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Talking to change in diabetes foot ulceration

Submission date	Recruitment status	[X] Prospectively registered
27/02/2024	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/02/2024	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
11/06/2026	Nutritional, Metabolic, Endocrine	[X] 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 November 2026

Who is funding the study?
The Chief Scientist Office, Health Improvement, Protection and Services Research Committee (UK)

Who is the main contact?
Dr Gordon Hendry, gordon.hendry@gcu.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
335427

Protocol serial number
HIPS/23/06

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

Primary study design
Interventional

Study design
Multi-centre randomized pilot trial

Study type(s)
Other

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(s)
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

Key secondary outcome(s)
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

Completion date
30/11/2026

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

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
80 Years

Sex
All

Total final enrolment
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
29/01/2026

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
NHS Lanarkshire
14 Beckford Street
Hamilton
Scotland
ML3 0TA

Study participating centre
NHS Fife
Hayfield House
Hayfield Road
Kirkcaldy
Scotland
KY2 5AH

Study participating centre
NHS Ayrshire and Arran
PO Box 13, Boswell House
10 Arthur Street
Ayr
Scotland
KA7 1QJ

Study participating centre
NHS Tayside
Kings Croos
Clepington Road
Dundee
Scotland
DD3 8EA

Sponsor information

Organisation

Glasgow Caledonian University

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes