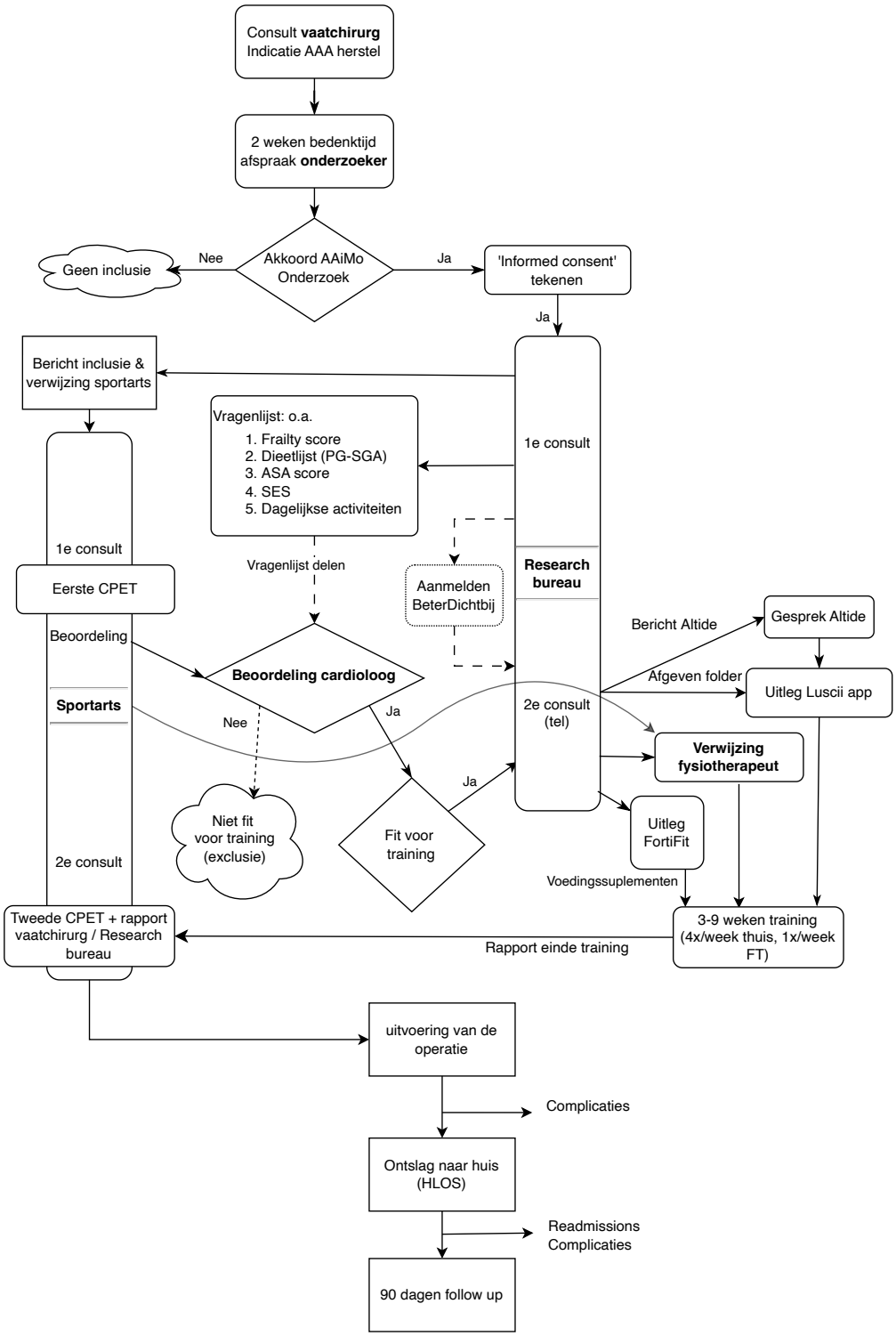

Figure 1: flow chart (https://app.diagrams.net) concerning the references of patients. FT= physical therapy, CPET= cardiopulmonary exercise test, HLOS= hospital length of stay.

2. STUDY POPULATION

2.1. Population (base)

Patients indicated for elective AAA-surgery. We expect this selection of patients to be motivated to follow the training schedule.

2.2. Inclusion criteria

- Subjects with an AAA and an indication for elective operative repair.
- Informed consent.
- Fit for training as judged by the specialist in sports medicine and the cardiologist.
- More than 18 years of age.

