ISRCTN09433624 https://doi.org/10.1186/ISRCTN09433624

# High-intensity interval exercise training prior to abdominal aortic aneurysm repair

**Submission date**
28/06/2013

**Recruitment status**
No longer recruiting

**Registration date**
28/06/2013

**Overall study status**
Completed

**Last Edited**
11/10/2017

**Condition category**
Circulatory System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Reduced fitness levels before major non-cardiac surgery (surgery not involving heart) are associated with an increased risk of complications and death following surgery. There is a convincing reason linking improved aerobic fitness to a reduction in adverse outcome following surgery. The oxygen requirements of the body are known to increase up to three times resting values as a consequence of major surgery (called the surgical stress response). A patient with adequate aerobic fitness is able meet these extra demands postoperatively, but patients with inadequate fitness levels are unable to cope, leading to a lack of oxygen reaching vital organs and subsequent perioperative (the time period describing the duration of a patient's surgical procedure, this commonly includes ward admission, anesthesia, surgery, and recovery) complications. It is known that improving fitness levels in the preoperative period will translate to reduced death and complications following major surgery. Research exists showing that elderly and unfit patients can be made fitter with exercise training over timeframes as short as 4 weeks. Despite this, no previous research has been conducted in non-cardiac surgery assessing the benefits of preoperative exercise training on reducing complications postoperatively. Any exercise programme needs to be well designed, safe and enjoyable for patients to achieve significant enough fitness improvements in such a short timeframe. It is also important that surgery is not unduly delayed as a result of any such preoperative interventions. High Intensity exercise training has been shown to be the most efficient way to achieve significant fitness improvements over such a tight time-course. This involves patients undertaking short sessions of hard exercise (between 1 and 4 minutes duration) followed by similar recovery periods. Abdominal Aortic Aneurysm (AAA) disease causes a swelling of the main artery in the abdomen (stomach). If this swelling is not surgically repaired it can expand and burst leading to premature death of affected individuals. Surgical repair in its own right is a high-risk operation with a significant risk of postoperative complications. Patients with AAA disease have a high incidence of underlying heart and lung disease often making them unfit for such high-risk surgery. This patient group therefore represent an ideal group to assess the potential benefits of preoperative exercise training (exercise training before surgery) on postoperative surgical outcome. We plan to undertake a feasibility study to explore the potential benefits of a 4-week high intensity aerobic interval-training programme, undertaken prior to surgery for AAA repair. This study is a feasibility study, designed to inform a subsequent larger trial.

Who can participate?
Any individuals over 18 years of age with an AAA

What does the study involve?
Safety is a primary concern at this feasibility stage of the study. All potential participants will undergo a thorough medical examination and fitness test (on an exercise bicycle) prior to study inclusion. Individuals identified with conditions likely to prohibit them from being able to undertake regular exercise, or where exercise may put them at particularly high risk, will be excluded on safety grounds. This study is aimed at comparing preoperative exercise training against usual care (no exercise training) before AAA surgery. Patients will be randomly allocated to either group with a 50:50 chance of either. All patients will undergo baseline assessments of fitness and quality of life (through validated questionnaires). Participants in the exercise group will then undergo a 4-week exercise programme, which will be in-hospital and supervised by an experienced physiotherapist. The exercise will be undertaken on a stationary gym bicycle, 3 times per week. Each session will have a total of 16 minutes of high intensity exercise (broken down into 2-4 minute bouts followed by similar length recovery periods) and last approximately 45 minutes in total. The high intensity exercise has been designed to be safe, manageable and enjoyable for patients whilst maintaining a high safety profile. During this 4-week period the usual care participants will not undertake any regular exercise. All participants will then have repeat fitness and quality of life assessments the following week (week 5). Surgery will be scheduled where possible for week 5. Participants will be followed up following surgery for complications until they are discharged home. Following discharge patients will be asked to keep a diary of interactions with health care providers e.g. GP, Consultant which is aimed at helping with the study health economic analysis. Researchers will then arrange a face-to-face review of participants 12 weeks following discharge to assess quality of life and run through the completed diary. A small number of participants (16 in total) will be invited to undertake an interview with the research nurse exploring study experiences. This interview will take approximately 60 minutes.

What are the possible risks and benefits?
Participants allocated to the usual care group will not be exposed to any risk beyond that of their usual management for the condition. Participants in the exercise group may be exposed to an increased risk of heart problems or aneurysm (balloon-like bulge in blood vessel) rupture during the exercise training sessions. The risk of both of these adverse outcomes has been thoroughly researched and the available literature suggests the absolute risk is very low for either complication (approximately 1: 10,000 per complication). Open surgery for AAA repair carries a risk of death and major complications of approximately 5% and 20% respectively. Clearly this risk may be significantly reduced if patients can be made fitter through the exercise training. We therefore believe that the 1:10,000 above is entirely offset by potential benefits of the exercise. This can only be examined further by undertaking the proposed research. Despite these risks, safety remains the number one priority of the study.

