

Talking to change in diabetes foot ulceration

Submission date 27/02/2024	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/02/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 11/06/2025	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Foot ulcers are wounds occurring below the ankle and can lead to serious complications including amputation and death and they occur in somewhere between 19-34% of people with diabetes. This common, devastating complication of diabetes is even more common in people exposed to higher levels of multiple deprivation. We found that individuals with diabetes living in the most deprived part of NHS Greater Glasgow and Clyde were four to five times more likely to experience a foot ulcer, amputation or death than those living in the least deprived areas. Current treatment approaches are not effective. Motivational interviewing is a special talking therapy that helps people improve their habits and behaviours that might improve their foot health. This study aims to see if using our talking therapy (Talking to Change), along with usual care, is better than just usual care for preventing diabetic foot ulcers.

Who can participate?

People with diabetes, a history of foot ulceration and residing in an area with a postcode in SIMD quintiles 1 or 2.

What does the study involve?

It involves attending for 3 research appointments (at the start, then 6 and 12 months later) where we will collect information about your diabetes, your feet, your health, fill in some short questionnaires and we will collect 2 small blood samples (to measure your blood sugar and how well your kidneys are working). You will then be randomly selected (using a computer) to receive either standard care, or our new talking therapy in addition to standard care. If you receive the talking therapy, you will attend for 2-3 additional appointments with a podiatrist.

What are the possible benefits and risks of taking part?

The possible benefits of taking part are that if you are randomised to the 'Talking to Change' group you might feel empowered to making healthier choices and notice improvements in your health/foot health. The risks of taking part are that completing the questionnaires and discussing any difficulties may be upsetting - you will be able to stop at any time.

Where is the study run from?

Glasgow Caledonian University (UK)

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

January 2024 to June 2026

Who is funding the study?

The Chief Scientist Office, Health Improvement, Protection and Services Research Committee (UK)

Who is the main contact?

Dr Ruth Barn, ruth.barn@gcu.ac.uk

Study website

<https://www.miditrial.com/>

Contact information

Type(s)

Public, Scientific, Principal Investigator

Contact name

Dr Ruth Barn

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

335427

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

HIPS/23/06, IRAS 335427

Study information

Scientific Title

Motivational interviewing for the prevention of diabetes related foot ulceration in people exposed to multiple deprivation: a pilot trial

Acronym

MIDI

Study objectives

Overall aim: to pilot test the proposed trial components and address uncertainties associated with conducting a future full-scale definitive randomised controlled trial of motivational interviewing for the prevention of diabetes related foot ulceration in people exposed to multiple deprivation.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 20/05/2024, West of Scotland REC 5 (West of Scotland Research Ethics Service, Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, United Kingdom; +44 (0)141 314 0213 ; WoSREC5@ggc.scot.nhs.uk), ref: 24/WS/0044

Study design

Multi-centre randomized pilot trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice, Hospital, Medical and other records, Other therapist office, Other

Study type(s)

Other

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

People with diabetes in areas exposed to multiple deprivation (SIMD 1 and 2).

Interventions

The intervention in this pilot study is motivational interviewing and is described as a collection of techniques defined as a collaborative, person centred form of guiding to elicit and strengthen motivation for change. Motivational interviewing originated as a counselling approach encompassing a broad collection of techniques to support people to explore and resolve ambivalence about behavioural change. It will be delivered individually, face to face over a series of 2-3 sessions with the same podiatrist trained in the technique. Participants will be randomised

to either MI + usual care or usual care at a 2:1 ratio. Randomisation will be conducted using a telephone randomisation service after completion of baseline measurements. Minimisation techniques will be applied to control for the following variables: health board region; deprivation quintile; sex. Usual care will be provided to both groups on an individual basis as required, typical usual podiatry care interventions for this group includes, but is not limited to: offloading insoles, foot health advice and pressure lesion reduction.

Intervention Type

Behavioural

Primary outcome measure

1. Foot ulceration event measured using patient records at 6 and 12 months
2. Foot ulceration event rate feasibility in terms of data completeness at 6 and 12 months

Secondary outcome measures

Patient reported outcome measures recorded at baseline, 6 and 12 months follow up except GROC collected only at 6 and 12 months:

1. Quality of life (EQ-5D-5L)
2. Diabetes related stress (PAID-5)
3. Depression (PHQ9)
4. Resource use questionnaire (RUQ)
5. Adapted global rating of change score (GROC)
6. Bloods for HbA1c and eGFR

Overall study start date

08/01/2024

Completion date

30/06/2026

Eligibility

Key inclusion criteria

1. Adults ≥ 18 years with diabetes
2. History of diabetes foot ulceration
3. Exposure to the greatest level of multiple deprivation based on most recent postcode categorised as SIMD quintiles 1 and 2.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

80 Years

Sex

Both

Target number of participants

60

Key exclusion criteria

1. Diagnosed psychosis, learning disability impacting on cognitive ability or any other reason why a conversation based intervention would not be appropriate
2. People who require a translator due to the loss of the relational aspects of motivational interviewing

Date of first enrolment

25/11/2024

Date of final enrolment

30/11/2025

Locations**Countries of recruitment**

Scotland

United Kingdom

Study participating centre**NHS Lanarkshire**

14 Beckford Street

Hamilton

United Kingdom

ML3 0TA

Study participating centre**NHS Greater Glasgow and Clyde**

J B Russell House

Gartnavel Royal Hospital

1055 Great Western Road Glasgow

Glasgow

United Kingdom

G12 0XH

Study participating centre**NHS Ayrshire and Arran**

PO Box 13, Boswell House

10 Arthur Street

Ayr
United Kingdom
KA7 1QJ

Study participating centre

NHS Tayside

Kings Croos
Cleington Road
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United Kingdom
DD3 8EA

Sponsor information

Organisation

Glasgow Caledonian University

Sponsor details

Glasgow Caledonian University
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Sponsor type

University/education

Website

<http://www.gcu.ac.uk/>

ROR

<https://ror.org/03dvm1235>

Funder(s)

Funder type

Government

Funder Name

Chief Scientist Office

Alternative Name(s)

CSO

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Planned publications in high impact journals alongside conference presentations to podiatry and diabetes professional groups.

Intention to publish date

01/04/2027

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

Data sharing statement to be made available at a later date