

# Resistance exercise and non-alcoholic fatty liver disease

<b>Submission date</b> 23/04/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 23/04/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 29/07/2013	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Michael Trenell

**Contact details**  
Westgate Road  
Newcastle Upon Tyne  
United Kingdom  
NE4 6BE

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
6955; G0802536

## Study information

**Scientific Title**

The effect of resistance exercise on metabolism and liver lipid in people with non-alcoholic fatty liver disease

### **Study objectives**

The purpose of the study is to characterise the effects of resistance exercise upon factors which influence the development and progression of non-alcoholic fatty liver disease (NAFLD). The primary aim is to observe whether performing resistance exercise reduces liver lipid content in people with NAFLD. The secondary aims are to understand the influence of resistance exercise upon factors which influence the development of NAFLD: insulin sensitivity, lipid oxidation, regional adiposity and cytokine production.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

County Durham and Tees Valley 2 REC approved on the 28th September 2009 (ref: 09/H0908/48)

### **Study design**

Non-randomised interventional prevention and treatment trial

### **Primary study design**

Interventional

### **Secondary study design**

Non randomised controlled trial

### **Study setting(s)**

GP practice

### **Study type(s)**

Prevention

### **Participant information sheet**

Not available in web format, please contact [kate.hallsworth@ncl.ac.uk](mailto:kate.hallsworth@ncl.ac.uk) to request a patient information sheet

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

Topic: Metabolic and Endocrine, Oral and Gastrointestinal; Subtopic: Metabolic and Endocrine (all Subtopics); Disease: Metabolic & Endocrine (not diabetes), Hepatology

### **Interventions**

Participants will be assigned to the exercise or control group. The exercise group will undergo 8 weeks of resistance training 3 times per week. The intensity of the programme will be tailored to each individual and be increased progressively over the 8 weeks. The control group will continue with standard clinical care. Follow up length: 4 months.

### **Intervention Type**

Other

### **Phase**

Not Specified

**Primary outcome measure**

A quantitative measure of liver fat will be made using H magnetic resonance spectroscopy. Primary and secondary outcome measures will be made at baseline and after the 8 week exercise intervention/8 week control period.

**Secondary outcome measures**

1. Insulin sensitivity
2. Lipid oxidation
3. Cytokine production
4. Regional adiposity
5. Body composition

Primary and secondary outcome measures will be made at baseline and after the 8 week exercise intervention/8 week control period.

**Overall study start date**

01/08/2009

**Completion date**

01/06/2010

**Eligibility****Key inclusion criteria**

1. Diagnosed NAFLD or raised liver enzymes
2. Type 2 diabetes (diet or metformin controlled)
3. Body mass index (BMI) between 25 - 35 kg/m<sup>2</sup>
4. Aged 18 - 70 years
5. Subjects should not already take part in regular exercise

**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

**Key exclusion criteria**

1. Subjects with kidney disease or in vivo ferrous metal
2. Subjects that have other pre-existing medical conditions which could prevent them from exercising 3 x per week

3. Subjects with type 2 diabetes on insulin or insulin sensitising treatments
4. Subjects with advanced liver disease

**Date of first enrolment**

01/08/2009

**Date of final enrolment**

01/06/2010

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre****Westgate Road**

Newcastle Upon Tyne

United Kingdom

NE4 6BE

## **Sponsor information**

**Organisation**

Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

**Sponsor details**

Midwifery Research Dept

Leazes Wing

Queen Victoria Road

Newcastle upon Tyne

England

United Kingdom

NE1 4LP

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.newcastle-hospitals.org.uk/>

**ROR**

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

# Funder(s)

## Funder type

Research council

## Funder Name

Diabetes UK (UK)

## Alternative Name(s)

DIABETES UK LIMITED, British Diabetic Association

## Funding Body Type

Private sector organisation

## Funding Body Subtype

Trusts, charities, foundations (both public and private)

## Location

United Kingdom

## Funder Name

Medical Research Council (MRC) (UK) (ref: G0802536)

## Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

United Kingdom

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## 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	01/09/2011		Yes	No