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REDUCE Trial: Reducing the impact of diabetic foot ulcers (DFUs)

Submission date
21/04/2022

Recruitment status
No longer recruiting

Registration date
12/05/2022

Overall study status
Completed

Last Edited
14/04/2026

Condition category
Nutritional, Metabolic, Endocrine

[_] 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
Diabetic foot ulcers (DFUs) are poorly healing wounds below the ankle affecting 25% of people with diabetes. Less than half of people will be ulcer-free after 6 months of treatment, and the same number will experience another ulcer within a year.
Current treatments to prevent and heal ulcers do not work well. People's thoughts, feelings and behaviours can affect the risk of getting DFUs and how they heal. We have developed a new way of helping people with diabetes who have had a foot ulcer previously, called 'REDUCE'. The package includes 8 one hour sessions with a healthcare
professional (HCP), such as a diabetes nurse, and support through a website. The REDUCE training programme and trial procedures have been refined following the pilot.

Aims: To investigate the effectiveness and cost-effectiveness of the REDUCE intervention compared with patients who receive usual care following their healed diabetic foot ulcers.

Who can participate?
Adults over 18 years, with diabetes and a recently healed diabetic foot ulcer.

What does the study involve?
Half of the participants will be randomly allocated to receive the REDUCE package and half to receive their usual care. Patients will be identified by their clinical care team or screening of clinic lists.
All participants will complete a questionnaire at the start of the study, 6 weeks, 3, 6 and 18 months. 20 REDUCE package participants will be interviewed at the start, 3 and 6 months later. HCPs will be interviewed during the study/after they have delivered all their REDUCE sessions; sessions will be recorded to check how closely they are following the delivery of the REDUCE programme. A participant's use of NHS resources during their time in the study (e.g. new admissions to hospital, new foot ulcers) will be collected.

What are the possible benefits and risks of participating?
We cannot promise that taking part in this study will help participants directly. However, by taking part, they can help find out whether REDUCE works and potentially the care that people like themself receive in the future. We are not anticipating the interview will cause them any

distress, but if it does they can ask the researchers to stop the interview at any time. There are no anticipated risks in taking part in this study. The study will require some of their time to undertake the tasks, but we have tried to ensure these are not burdensome. We do not anticipate the questionnaires or the REDUCE intervention and interviews (for those allocated to receive them) will cause participants any distress. For each completed questionnaire participants will receive a £5 shopping voucher and a further £5 voucher for completing all 5 questionnaires.

Where is the study run from?
University Hospitals of Derby and Burton NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
May 2018 to March 2026

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
Dr Natasha Mitchell, natasha.mitchell@york.ac.uk
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Contact information

Type(s)
Scientific

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Additional identifiers

Central Portfolio Management System (CPMS)
52184

Integrated Research Application System (IRAS)
274384

Protocol serial number
RP-PG-0618-20001

Study information

Scientific Title
Reducing the impact of diabetic foot ulcers (REDUCE): A effectiveness and cost-effectiveness randomised controlled trial

Acronym
REDUCE RCT

Study objectives
Participants who receive the REDUCE Intervention will have a greater number of ulcer free days compared to those who did not receive the REDUCE Intervention

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/04/2022, Wales REC 3 (Health and Care Research Wales Support and Delivery Centre, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, UK; +44 2920 230457; Wales.REC3@wales.nhs.uk), ref: 22/WA/0053

Study design
Multi-centre randomised controlled trial with a process evaluation study and health economic evaluation

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions

Participants will be patients diagnosed with diabetes with a recently healed diabetic foot ulcer and also Health Care Professionals (HCPs). We will recruit 544 patients aged over 18 with a recently healed diabetic foot ulcer and 15 HCPs for the trial.
The trial has been designed to last 58 months, each participant is in the trial for 18 months following randomisation.

After obtaining consent and following the completion of all baseline data collection, trial participants will be randomised 1:1 to the intervention and control arms
• REDUCE Intervention: REDUCE Intervention plus usual care (intervention arm)
Eight weeks of one hour one-to-one sessions with a healthcare professional trained to deliver the REDUCE intervention. Participants will also be able to access the web or booklet-based maintenance intervention. During the intervention period participants will continue to receive usual standard care.
• Usual care alone (control arm): Participants will receive usual standard care.
Participants randomised to the intervention group will have their details passed to the REDUCE intervention delivery team to arrange the intervention sessions. At this time participants will be sent a copy of the handbook and their website log-in details.

Follow-up: All participants will be sent a follow up questionnaire by post or email link (for online completion) for them to complete; postal questionnaires will include a freepost envelope for its return. Follow up questionnaires will include all the same psychological and behavioural measures that were completed at baseline. Follow up will be at 6 weeks, 3, 6 and 18 months post randomisation. Health economic data will be collected from all participants at baseline, 6 and 18 months post randomisation, they will be incorporated into the main follow up questionnaires for participants.
Clinical outcome follow-up: Blinded outcome assessors will review relevant health care records, to include but not limited to, secondary care, GP, community health, community podiatry and private podiatry records to capture clinical outcomes and resource use for all participants at six, 12 and 18 months post randomisation.

Recruitment & eligibility (Healthcare Professionals Participants): Healthcare Professionals who are responsible for the delivery of the intervention will be recruited into the study as participants. The purpose of their inclusion is to gather data on the intervention training, intervention delivery and their experiences of this. Eligible Healthcare Professional will be provided with an information sheet together with a consent form and contact details form about taking part in the REDUCE study. During the delivery of the intervention sessions the Healthcare Professional responsible for the intervention delivery will also collect intervention session data on each intervention participant.