2.3. Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- Patients with an acute indication for surgery (symptomatic or ruptured AAAs)
- Patients with an indication for priority surgery (semi-elective; within three weeks):
    - saccular aspect (16)
- Patients with tissue disorders (e.g. Marfan or other).
- Patients unfit for training (i.e. arrhythmogenic cardiomyopathy or electrical abnormalities of genetic origin (17))
- Patients unable to understand the objectives of this study.
- Patients unable to understand digital devices.

2.4. Sample size calculation

A multivariable regression analysis will be performed to identify important risk factors, such as a low fitness at the beginning of the training, a low or high BMI ($20 \leq BMI \leq 31$), and a low or high age ($50y \leq age \leq 90y$)(18). With the rule of thumb requiring 10 subjects per variable, and a chance of improvement of 50% (3 variables (fitness t= 0, BMI, and age) x 10 subjects x 0,5= 60); 60 patients will be required to include. Inclusion of one hundred patients will be necessary to perform a multivariable regression analysis with three variables, assuming an exclusion rate of 20%, and a drop-out rate of 20%.
Three small sample, randomized controlled trials showed higher VO2 at VAT after 3, 6, or 9 weeks of training in gastroenterological cancer patients, patients with AAA, and rectal cancer patients, respectively: of 10,1%; 18%; or 29% (Table 1)(11, 19, 20).

Study	Inclusion	n	Wks	% Impro-vement	VO2 t=0	SD	95%CI	VO2 t=1	SD	95%CI	ΔVO2
Berkel(19)	GE-patients	28	3	10,1	9,6	1,2	9,1 - 10,1	10,5	1,36	10 - 11,1	0,9
Barakat(11)	AAA patients	20	6	18	12,2		10,5 - 14,9	14,4		12,3 - 15,4	2,2
Loughney(20)	Rectal CA	17	9	29	11,6	3,4	9,9 - 13,3	15	4,2	12,7 - 17,3	3,4
	total	65									

Table 1. Three randomized controlled trials evaluating fitness after training. Wks= weeks, SD= standard deviation, GE= gastroenterological, AAA= abdominal aorta aneurysm, and CA= cancer.

These patients reached an improvement ranging from 0.9 ml/kg/min up to 3.4 ml/kg/min (assumed mean 1.5 ml/kg/min). When subdividing the group of patients into a group with increased fitness (> 1.5 ml/kg/min) and a group without increased fitness (≤ 1.5 ml/kg/min), a dichotomous outcome is reached.

The multivariable analysis will be performed with other patient specific characteristics, as well, such as comorbidities. Modifiable factors will be analyzed as well, such as dietary habits, social economic status, frailty score, and other information collected in the questionnaires.

3. TREATMENT OF SUBJECTS

Standard AAA treatment is performed according to current international guidelines. Preparation, preceding this treatment, is adjusted to improve the condition of the patient in the participating centers. Because of the relatively new aspect of training of AAA patients, this will be performed under close observation using a home-monitoring device and the Luscii app.

3.1. Investigational product/treatment

Preoperative questionnaire

In future surgery strategies it is essential to identify patients able to improve their aerobic fitness, by means of a preoperative questionnaire. It has been found that age, frailty, cognitive decline, and disability influence ICU stay in patients over 80 years of age. Of which the clinical frailty scale predicts mortality (21). Patient-reported outcome (PRO) of their own frailty status had more predictive discrimination in surgical patients (22). Whereas physical functioning, instrumental activities of daily living (IADL), and activities of daily living (ADL) are predictive for vascular comorbidities, heart disease and mortality in older Americans with or without diabetes mellitus (DM)(23). Ultimately, the social economic status seems to be of utmost importance in the development of vascular diseases (24).

The following questionnaires are used:

- Age, medical history, medication, smoking, and drinking habits.
- Place of living (postal code).
- Clinical Frailty scale = CSHA CFS (Box 1), frail patients 5 and above.
- Informant questionnaire on cognitive decline in the elderly (IQCODE, 16 questions). Cognitive decline $\geq$ 3,5.
- Ability with the Katz physical, IADL, and ADL score (23):
    - Physical functioning tasks: two mobility tasks (walking several blocks, climbing one flight of stairs) and two strength tasks (lifting 10 pounds, pushing an object).
    - IADL tasks: three cognitive IADLs (using the telephone, managing money, taking medications) and two complex IADLs (grocery shopping, preparing meals)
    - ADL tasks: six personal care tasks (transferring in/out of bed, dressing, bathing, walking across a room, toileting, eating). Defining $\leq$ 4 as disabling.
- Patient reported outcome (PRO) frailty (25).
- ASA-score.
- Dietary habits, intake of fruits, vegetables, nuts, red meat or fast food. 2-4x a month, 2-3 x a week, 4-5x a week or daily. Because consumption of fruit, vegetables and nuts 3 times a week is negative associated with aneurysms, whereas consumption of red meat and fast food are positively correlated with abdominal aneurysms (26).

