ISRCTN16000053 https://doi.org/10.1186/ISRCTN16000053

The health impacts of seated arm ergometry training in diabetic foot ulcer patients

Submission date
16/09/2019

Recruitment status
No longer recruiting

Registration date
16/09/2019

Overall study status
Completed

Last Edited
14/10/2024

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
The main focus of this research concerns diabetic foot ulcers. The raised blood sugar levels of those with diabetes can cause nerve damage and loss of sensation in the feet. This allows 'painless' wounds to go unnoticed and get worse over time. Raised blood sugar levels can also lead to the narrowing of vessels and reduced blood flow to the feet. Loss of foot sensation and reduced blood flow can leave a person with diabetes vulnerable to developing patches of broken skin under the foot that are difficult to heal, known as diabetic foot ulcers. Doctors advise people with diabetic foot ulcers to stay off their feet as much as possible to help heal an ulcer. This often leads to high amounts of sitting time and reduced time spent being physically active which can further worsen their health over time. Keeping diabetic foot ulcer patients physically active while remaining off their feet is an area of research that is yet to be explored. The aim of this study is to investigate whether 12 weeks of seated upper-body exercise training using an arm ergometer (for a minimum of 30 minutes, three times per week) can improve fitness, health, quality of life, physical function, body composition and ulcer area in this population.

Who can participate?
Patients aged 18 to 75 who are receiving DFU treatment

What does the study involve?
Participants are randomly allocated to the intervention group or the control group. The intervention group undertake seated arm ergometry training where they exercise at a moderate intensity 3 times per week for 12 weeks. Meanwhile, participants allocated to the control group continue to receive standard care as usual without an arm ergometry exercise training intervention. The change in fitness before and after the intervention period will be compared between the two groups.

What are the possible benefits and risks of participating?
The assessment visits will provide participants with a unique insight into their health and fitness, something that would be expensive if done privately. Those allocated to the exercise intervention group will also have an exercise programme independently tailored to their needs by an exercise physiologist, something that would also be expensive if done privately. With any

exercise programme, there is a slight increased risk of a heart event or injury, but this risk will be minimised through a detailed assessment of heart rhythm and electrical activity by a cardiac nurse during the first assessment visit. Target heart rates set by the exercise physiologist before each exercise session will be aimed at a 'moderate' intensity, ensuring that 'overexertion' does not occur, limiting the risk of injury. A 5-minute warm-up and cool-down period will also be done before and after each exercise session to facilitate further risk reduction of injury.

Where is the study run from?
University Hospitals of Leicester NHS Trust (UK)

When is the study starting and how long is it expected to run for?
June 2019 to December 2024

Who is funding the study?
1. Diabetes UK
2. Novo Nordisk UK Research Foundation

Who is the main contact?
Dr Matthew McCarthy
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS: 42904

Study information

Scientific Title
The effects of seated exercise training on cardiorespiratory fitness in patients with diabetic foot ulcers: a randomised controlled trial

Acronym
The 'SIT and be FIT' study - Version 1.0

Study objectives
Keeping diabetic foot ulcer patients physically active while remaining off their feet is an area of research that is yet to be explored. The aim of this study is to investigate whether 12 weeks of seated upper-body exercise training using an arm ergometer (for a minimum of 30 minutes, three times per week) can improve cardio-respiratory fitness, cardio-metabolic health, quality of life, physical function, body composition and ulcer area in this population.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/08/2019, Yorkshire and the Humber – Leeds West (NHSBT Newcastle Blood Donor Centre, Holland Drive, HRA Newcastle, NE2 4NQ, UK; Tel: +44 (0)207 1048 088; Email: nrescommittee.yorkandhumber-leedswest@nhs.net), ref: 19/YH/0269

Study design
Randomised; Interventional; Design type: Treatment, Physical, Other

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Diabetic foot ulcer

Interventions
The study will recruit 60 patients with active diabetic foot ulceration. Individuals that register their interest in the study (providing they have read the participant information sheet) will be booked in for a baseline visit at the Leicester Diabetes Centre (LDC). Each baseline visit will take

approximately 3 hours. Participants will have the opportunity to ask any questions they may have about the study and informed consent will be obtained by a trained member of staff. The participant will be reassured that they can withdraw from the study at any time without giving any reason and that this will not affect their usual care.

All participants will be expected to arrive at their baseline visit under fasted conditions. Once informed consent is obtained from the participant, they will have a fasted blood sample taken by a phlebotomy trained nurse named on the delegation of authority log. Following this, anthropometric and demographic variables will be taken including: age, body weight, body fat percentage (measured using bio-electric impedance scales), height, waist circumference and arm circumference. Further analysis of regional muscle mass and bone density will then be further determined through a DEXA Scan.

Prior to the more physically demanding aspects of the baseline visit, participants will then be issued with a standardised meal consisting of a Bagel with Margarine and Complan protein powder mixed with whole milk (this is consistent with several studies conducted at the Leicester Diabetes Centre to date and has been well received by participants). Alternate meals will be provided for those with special dietary preferences.