Qualitative study (Participants): A sub-sample of approximately 20 participants who are randomised to the REDUCE intervention arm will be invited to take part in the interviews. Where possible, individuals will be interviewed at baseline and approximately three months and six months later. However, some individuals may be offered a one-off interview at the 6-month time point only; for example, if an individual is recruited to replace a participant who withdraws from the longitudinal interviews. The interviews will examine: participants' expectations of the REDUCE programme and their illness perceptions and self-management practices pre-trial; participants' engagement with the different elements of REDUCE Intervention (initiation and maintenance phases) and whether, how, and, why, this engagement leads psychological and behavioural changes; and, barriers/facilitators to maintenance of key self-management behaviours over time. These interviews will be undertaken by an experienced qualitative

researcher at the University of Edinburgh, by telephone or virtually at a time convenient to participants. They are expected to last around 45-60 minutes and will be digitally audio recorded using an encrypted device and transcribed.

Qualitative study (Healthcare Professional Participants): All healthcare professionals involved in intervention delivery will be given the opportunity to take part in an interview in the later stages of the REDUCE trial (by which stage they should have a substantial body of experience upon which they can draw). However, some interviews may take place earlier – if, for example, a healthcare professional leaves their post early. The interviews will explore healthcare professionals' experiences of delivering the 1-to-1 sessions (including any difficulties and challenges encountered), their views about which patients benefit most/least from receiving REDUCE, and why, and their views about the resourcing and support colleagues would need to deliver the REDUCE programme in routine clinical care. These interviews will be undertaken by an experienced qualitative researcher at the University of Edinburgh, by telephone or virtually at a time convenient to health professionals. They are expected to last around 45-60 minutes each and will be audio recorded using an encrypted digital device, and then transcribed.

Intervention Type
Behavioural

Primary outcome(s)
Total ulcer free time with limbs intact over 18 months as measured in days using patient records

Key secondary outcome(s))
1. Clinical outcomes (these will be collected from clinical notes over the 18-month follow-up):
1.1. Whether the patient remained ulcer-free
1.2. Time to re-ulceration (measured in days)
1.3. Total number of ulcers
1.4. Proportion of patients deceased
1.5. Time to death
1.6. Whether patient had major amputation
1.7. Time to major amputation operation
1.8. Whether patient had minor amputation operation
1.9. Time to minor amputation
1.10. Days in hospital related to foot ulcer disease
1.11. Days in hospital not related to foot ulcer disease
2. Psychological/behavioural risk factors targeted in REDUCE to examine mechanisms at Baseline, 6 weeks, 3 months, 6 months & 18 months post-randomisation.
2.1. Brief Illness Perception Questionnaire (B-IPQ): Examines the participant's perception of their illness
2.2. Cognitive and Behavioural Responses Questionnaire (CBRQ) – short version: Examines participant's beliefs about their symptoms
2.3. Patient Health Questionnaire-9 (PHQ-9): Assesses depression
2.4. International Physical Activity Questionnaire - Elderly (IPAQ-E) – short form: Assesses participant physical activity
2.5. Nottingham Assessment of Functional Footcare (NAFF): Examines foot self-care behaviours
2.6. Scale of Positive And Negative Experience (SPANE-P) - positive items only: Examines positive feelings
2.7. Social Provisions Scale (SPS): Examines social relationships and support
3. Economic outcomes to examine cost-effectiveness at Baseline, 6 months and 18 months post-randomisation.

3.1. ICEpop CAPability measure for Adults (ICECAP-A): Measures capability in adults including attachment, stability, achievement, enjoyment and autonomy
3.2. EQ5D-5L consisting of the EQ5D descriptive system and the EQ Visual Analogue Scale (EQ VAS): Measures mobility, self-care, usual activities, pain/discomfort and anxiety/depression

Completion date
27/03/2026

Eligibility

Key inclusion criteria
1. Has diabetes [according to World Health Organization (WHO) criteria].
2. Is aged 18 years or over.
3. Has two lower limbs (i.e. has not had major amputation of either lower limb).
4. Has a recently healed diabetic foot ulcer (if more than one, all must be healed), defined as fully epithelialised with no drainage, for a minimum two weeks.
5. Has the cognitive capacity to provide informed consent, to engage with the study intervention (as digital and written handbook versions), to take part in interviews (if randomised to the intervention and selected as part of a sub-sample), and to provide follow-up data
6. Has sufficient command of English language and is able to engage with the intervention and to provide follow-up data.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
110 years

Sex
All

Total final enrolment
559

Key exclusion criteria
1. Has active Charcot Neuro-osteoarthropathy.
2. Presence of active diabetic foot ulceration.
3. In the acute phase of a diagnosed mental illness where being approached about participation could be an extra burden (e.g. currently under the care of MH crisis team or admitted to hospital at the time of recruitment).
4. Has previously been randomised to the REDUCE pilot trial.

5. Has previously been randomised to this REDUCE trial.
6. Is currently taking part in another study which would affect the outcomes of this study (e.g. diabetic foot ulcer wound healing medicinal product trial or other behavioural intervention study).

Date of first enrolment
01/05/2022

Date of final enrolment
27/09/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Derby Hospital
Uttoxeter Road
Derby
England
DE22 3NE

Study participating centre
Norfolk & Norwich University Hospital
Colney Lane
Colney
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NR4 7UY

Sponsor information

Organisation
University Hospitals of Derby and Burton NHS Foundation Trust

ROR
https://ror.org/04w8sxm43

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

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
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol file	version 1.0	17/02/2022	07/07/2022	No	No
Protocol file	version 3.3	13/08/2024	11/03/2026	No	No