Preoperative exercises

The treatment consists of a daily training at home during weekdays, according to the instructions of a physical therapist, under the supervision of a specialist in sports medicine, and responsibility of the principal investigator. This home training is initiated after heartrate (HR), blood pressure (RR) and oxygenation (SpO2) measurement. Smoking people will be asked to communicate the number of cigarettes smoked each day.

Besides the home training, subjects will be asked to attend a weekly training at the physical therapist. Again, HR, RR and pO2 will be communicated through the home monitoring device.

Before starting the three-to-nine-week training, a cardiopulmonary exercise test (CPET) at the specialist in sports medicine is performed to objectively assess VO_2 at the VAT and other variables related to aerobic fitness. The CPET will be an extra burden to our subjects. After 3-9 weeks of training, this CPET will be repeated to monitor improvement or deterioration of the subjects.

3.2. Use of co-intervention (if applicable)

If unknown cardiologic abnormalities are found during the screening, medication will be adjusted to improve the heart condition of the patient. This is part of the routine workup before an AAA treatment.

3.3. Escape medication (if applicable)

Not applicable

4. INVESTIGATIONAL PRODUCT

Not applicable, prehabilitation in AAA-surgery will be tested.

5. NON-INVESTIGATIONAL PRODUCT

Not applicable, neither a medicinal, a food product, nor a chemical compound will be investigated.

6. METHODS

6.1. Study parameters/endpoints

6.1.1. Main study parameter/endpoint

It is aimed to identify AAA patients who improve most from home monitored training, i.e., patients with an improvement of their VO2 at VAT. Patients with poor fitness are expected to benefit most.

6.1.2. Secondary study parameters/endpoints

To evaluate the preliminary effectiveness of an on average six-week home-monitored prehabilitation program in patients with AAA scheduled for elective AAA-repair to improve the preoperative VO2 at the ventilatory anaerobic threshold (VAT). Yet, it is uncertain if diet, SES, frailty score, and other patient characteristics may predict the improvement of fitness within 6 weeks, on average.

Other secondary aims are program feasibility (recruitment rate, adherence, completion rate, drop-out rate, attrition rate, and adverse events); the (preliminary) effect of the program on other cardiopulmonary exercise testing (CPET) values; as well as the effect of the program with the Luscii-app. The individual (preliminary) effect of prehabilitation on other CPET values are evaluated, as well, and the postoperative course in patients after AAA repair; by collecting data on the surgical intervention and postoperative outcomes.

6.1.3. Other study parameters (if applicable)

Other parameters will be monitored, such as the number of complications (MACEs, MALEs, and others), hospital length of stay, number of readmissions, and mortality.

6.2. Randomisation, blinding and treatment allocation

It is not intended to perform randomization in this single-arm intervention study. Included subjects will be followed during their preparation before an AAA repair. These findings will be compared between patients with and without improvement after training (age, ASA, smoking, hypertension, dyslipidemia, diabetes, et cetera).

6.3. Study procedures

Patients with an indication for AAA repair are routinely prepared for this operation with a visit at the anesthesiologist and the cardiologist. After the indication is set, the minimal waiting time for the operation is usually six weeks on average. This gives the

subject the opportunity to start training. Surgery will not be postponed for this pilot study.
After the indication and informed consent, a questionnaire will be completed with the help of a professional research-nurse, and a cardiologic consultation will be performed. When subjects are fit for training, they will be informed about the use of the home-monitoring device. This will be followed by a visit at physical therapist (Figure 1).

Estimation of costs Aneurysm in motion					
	WZA (40 patients)		**Treant (60 patients)**		**Totals**
Intake Luscii	€ 32	€ 1.280	€ 32	€ 1.920	€ 3.200
Alert Luscii	€ 14,70	€ 588	€ 14,70	€ 882	€ 1.470
Costs research bureau (30 minutes)	€ 20	€ 800	€ 20	€ 1.200	€ 2.000
	Totaal 1 jaar	€ 2.668		€ 4.002	
Both hospitals					**€ 6.670**

Table 2: Expected costs in participating hospitals, without insurance costs.

