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Resistance exercise and non-alcoholic fatty liver disease

Submission date 23/04/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/04/2010	**Overall study status** Completed	
Last Edited 29/07/2013	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Prevention

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(s)
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.

Key secondary outcome(s))
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.

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^2
4. Aged 18 - 70 years
5. Subjects should not already take part in regular exercise

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

England

Study participating centre

Westgate Road
Newcastle Upon Tyne
United Kingdom
NE4 6BE

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Research council

Funder Name
Diabetes UK (UK)

Alternative Name(s)
The British Diabetic Association, 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

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	01/09/2011		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes