

# Exercise and non-alcoholic steatohepatitis

<b>Submission date</b> 08/01/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results <input type="checkbox"/> Individual participant data
<b>Registration date</b> 09/01/2015	<b>Overall study status</b> Completed	
<b>Last Edited</b> 22/08/2016	<b>Condition category</b> Nutritional, Metabolic, Endocrine	

## Plain English summary of protocol

### Background and study aims

Fatty liver disease is a term used to describe a range of conditions caused by a build-up of fat within the liver. A normal liver should have no, or very little, fat. Simple fatty liver, which is harmless, is common in people who are overweight or obese. Over time, however, simple fatty liver can develop into non-alcoholic steatohepatitis (NASH) where the liver becomes inflamed. At this stage, people might experience a dull ache in their abdomen but it often has no symptoms. Persistent inflammation of the liver can develop into fibrosis where fibrous scar tissue develops around liver cells and blood vessels. The liver is still able to function normally at this stage. The final stages are cirrhosis and end-stage liver disease, in which the scarring is so extensive that the liver shrinks, becomes lumpy and begins not to function normally. Recent information has shown that exercise may help people with fatty liver. It may help reduce the amount of fat in the liver by increasing the ability of the body to burn fat and increasing the sensitivity of the body to food. Evidence also suggests that exercise may help to reduce active injury and inflammation in the liver. We want to show the effect of exercise on the levels of fat, injury and inflammation in the liver and the sensitivity of the body to food.

### Who can participate?

Adults aged at least 18 with diagnosed NASH, who not do a lot of exercise and are at a stable weight.

### What does the study involve?

Participants are randomly allocated into one of two groups. Those in group 1 (intervention group) undergo 12 weeks of supervised exercise. Those in group 2 (control group) do not attend any exercise sessions. Both groups of participants go to the research facility 5 times throughout the 12 week exercise period, in which the amount of fat in the liver is measured (using a magnetic resonance scanner) and blood tests are taken to check for liver injury and inflammation.

### What are the possible benefits and risks of participating?

Being more physically active may be beneficial to the level of fat, injury and inflammation in the liver and if sustained after the study, may help in preventing other complications such as heart disease and diabetes. Participants in the intervention group have supervised exercise sessions (like a personal trainer) which will teach them about their body, show them how to exercise correctly and help them become more physically fit. Participants in the control group are given

the opportunity to do a individualised exercise programme. There are minimal risks to taking part in the exercise programme.

Where is the study run from?

University of Newcastle upon Tyne (UK)

When is the study starting and how long is it expected to run for?

January 2013 to November 2014

Who is funding the study?

National Institute for Health Research (UK)

Who is the main contact?

Ms Julia Maddison

## Contact information

### Type(s)

Scientific

### Contact name

Ms Julia Maddison

### Contact details

University of Newcastle upon Tyne  
Mitochondrial Research Group  
Framlington Place  
Newcastle upon Tyne  
United Kingdom  
NE2 4HH

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

13894

## Study information

### Scientific Title

The effect of exercise on active liver injury, inflammation and liver lipid in people with non-alcoholic steatohepatitis

### Study objectives

To characterise the effects of resistance exercise upon factors which influence the development and progression of non-alcoholic steatohepatitis (NASH).

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Sunderland NRES committee, 02/01/2013, ref: 13/NE/0041

**Study design**

Randomised; Interventional

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Other

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

**Health condition(s) or problem(s) studied**

Topic: Metabolic and endocrine disorders, Hepatology; Subtopic: Metabolic and Endocrine (all Subtopics), Hepatology; Disease: Metabolic & Endocrine (not diabetes), All Hepatology

**Interventions**

Participants will undergo five metabolic assessment visits to the research facility, interspersed by either 12 weeks of supervised exercise therapy or continue their normal care.

**Intervention Type**

Behavioural

**Primary outcome measure**

Liver lipids, abdominal fat content, insulin sensitivity; Timepoint(s): 12 weeks

**Secondary outcome measures**

N/A

**Overall study start date**

01/03/2013

**Completion date**

10/11/2014

## Eligibility

### Key inclusion criteria

1. NASH confirmed by liver biopsy; this is the study group
2. Sedentary; we are looking at the effect of increased exercise
3. The person's weight needs to be stable as we are interested in the independent effect of exercise
4. Aged 18 years and over
5. Understanding of English (as without this supervised gym visits will not be possible)

### Participant type(s)

Patient

### Age group

Adult

### Lower age limit

18 Years

### Sex

Both

### Target number of participants

Planned Sample Size: 28; UK Sample Size: 28; Description: 14 participants per group to allow 3 people from each group to leave the study and retain sufficient power.

### Key exclusion criteria

1. NASH confirmed by liver biopsy; this is the study group
2. Sedentary; we are looking at the effect of increased exercise
3. The person's weight needs to be stable as we are interested in the independent effect of exercise
4. Aged 18 years and over
5. Understanding of English (as without this supervised gym visits will not be possible)

### Date of first enrolment

01/03/2013

### Date of final enrolment

01/03/2015

## Locations

### Countries of recruitment

England

United Kingdom

**Study participating centre**  
**University of Newcastle upon Tyne**  
Mitochondrial Research Group  
Framlington Place  
Newcastle upon Tyne  
United Kingdom  
NE2 4HH

## Sponsor information

### Organisation

Newcastle upon Tyne Hospitals NHS Foundation Trust

### Sponsor details

Midwifery Research Dept  
Leazes Wing  
Queen Victoria Road  
Newcastle upon Tyne  
England  
United Kingdom  
NE1 4LP

### Sponsor type

Hospital/treatment centre

### ROR

<https://ror.org/05p40t847>

## Funder(s)

### Funder type

Government

### Funder Name

National Institute for Health Research

### Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

**Location**

United Kingdom

## Results and Publications

**Publication and dissemination plan**

Will be presented at liver conferences such as the European Association for the Study of Livers

**Intention to publish date**

**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?
<a href="#">Results article</a>	results	01/01/2017		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No