Following these three explanations (home monitoring, questionnaires, and training), the subject will be asked to start their home training during office hours, following a communication with the communication center of the home monitoring (Luscii).
After each training and cooling down, parameters should be imported from the home-monitoring device and feedback will be given from the communication center. In case of anomalous measurements, the hospital will be contacted.

	Action	Conditions	Requirement Fit patients	Requirement Unfit patients
Inclusion criteria	Indication AAA repair	Elective repair	Eligible for inclusion	Eligible for inclusion
	Informed consent	Signed	Eligible for inclusion	Eligible for inclusion
Introduction	Questionnaire	Various characteristics	One hour	One hour
	Specialist sports medicine	Consultation and CPET	One hour	-
	Cardiologist	Safe to perform training Unsafe	Questionnaire and CPET -	- Follow up
	Explanation	Home monitoring device	One hour	-
	First visit physical therapist	At location physical therapist	One hour	-
3-9 weeks	Daily training at home	Four days a week	Four hours	-
	Weekly visit physical therapist	Once a week	One hour	-
Postop	Three months after the operation	Outpatient clinic	Ten minutes	Follow up

Table 3: time investment of the included subjects. AAA= aneurysm of the abdominal aorta; CPET= cardiopulmonary exercise test

6.4. 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.

6.4.1. Specific criteria for withdrawal (if applicable)

Not applicable.

6.5. Replacement of individual subjects after withdrawal

Not applicable

6.6. Follow-up of subjects withdrawn from treatment

Subjects who withdraw from the study will be followed three months after the AAA repair, when they approve the investigators to do so. This data will be used to compare HLOS, complications, and readmissions.

6.7. Premature termination of the study

Although recent literature acknowledges the safety of training in AAA patients, this study will be terminated when more than 10% of the included subjects die in course of their preparation of the operation.

A termination of the study will be advocated when more than half of the included subjects withdraw. When this is the case, it will be considered whether the training program is too heavy, or the condition of the patients is not sufficient to exercise the way they are asked to do.

7. SAFETY REPORTING

7.1. Temporary halt for reasons of subject safety

In accordance with the WMO, the sponsor will suspend the study if there is sufficient ground that continuation of the study will jeopardize 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.

7.2. AEs, SAEs and SUSARs

7.2.1. 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 staff will be recorded.

7.2.2. 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 preoperative hospitalization or prolongation of existing inpatients' hospitalization.
- results in persistent or significant disability or incapacity.
- requires urgent surgical intervention; 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 or urgent re-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 that result in death or are life threatening through the web portal *ToetsingOnline* to the accredited METC that approved the protocol, within 7 days of first knowledge for SAEs 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.

7.2.3. Suspected unexpected serious adverse reactions (SUSARs)

Not applicable

7.3. Annual safety report

Not applicable

7.4. 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 the end of study within the Netherlands, as defined in the protocol.

7.5. [Data Safety Monitoring Board (DSMB) / Safety Committee]

Not applicable, this pilot study of 100 patients is expected to close within two years. When a larger trial follows this pilot, data safety monitoring will be necessary.
Due to recent literature, it is expected that prehabilitation in all patients undergoing major surgery should be standard care. The initiation of preoperative training in patients does not involve the nature of the disease and it is not expected to harm patients. On the contrary, subjects will enlarge their fitness and increase their capabilities to contact the hospital with the Luscii app.

In the annual progress report inclusion and complications of the operations will be reported to the METc UMCG.

8. STATISTICAL ANALYSIS

8.1. Primary study parameter(s)

Comparison of patient characteristics between improved and non-improved patients, in relation to VO2 at VAT, will be done using a multivariable analysis. Data will be presented as mean and standard deviation or as median and interquartile range, as appropriate. Categorical data will be summarized by frequency and percentage within each cohort. The comparison of improved and non-improved patients will be done with an multivariable regression analysis.

8.2. Secondary study parameter(s)

To measure if patients with an indication for AAA-repair can improve their VO2 at VAT. The second measurement will be performed after a three to nine week training program, using the advice of a specialist in sports medicine, consults of a physical therapist and eHealth monitoring. To evaluate the effectiveness of the, on average, six-week home-monitored prehabilitation program, the difference in the VO2 at the ventilatory anaerobic threshold before the start of the training and after an average six weeks of prehabilitation will be analyzed using a paired samples t-test or Wilcoxon signed rank test, as appropriate. A repeated measurements analysis (mixed models in SPSS) will be performed to assess changes over time in continuous variables. P values <0.05 will be considered statistically significant. Modifiable factors will be analyzed as well, such as dietary habits, social economic status, frailty score, and other information collected in the questionnaires.
To evaluate the feasibility of the average six-week home-monitored prehabilitation program, adherence or compliance, adverse events, motivation, and patient appreciation will be described by use of descriptive statistics. Descriptive statistics will be used to present data on perioperative variables and postoperative progress.

8.3. Other study parameters

Not applicable.

8.4. Interim analysis (if applicable)

Not applicable

9. ETHICAL CONSIDERATIONS

9.1. Regulation statement

We will perform all study procedures according to the Declaration of Helsinki, the Medical Research Involving Human Subjects Act (in Dutch: Wet Medisch-wetenschappelijk Onderzoek met Mensen [WMO]) and the Dutch Personal Data Protection Act.

9.2. Recruitment and consent

At the indication for AAA repair, patients will be informed by the treating vascular surgeon. Patients will receive an information document from their treating physician. Eligible subjects receive an appointment with the (co)investigator within one week. When they agree during an appointment with the (co)investigator, patients need to sign a declaration of informed consent. Eligible patients will be given a minimum of 24 hours, and a maximum of 2 weeks, to determine participation. When informed consent is signed, all subjects will complete the questionnaire and will perform a CPET. Bases upon the result of these tests the cardiac evaluation is made, if necessary complemented by other diagnostics. After training and during their surgery, patients will be followed until 30 days hereafter (Figure 1).

9.3. Objection by minors or incapacitated subjects (if applicable)

Not applicable

9.4. Benefits and risks assessment, group relatedness

Not applicable

9.5. Compensation for injury

For all research sites liability insurances are provided for the principal investigator has a liability insurance which is in accordance with article 7 of the WMO. The sponsor has an insurance which is in accordance with the legal requirements in the Netherlands (Article 7 WMO). These insurances provide coverage for damage to research subjects through injury or death caused by the study. The insurances apply to the damage that becomes apparent during the study or within 4 years after the end of the study.

9.6. Incentives (if applicable)

Not applicable

10. ADMINISTRATIVE ASPECTS, MONITORING AND PUBLICATION

10.1. Handling and storage of data and documents

Patient data will be handled in correspondence with the EU General Data Protection Regulation and the Dutch Act on Implementation of the General Data Protection Regulation. Data will be stored analogue in pseudonymised case report forms (CRF). Pseudonymisation will be performed using a code, and besides name, date of birth and sex, we will not register personal details in the decoding list. The code will be formed by a number appointed to the site of inclusion, the year and month, and the chronologic order of patients included in the center of inclusion. The key document to the codes will be kept on a secured server at each location under the responsibility of the local investigator. Data is stored for 15 years.

10.2. Monitoring and Quality Assurance

The CE certificate of the Luscii app describes the following about data management: “Clinical engine software for remote patient monitoring”, data will be stored in the cloud maintained according to ISO standards in AWS data centers in Frankfurt (Germany); mentioned at the Luscii website. These data are supervised by a medical officer, aka the designated Data Controller. Data will be stored according to the rules of the new privacy legacy and guaranteeing the GDPR (General Data Protection Regulation).

10.3. Amendments

We will notify the METC UMCG and competent authority about substantial amendments. We will inform the sponsor to record and file non-substantial amendments and we will inform the METC UMCG and competent authority.

10.4. Annual progress report

The project leader will submit a summary of the progress of the trial to the METC UMCG once a year, with information on the date of inclusion of the first subject, numbers of subjects included and numbers of subjects that have completed the study, serious adverse events, other problems, and amendments. It is to be expected to finish the study within two years of time. The final report will be submitted accordingly.

10.5. Temporary halt and (prematurely) end of study report

The sponsor will notify the METC UMCG and the competent authority of the end of the study within a period of 90 days. The end of the study is defined as completion of study procedures in the last patient. The sponsor will notify the METC UMCG immediately of a temporary halt of the study, including the reason of such an action. In case the study is ended prematurely, the sponsor will notify the METC UMCG and the competent authority 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 METC UMCG and the Competent Authority.

10.6. Public disclosure and publication policy

We will write a manuscript about the results of this study, which we will submit to a peer-reviewed scientific medical journal. After publication we will make the dataset publicly available on request. This raw data should be made available for future research, unrelated to patient identity.