Where is the study run from?
The study will be undertaken in one of three hospitals where AAA surgery is undertaken; Middlesbrough, Sheffield and York. The exercise training will be undertaken in a safe environment, within each hospital, which is easily accessible for participants.

When is the study starting and how long is it expected to run for?
The study is expected to start in July/August 2013. We expect it will last nearly 2 years to completion.

Who is funding the study?
The study is funded through the Department of Health, Research for Patient Benefit programme.

Who is the main contact?
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# Contact information

### Type(s)
Scientific

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# Additional identifiers

### Protocol serial number
14483

# Study information

### Scientific Title
High-intensity Interval exercise Training prior to Abdominal Aortic Aneurysm repair: a feasibility study (HIT AAA)

### Acronym
HIT AAA

### Study objectives
The aims of this study are:
1. To establish the most appropriate primary outcome measure for a subsequent definitve trial these include: complication rates following surgery, hospital length of stay, quality of life and cost-effectiveness analysis
2. Establish the suitability of the High Intensity exercise training in patients with AAA disease
3. Examine patients preferences for exercise or usual care through qualitative patient interviews.

### Ethics approval required
Old ethics approval format

## Ethics approval(s)
Sunderland REC, 29/04/2013, ref: 13/NE/0116

## Study design
Parallel-group randomised controlled feasibility study

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Topic: Cardiovascular, Generic Health Relevance and Cross Cutting Themes; Subtopic: Cardiovascular (all Subtopics), Generic Health Relevance (all Subtopics); Disease: Anaesthetics, Cardiac Surgery

## Interventions
The intervention being assessed during this feasibility project is high intensity interval exercise training (HIT). Participants allocated to this group will exercise 3 times per week, on a stationary exercise cycle, for a 4-week period. The HIT element of the training involves intermittent bouts of 2-4 minutes of 'hard exercise' followed by similar length interspersed recovery periods. In total each exercise session will last approximately 45 minutes, and will critically involve 16 minutes of HIT.

The usual care group will not receive any exercise training.

Patients will be followed up until 12 weeks after leaving.

## Intervention Type
Other

## Phase
Not Applicable

## Primary outcome(s)
The principal outcome objective of this study is to explore potential primary outcomes for a subsequent definitive randomised controlled trial (RCT).
The physiological rationale suggests a causal pathway between adaptations consequent to exercise training and reduced mortality and morbidity. Potential primary outcomes for a definitive trial therefore include 30-day mortality, morbidity [Post-Operative Morbidity Survey (POMS) score], Quality of life (SF-36 and EQ5D), hospital length of stay, costs and cost-effectiveness.

## Key secondary outcome(s))
1. Examine the suitability of the exercise training for a subsequent definitive RCT High-intensity interval training shows much promise as a time efficient, enjoyable, and effective intervention for improving fitness. However, it has not been employed with AAA patients awaiting repair. This will specifically involve assessing compliance, safety and enjoyment of the exercise intervention.
2. Examine the willingness of patients to be randomised and explore potential patient

preferences.
In RCTs patients might have strong treatment preferences resulting in a refusal to be randomised, affecting the generalisability of results. Or, they might agree to be randomised but suffer from resentful demoralisation if they end up in the non-preferred arm of the trial leading to poor compliance. This issue requires examination in a feasibility study, as the preference effects for exercise vs. control in this patient population are unknown.
Theoretically, patients might have a preference for the exercise arm due to a belief in the benefits. Notwithstanding the patient information provided, others might be fearful of engaging in high-intensity exercise prior to surgery and therefore might exhibit a preference for the control arm. These issues could affect the success of a definitive trial.

### Completion date
28/02/2015

## Eligibility

### Key inclusion criteria
1. Patients undergoing open or endovascular repair of a 5.5-7.0cm infrarenal abdominal aortic aneurysm
2. Age >=18 years (male and female)

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Key exclusion criteria
1. Refusal or inability to provide informed consent
2. Conservative management of Abdominal Aortic Aneurysm (AAA)
3. Suprarenal or thoracic aneurysms
4. Emergency AAA repair
5. Infrarenal AAA >7 cm
6. Contra-indication to undertaking Cardiopulmonary exercise test (CPET) or exercise training
7. Body mass index (BMI) <20 or >40 kg/m2
8. Participants identified as being 'high risk' clinically or consequent to CPET. This would include potential participants identified with conditions likely to be overtly exacerbated by exercise training e.g. unstable angina

### Date of first enrolment
01/08/2013

**Date of final enrolment**
28/02/2015

# Locations

**Countries of recruitment**
United Kingdom

England

**Study participating centre**
**James Cook Hospital**
Middlesbrough
United Kingdom
TS4 3BW

# Sponsor information

**Organisation**
South Tees Hospitals NHS Trust (UK)

**ROR**
https://ror.org/02js17r36

# Funder(s)

**Funder type**
Government

**Funder Name**
NIHR (UK) - Research for Patient Benefit (RfPB); Grant Codes: PB-PG-1111-26068

# Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 09/01/2017 | | Yes | No |
| Results article | results | 01/12/2017 | | Yes | No |
| Protocol article | protocol | 10/01/2014 | | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |