# Abdominal Aneurysm in Motion Physical therapy for patients with an indication for AAA repair; a pilot, correlation study

Published: 03-09-2024
Last updated: 30-01-2025

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Aneurysms and artery dissections |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON57003

**Source**
ToetsingOnline

**Brief title**
AAiMo

### Condition

- Aneurysms and artery dissections

**Synonym**
Abdominal Aneurysm or an Enlarged abdominal artery

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Groningen

**Source(s) of monetary or material Support:** Deze pilot studie wordt uitgevoerd met de goodwill van participerende zorgmedewerkers.

## Intervention

**Keyword:** Abdominal aneurysm, Condition, Physical Therapy, Prehabilitation, Training

## Outcome measures

### Primary outcome

The main endpoint is the analysis of patients who improve from training

compared to patients who do not improve from training. Variables that will be

checked are: initial fitness, BMI and age.

### Secondary outcome

Secondary endpoints are:

- the change in VO2 at the ventilatory anaerobic threshold (VAT) after the (on

average) 6-weeks 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 peak, oxygen uptake efficiency slope, and

response profiles.

- Postoperative events will be compared in relation to the subgroup analysis of

patients benefiting from training or not.

# Study description

### Background summary

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 (1-4).
Hypothesis: Training of patients awaiting their surgery for an AAA improves preoperative aerobic fitness. Some patients will benefit more from these training sessions than other patients.

## Study objective

The main objective is to study to separate patients who benefit from training, from patients who do not benefit from training and identify factors that impede training capability. Secondary objective 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 an intervention study. Patients, elected and fit for AAA surgery, are included 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 remote supervision of a specialist in sports medicine and a physical therapist, using home monitoring by means of the Luscii app.

## Intervention

Patients with 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 unfit for training will be excluded. This is evaluated by the cardiologist. Subjects fit for training start with home monitoring (pulse oximeter and sphygmomanometer) under the remote supervision of a physical therapist. Before and after three-to-nine-week (on average six weeks) training, subjects are evaluated by a specialist in sports medicine, to evaluate change of aerobic fitness with a CPET. All patients, fit and unfit for training, will be followed until three months postoperative.

## Study burden and risks

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 awaiting surgery, patients will be asked to train. This will be tiresome but rewarding; we expect to accomplish an increase in condition. The elderly seems capable of performing home monitoring. The extra energy and proteins necessary for the training will be substituted with extra FortiFit. 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, (1-4, 6). 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 (7). 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. The benefits may be substantial for preparation improves outcome, patients will have been taught to train, and home monitoring improves extramural communication and ease hospital capacity issues.

## Contacts

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

**Age**
Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

1) Age 18 years or older
2) Diagnosed with an aneurysm of the abdominal aorta
3) Indication for a vascular intervention to prevent spontaneous rupture
4) Signed informed consent
5) Proven fit for training with a cardiopulmonary exercise test (CPET)

### Exclusion criteria

- Patients with an acute indication for surgery (symptomatic or ruptured AAAs)
- Patients with an indication for priority surgery (semi-elective; within three weeks)
- Patients with tissue disorders (e.g. Marfan or other).
- Patients for whom it is unsafe to train (high RR > 200mmHg, arrhytthmogenic cardiomyopathy, or electrical abnormalities).
- Patients unable to understand the objectives or the devices of this study.

## Study design

### Design

**Study type:** Interventional

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| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Prevention |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 21-11-2024 |
| Enrollment: | 100 |
| Type: | Actual |

# Ethics review

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| Approved WMO Date: | 03-09-2024 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| CCMO | NL82992.042.23 |