While consuming the meal, participants will be issued with several basic questionnaires aimed at assessing their quality of life. Specifically, these will include the Cardiff Wound Impact Schedule questionnaire, the Short Form (36-item) Health Survey, the EQ5D -5L Questionnaire, the Depression and Anxiety HADS Questionnaire, and the Diabetes Distress Scale (DDS-17). The MRC Breathlessness Questionnaire and the UKDDQ Dietary Intake Questionnaire will also be populated. All the above questionnaires will be included in a single questionnaire booklet.

Once completed, participants will then move onto the physical function testing whereby there will be two tests observing upper body function and a performance battery undertaken to observe lower body function. These are detailed below:
1. Hand grip strength test - Participants will be asked to grip a digital hand held dynamometer as hard as possible three times on each side, with the elbow flexed at a right angle and the forearm in neutral position. The maximum of the readings generated is taken as the maximum grip strength.
2. Arm curl test - This test involves lifting a dumbbell (5lbs for women and 8lbs for men) as many times in 30 seconds as possible. This forms part of the 'Senior Fitness Test' performance battery and will be conducted on the dominant arm side. The subject sits on a chair, holding the dumbbell in their hand with palms facing towards the body and arm fully extended. With the upper arm braced against the body, participants will lift the lower arm gradually turning the palm up during the upward phase (flexion with supination). The arm should then be lowered back to the original position.
3. Short Physical Performance Battery (SPPB). SPPB consists of three parts: the balance test, the gait speed test and the chair stand test. This test is a widely used instrument for assessing lower extremity function. Balance testing requires participants to complete a) side-by-side stand, b) semi-tandem stand and c) tandem stand each lasting for
about 10 seconds. The second part assesses participant's gait speed by measuring their time taken to walk 4 meters at a normal pace. The third part of the assessment requires participants to rise from a steel chair with their arms across their chest five times. SPPB scores range from 0 to 12. Score 12 indicates the highest degree of physical
function while the lowest scores 0-3 indicates severe functional limitations. Importantly, if a participant is unable or uncomfortable with certain parts of the SPPB, this will be taken note of and will not be undertaken.

The final part of this baseline visit will consist of the maximal exercise test. Prior to this the cardiac nurse named on the delegation of authority log will undertake a full medical history check, a physical examination, a blood pressure check and will observe the resting electrical activity of the heart through Electrocardiography. Further to this, providing the cardiac nurse deems the participant as 'safe to exercise', each participant will undergo a maximal exercise test. During the maximal exercise test, all participants will pedal at 70 revs per minute on the arm ergometer (hand bike) device. Power requirements will then be increased as a linear ramp at a rate of 6W/min for females and 10w/min for males. All participants will receive encouragement to continue with this progressive exercise for as long as possible subject to the satisfaction of the cardiac nurse that the patient is fit to continue. Throughout the test, participants will be expected to continuously breathe into a mask that will allow the research team to determine peak oxygen consumption (VO2 peak), which is our primary outcome measure. ECG derived heart activity will also be closely monitored by the cardiac nurse throughout this test for safety purposes.

This marks the end of the baseline visit and all participants will be sent away with a wrist-based physical activity monitor that they will be expected to wear for 7 consecutive days to quantify their habitual physical activity levels. This will be provided alongside a sleep log to document: a) the time you woke up, b) the time you got out of bed, c) the time you got into bed, d) the time you fell asleep, all of which will assist with data interpretation.

On completion of this baseline visit, participants will be randomised to one of two groups. 1) Standard care control group (who will continue to receive standard care as normal and will simply attend the baseline and follow-up visits only) 2) Exercise intervention group.

Participants allocated to the 'Exercise intervention' group will be supported in completing up to 30 - 50 mins of seated exercise 3 times per week at a moderate intensity (between 65-75% of peak heart rate) for 12 weeks. This will be achieved through using arm ergometers (hand bikes) set up in the Leicester Diabetes Centre’s gym facility and in the participants home environment (36 sessions in total). All exercise sessions prescribed will be specific to the individual’s ability and progressions made accordingly by exercise physiologists. Participants are required to wear a Heart Rate monitor throughout all exercise sessions, this will allow the exercise physiologist to prescribe a speed
and/or resistance of arm ergometry to a level that elicits a heart rate response within the set targets. Exercise prescriptions will be progressive in nature, with resistance and duration increasing as participant’s fitness increases. Where feasible, the duration will progress up to 150 mins/week (50mins exercise per session) in line with physical activity guidelines. A five-minute warm-up and cool-down period will also be incorporated.

Further to the completion of the 12-week exercise regime (or simply 12 weeks further to the baseline visit for those in the standard care control group). Participants will be invited to the Leicester Diabetes Centre for their final follow-up visit. During the follow-up visit, the exact same measurements will be taken as per the baseline visit for direct pre-post comparison. Hence, the baseline and follow-up visits will mimic one another.