11. STRUCTURED RISK ANALYSIS

11.1. Potential issues of concern

a. Level of knowledge about mechanism of action

Previous studies have investigated the risk of training in AAA patients (8, 9, 27, 28) and in patients with a thoracic aorta aneurysm (TAA)(29). These studies do not report mortality due to training or exercise. Thanks to the change in preoperative management, patients are offered home monitoring to intensify daily communication with the hospital, and to enhance safety.

b. Previous exposure of human beings with the test product(s) and/or products with a similar biological mechanism

Human beings with an AAA have been exposed to exercise previously.

c. Can the primary or secondary mechanism be induced in animals and/or in *ex-vivo* human cell material?

Not applicable

d. Selectivity of the mechanism to target tissue in animals and/or human beings

Not applicable

e. Analysis of potential effect

The potential effect of exercise is improvement of condition. A side effect might be elevation of blood pressure, but it is expected to contain the aneurysm, as no side effect have been mentioned previously (see section 10.1a as well).

f. Pharmacokinetic considerations

Not applicable

g. Study population

Patients with an indication for AAA repair, endovascular or open. Standard care is performed. Subjects are asked to improve their condition with exercise training.

h. Interaction with other products

Not applicable

i. Predictability of effect

Not applicable

j. Can effects be managed?

Due to home monitoring and weekly follow up by the physical therapist, effects of the training are followed closely. In case of deterioration, treating physician will be contacted. Either through the Luscii app, by email or by telephone.

11.2. Synthesis

The risks of this study are very low. To reduce the risk, patients will be monitored during their study activities.

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Appendix 1; Exercise scheme for monitoring at home

	Datum	Tijd start training	Zuurstof saturatie	Bloed druk	Tijd einde training	Zuurstof saturatie	Bloed druk	Verzonden naar de Luscii app?
Ma								Ja / Nee
Di								Ja / Nee
Woe	Fysio							Ja / Nee
Don								Ja / Nee
Vrij								Ja / Nee
Ma								Ja / Nee
Di								Ja / Nee
Woe	Fysio							Ja / Nee
Don								Ja / Nee
Vrij								Ja / Nee
Ma								Ja / Nee
Di								Ja / Nee
Woe	Fysio							Ja / Nee
Don								Ja / Nee
Vrij								Ja / Nee
Ma								Ja / Nee
Di								Ja / Nee
Woe	Fysio							Ja / Nee
Don								Ja / Nee
Vrij								Ja / Nee
Ma								Ja / Nee
Di								Ja / Nee
Woe	Fysio							Ja / Nee
Don								Ja / Nee
Vrij								Ja / Nee
Ma								Ja / Nee
Di								Ja / Nee
Woe	Fysio							Ja / Nee
Don								Ja / Nee
Vrij								Ja / Nee
Ma								Ja / Nee
Di								Ja / Nee
Woe	Fysio							Ja / Nee
Don								Ja / Nee
Vrij								Ja / Nee

Appendix 2; Exercise scheme at home and with the physical therapist

Maandag	**Dinsdag**	**Woensdag**	**Donderdag**	**Vrijdag**
20 minuten wandelen	20 minuten fietsen	Fysiotherapeut	20 minuten wandelen	20 minuten fietsen
2 minuten traplopen	2 minuten traplopen	Steep ramp test	2 minuten traplopen	2 minuten traplopen
1 minuut opstaan-zitten-opstaan	1 minuut opstaan-zitten-opstaan	HIIT	1 minuut opstaan-zitten-opstaan	1 minuut opstaan-zitten-opstaan

Table: example of a weekly training program

<u>Thuis (4x per week): vaste tijd (bvb. 9u – 10u) overeengekomen met de fysiotherapeut.</u>
Van tevoren zuurstofsaturatie, pols, RR en aantal sigaretten via de Luscii app
Op basis van CPET:

- 10 / 20 / 30 minuten per dag matig-intensief actief zijn (thuis, mensen merken dat ze meer moet ademhalen):
    - Wandelen
    - Fietsen
- 1 / 2 / 5 minuten hoog-intensief (thuis):
    - Traplopen
    - Opstaan uit de stoel en weer gaan zitten.

