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Does resistance training exercise help prevent frailty and loss of independence for older people with insulin treated diabetes? The EXPLODE Trial

Submission date
15/07/2020

Recruitment status
No longer recruiting

Registration date
03/08/2020

Overall study status
Completed

Last Edited
16/01/2023

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
There are 3.7 million people in the UK with diagnosed diabetes (both Type 1 and Type 2), with approximately 80% treated with insulin or requiring insulin treatment at some stage of the disease. While diabetes complications such as cardiovascular disease are well known, often unappreciated complications are the accelerated rate of sarcopenia (loss of bone mass), increased frailty, and loss of independence that can come from years of exposure to hyperglycaemia and inflammation.

Leading a physically active life can be problematic for those with insulin-treated diabetes due to blood glucose control disruption. However, resistance (weight) training carries less risk of a loss of blood glucose control, compared to other forms of exercise. Moreover, in other groups of people with frailty, resistance training has been shown effective in improving physical function. With the increasing prevalence of diabetes, planning for the management of this patient group in later life is vital.

The aim of this study is to test the use of resistance exercise to improve physical function in older patients with insulin treated diabetes, who are mildly frail. This study also aims to increase understanding of the impact of resistance training on patients with diabetes psycho-socially. Findings will be used to inform a future trial should the training prove acceptable and feasible.

Who can participate?
Thirty patients with insulin-treated diabetes (type 1 and 2), and thirty without (matched for age and frailty), aged 60 or over, will be recruited.

What does the study involve?
All participants will complete blood and physical testing. Fifteen of each group will then be randomised to a four-week supervised resistance training programme, designed to increase muscle mass/strength. All participants will then repeat the physical testing. A subset will be

interviewed before and after the training programme to understand their perceptions of training, and living with diabetes (where relevant) as they have aged.

What are the possible benefits and risks of participating?
There is no direct benefit for participants. However, exercise is repeatedly shown to be of benefit, both physically and mentally.

All participants will be screened before taking part in the study, to ensure that they do not have any conditions which exercise may exacerbate. This is to ensure safety.

The resistance training programme is designed to be accessible to all, building gradually over the four week period. Participants will be fully supervised, and weights will be adjusted to what they can easily lift (rather than a specific kilogram weight).

Blood samples will be taken as part of the study, there is the risk of slight discomfort or bruising. These risks will be minimised by samples being taken by experienced clinical staff.

The study requires frequent visits to the CRF which may cause a time inconvenience for participants. Participants will be reimbursed £50 for taking part in the study as compensation for their time. Transportation will be provided for all visits. Participants' visits will also be scheduled at the convenience of the participant, such that any inconvenience is minimised.

Where is the study run from?
Newcastle University (UK) and the Clinical Research Facility at the Royal Victoria Infirmary, Newcastle-upon-Tyne (UK)

When is the study starting and how long is it expected to run for?
From December 2019 to April 2025

Who is funding the study?
Internal Newcastle University funding supported by the Wellcome Trust small grant scheme (UK)

Who is the main contact?
Dr Daniel West
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
269661

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 269661

Study information

Scientific Title
EXercise to Prevent frailty and Loss Of independence in insulin treated older people with DiabetEs: The EXPLODE Trial

Acronym
EXPLODE

Study objectives
The aim of this trial is to characterise the physical function, cardiovascular health, and the health and wellbeing of older people living with diabetes, and compare that to a matched control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Pending review on 15/07/2020, NHS North East - Newcastle & North Tyneside 2 Research Ethics Committee (NHS BT Blood Donor Centre, Holland Drive, HRA Newcastle, UK, NE2 4NQ; newcastlenorthtyneside2.rec@hra.nhs.uk; +44 (0)207 104 8222). ref: 20/NE/0178

Study design
Single-centre interventional parallel group feasibility randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Type 1 diabetes and type 2 diabetes treated with exogenous insulin

Interventions
All participants will complete baseline blood and physical testing. Participants will then be randomised (1:1 ratio) to either:
1. Intervention group, a 4-week programme of supervised resistance exercise training
2. Control group, where participants will be instructed to carry on with any usual activity as normal

Randomisation will be carried out online by a member of the study team, using https://www.sealedenvelope.com

All participants will then repeat the physical testing. A subset will also be interviewed before and after the training programme to understand their perceptions of training, and living with diabetes (where relevant) as they have aged.

Intervention Type
Behavioural

Primary outcome measure
Feasibility of carrying out a larger trial, measured using recruitment and retention rate, and the acceptability of intervention of resistance exercise as assessed using an interview of a subset of participants at baseline and 5 weeks

Secondary outcome measures
1. Body composition measured using height, weight, waist circumference, percentage body fat, and percentage fat-free mass using bioelectrical impedance analysis at baseline and 5 weeks
2. Isometric strength measured using a torque and strain gauge at baseline and 5 weeks
3. Handgrip strength measured using a digital handgrip dynamometer at baseline and 5 weeks
4. Gait speed measured using three 4 m walking tests on digital timing gates at baseline and 5 weeks
5. Timed sit to stand, measured using five sit to stand movements at baseline and 5 weeks
6. Cardiovascular health measured using resting blood pressure, HbA1c, blood lipid profile, and inflammatory cytokines at baseline and 5 weeks
7. Wellbeing, activity levels, and (where applicable) views on the resistance training programme and diabetes management, measured narratively using a nested qualitative interview study at baseline and 5 weeks

Overall study start date
01/12/2019

Completion date
01/04/2025

Eligibility

Key inclusion criteria
1. Aged ≥60 years
2. Rockwood Clinical Frailty Score of 3 or 4
3. Diagnosis of type 1 or type 2 diabetes mellitus, or age and frailty matched non-diabetic control

Participant type(s)
Mixed

Age group
Adult

Lower age limit
60 Years

Sex

Both

Target number of participants
60

Key exclusion criteria
1. Myocardial infarction in the last 12 months
2. Stroke in the last 12 months
3. Renal failure in the last 12 months
4. Liver disease in the last 12 months
5. Inability to give consent

Date of first enrolment
01/10/2020

Date of final enrolment
31/01/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Newcastle upon Tyne Hospitals NHS Foundation Trust
Leazes Wing Main Entrance
Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
NE1 4LP

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

Sponsor details
Level 1, Regent Point
Regent Farm Road
Gosforth
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England

United Kingdom
NE3 3HD
+44 (0)1912824520
nuth.nuthsponsorship@nhs.net

Sponsor type
Hospital/treatment centre

Website
http://www.newcastle-hospitals.org.uk/

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
University/education

Funder Name
Faculty of Medical Sciences, Newcastle University

Alternative Name(s)
FMS

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
Wellcome Trust

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal and at scientific conferences

Intention to publish date
30/09/2026

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		08/12/2021	10/12/2021	Yes	No
HRA research summary			28/06/2023	No	No