It is also worth noting that ulcer area (another secondary outcome) will be determined by clinicians/nurses during the patients' routine foot care appointments at the Leicester Diabetes Centre's foot clinic, this measurement will not be undertaken during study visits. Efforts will be made to make sure routine foot appointments coincide as closely as possible to the baseline and follow-up visits.

Intervention Type

Behavioural

Primary outcome measure
Cardio-respiratory fitness measured via a maximal incremental exercise test and quantified by the maximal amount of oxygen consumed and utilised (VO2 peak) pre and post the 12-week intervention (baseline and follow-up)

Secondary outcome measures
1. Cardio-metabolic health assessed by a venous blood sample analysed for HbA1c, glucose, insulin and blood lipids (total cholesterol, high-density lipoprotein cholesterol, non-esterified fatty acids and triglycerides). These will be taken from venous blood while under fasting conditions both pre and post the 12-week intervention (baseline and follow-up). Also measured at these two timepoints will be blood pressure.
2. Quality of life assessed through a number of health-related quality of life questionnaires (Cardiff Wound Impact Schedule, The 36-Item Short Form Health Survey questionnaire, The EQ5D-5L instrument, The Hospital Anxiety and Depression scale and The Diabetes Distress Scale -17) pre and post the 12-week intervention period
3. Physical function assessed pre and post the 12 week intervention period:
3.1. Lower body physical function assessed by the Short Physical Performance Battery (SPPB) which assesses balance, walking speed and ability to sit and stand to and from a chair. Handgrip strength will be determined using digital handheld dynamometer
3.2. Upper body strength assessed via a 30-second arm curl test. This test involves lifting a dumbbell (5 lbs for women and 8 lbs for men) as many times in 30 seconds as possible and forms part of the 'Senior Fitness Test' performance battery
3.3. The effect of breathlessness on daily activities, assessed using the MRC breathlessness scale
4. Body composition assessed with dual-energy X-ray absorptiometry (DEXA) scanning which will derive a breakdown of; body fat, muscle mass and bone density. Bodyweight, height, waist circumference and arm circumference will be also measured pre and post the 12-week intervention period (baseline and follow-up)
5. Cross-sectional area of the foot ulcer determined by an acetate grid tracing method undertaken both pre and post the 12-week intervention period (baseline and follow-up)

Overall study start date
24/06/2019

Completion date
01/12/2024

Eligibility

Key inclusion criteria
Current inclusion criteria as of 03/05/2023:
1. Actively receiving or has received DFU treatment within the previous 12 months
2. Aged > = 18 years of age
3. Able to undertake upper body arm exercise (specifically arm ergometry)
4. Deemed safe to exercise further to cardiac nurse evaluation at baseline
5. Participant is willing to give informed consent to take part in the study

Previous inclusion criteria:
1. Actively receiving DFU treatment
2. > = 18 to < = 75 years of age

3. Able to undertake upper body arm exercise (specifically arm ergometry)
4. Deemed safe to exercise further to cardiac nurse evaluation at baseline
5. Participant is willing to give informed consent to take part in the study

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. Uncontrolled hyperglycaemia (HbA1c > 10% - Confirmed through baseline blood sample results)
2. Report taking part in regular (at least once a week) strenuous sport or activities
3. Under weight or with a Body Mass Index of < = 18.5 kg/m2
4. Existing heart problem (a cardiovascular event within the last 12 months or screened by cardiac nurse at baseline)
5. Co-morbidity that the research team consider to be a contraindication to their study involvement
6. Unable to communicate in written or verbal English
7. Unable to provide written informed consent

* In the circumstance that an individual is not sure whether they meet the necessary criteria, they will be reviewed by a medic (named on the delegation log) for a clinical decision to be made during their baseline visit (prior to engaging in any study-related tasks)

Date of first enrolment
01/11/2019

Date of final enrolment
01/11/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

University Hospitals of Leicester NHS Trust
Leicester Royal Infirmary
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Sponsor information

Organisation
University of Leicester

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Sponsor type
University/education

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Charity

Funder Name
Diabetes UK; Grant Codes: 18/0005883,

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
Novo Nordisk UK Research Foundation; Grant Codes: RM65G0161

Alternative Name(s)
The Novo Nordisk UK Research Foundation, ovo Nordisk Research Foundation UK, NNUKRF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
A protocol paper (detailing all aspects of the protocol, including the statistical analyses) will be submitted for publication as soon as possible. The researchers aim to publish the findings from this investigation within a year of the overall trial end date. The results of this trial will be published in peer-reviewed journals and through educational and conference presentations.

Intention to publish date
01/02/2025

Individual participant data (IPD) sharing plan
Primary results and datasets will be available from the corresponding author Dr Matthew McCarthy (mm636@le.ac.uk) on reasonable request and results will be reported on group-level only so that individual participant anonymity is maintained.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	21/06/2020	16/02/2021	Yes	No
HRA research summary			28/06/2023	No	No