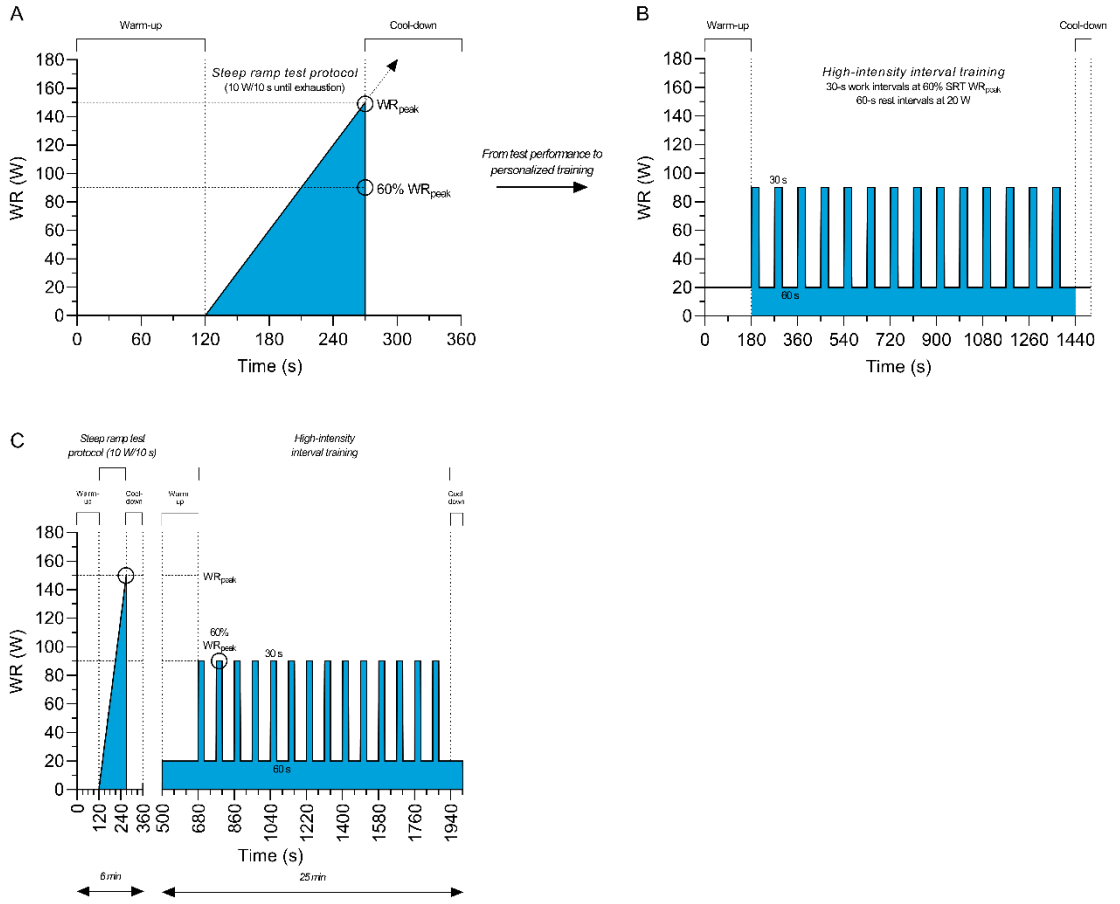
Na de training wederom O2, pols, RR via de Luscii app doorsturen.

<u>Één keer per week fysiotherapie</u>
Van tevoren zuurstofsaturatie, pols, RR en aantal sigaretten via de Luscii app
Op basis van aangepaste steep ramp test (10 W /10 s):
Nadat de aangepaste SRT op baseline is uitgevoerd (Figuur 1, Grafieken A en C), kan het (gedeeltelijk) gesuperviseerde trainingsprogramma, bestaande uit 3 HIIT-sessies van 25 minuten per week, worden uitgevoerd in de leefomgeving van de patiënt (in de eerste lijn of thuis).

- Elke trainingssessie bestaat uit een warming-up van 3 minuten op een belasting van 20 W, gevolgd door 14 arbeidsintervallen van 30 seconden op een hoge intensiteit van 60% van de SRT Wpiek
- Afgewisseld met 14 herstelintervallen van 60 sec op een lage intensiteit van 20 W

- Waarna een cooling-down van 1 minuut volgt op een belasting van 20 W (Figuur 1, grafieken B en C).

De trainingsintensiteit tijdens de arbeidsintervallen met hoge intensiteit komt overeen met ongeveer 90% van de CPET Wpiek. De aangepaste SRT dient wekelijks of tweewekelijks herhaalt te worden om veranderingen in de cardiorespiratoire fitheid te monitoren, terwijl het programma dienovereenkomstig kan worden aangepast om een adequate trainingsprikkel te behouden.



Appendix 3; Automatized answers Luscii.

Pulsoximeter		
Eerste meting (voor de training)	Zuurstofsaturatie 95 of lager	Je zuurstofgehalte is te laag om te beginnen met de training. Ga even rustig zitten, haal een paar keer diep adem en meet je zuurstofgehalte over een kwartier nog een keer. Je vindt de meting Zuurstofgehalte voor de training bij Zelfzorg onder het kopje Metingen. Zorg ervoor dat je handen warm zijn en haal eventuele nagellak of gelnagels weg. Blijft je zuurstofgehalte lager dan 95%? Overleg dan met je fysiotherapeut of je mag gaan trainen.
Eerste meting (voor de training)	Zuurstofsaturatie 95,1 of hoger	Je zuurstofgehalte is goed, je kan starten met je training. Vergeet niet om na de training je metingen in te vullen!
Tweede meting (na de training)	Zuurstofsaturatie 90 of lager	Je zuurstofgehalte is aan de lage kant. Train morgen iets minder hard en bespreek dit advies met je fysiotherapeut.
Tweede meting (na de training)	Zuurstofsaturatie 90 of hoger	Goed gewerkt, volgende keer weer een stukje beter. Gefeliciteerd!
Pols		
Eerste meting (voor de training)	Hartslag 70 of lager	Je hartslag is wat laag. Doe een lichte warming-up en bespreek dit advies met je fysiotherapeut. Meet na de warming-up nog een keer je hartslag. Je vindt de meting Hartslag voor de training bij Zelfzorg onder het kopje Metingen. Blijft je hartslag lager dan 70? Overleg dan met je fysiotherapeut of je door mag gaan met trainen.
Eerste meting (voor de training)	Hartslag 120 of hoger	Je hartslag is wat snel. Ga even rustig zitten en meet je hartslag over een kwartier nog een keer. Bespreek deze meting met de fysiotherapeut.
Tweede meting (na de training)	Hartslag 100 of hoger	Je hartslag is op dit moment wat hoog. Train morgen iets minder hard en bespreek dit advies met je fysiotherapeut.
Derde meting (30 seconden na de training)	Hartslag 120 of hoger	Kan een foute meting zijn. Als het morgen weer zo is, even met de fysiotherapeut bespreken, alstublieft.
Bloeddruk		
Eerste meting (voor de training)	Bovendruk 200mmHg of hoger	Ga niet trainen, meld deze meting volgende keer bij de fysiotherapeut
Eerste meting (voor de training)	Bovendruk onder de 200mmHg	U kan starten met trainen.
Tweede meting (na de training)	Bovendruk 200mmHg of hoger	Stop met trainen, meld deze meting volgende keer bij de fysiotherapeut
Tweede meting (na de training)	Bovendruk onder de 200mmHg	Goed gewerkt, volgende keer weer een stukje beter. Gefeliciteerd!
Stappenteller		
Aantal stappen 5.000-7.500		Je hebt goed getraind vandaag! Probeer dit vol te houden tot aan de operatie.
Te weinig stappen gezet (minder dan 5.000)		Probeer morgen iets meer te trainen zodat je conditie beter wordt voor de operatie. Een betere conditie zorgt voor minder complicaties en een sneller herstel.
Voldoende stappen gezet (meer dan 7.500)		Je hebt goed getraind vandaag! Probeer dit vol te houden tot aan de operatie.

Veel stappen gezet (meer dan 10.000)		Je doet het geweldig en traint fantastisch! Dit zorgt voor een goede conditie en dus een sneller herstel na de operatie!
Roken		
Roken 1-5 sigaretten		Je bent er bijna, stoppen met roken is een kwestie van geduld en doorzettingsvermogen. Nog even doorzetten!
Roken 6-20 sigaretten		Je rookt niet veel, maar elke sigaret minder verkleint het risico. Probeer elke dag iets minder te roken.
Roken > 20 sigaretten		Het is je nog niet gelukt om te stoppen met roken. Minder sigaretten per dag helpt ook! Elke sigaret die je minder rookt zorgt voor een kleiner risico. Probeer dus elke dag iets minder te roken. Je kan het!
Patiënt rookt niet (0 sigaretten per dag.		Je hebt aangegeven niet (meer) te roken, heel goed! Dit zorgt voor een kleiner risico op complicaties en een sneller herstel na de operatie.