ISRCTN15460422 https://doi.org/10.1186/ISRCTN15460422

Reducing the impact of diabetic foot ulcers on patients and the NHS

Submission date
12/05/2021

Recruitment status
No longer recruiting

Registration date
19/05/2021

Overall study status
Completed

Last Edited
13/03/2023

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
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. Researchers have developed a new way of helping people with diabetes who have had a foot ulcer previously, called 'REDUCE'. The package includes eight 1-hour sessions with a healthcare professional (HCP), such as a diabetes nurse, and support through a new website. The aim of this study is to explore if the REDUCE training programme or trial procedures need amending before conducting the main trial.

Who can participate?
Patients aged over 18 who have recently healed from their diabetic foot ulcer

What does the study involve?
Participants are randomly allocated to the intervention group or the control group. Participants who are allocated to the intervention will take part in eight REDUCE intervention sessions. Participants in the control group will receive the usual standard care. All participants will be asked to complete questionnaires at the start of the study and after 6 and 12 weeks. Those who have been allocated to the intervention group will also be asked to take part in interviews at the start of the study and after 12 weeks.

What are the possible benefits and risks of participating?
The researchers cannot promise that taking part in this study will help participants directly. However, by taking part, they can help improve the REDUCE package and potentially the care that people receive in the future. The researchers 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. The researchers do not anticipate the questionnaires or the REDUCE package and interviews (for those allocated to receive them) will cause participants any distress.

Where is the study run from?
York Trials Unit, University of York & University of Nottingham (UK)

When is the study starting and how long is it expected to run for?
May 2018 to January 2022

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

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
274356

Central Portfolio Management System (CPMS)
48920

Study information

Scientific Title
Reducing the impact of diabetic foot ulcers: a pilot trial

Study objectives
Aim: To explore if the REDUCE training programme or trial procedures need amending before conducting the main trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/04/2021, Wales REC (3 Health and Care Research Support Centre, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, UK; +44 (0)29 2078 5735; Wales.REC3@wales.nhs.uk), REC ref: 21/WA/0110

Study design
Randomized; Both; Design type: Treatment, Prevention, Process of Care, Education or Self-Management, Psychological & Behavioural, Complex Intervention, Validation of outcome measures

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Diabetes

Interventions
This study is a mixed-methods external randomised controlled trial, collecting quantitative and qualitative data. Recruitment will be carried out from two clinical sites. Participants will be patients diagnosed with diabetes with a recently healed diabetic foot ulcer and also Health Care Professionals (HCPs). The design of this pilot will mirror the main features of the effectiveness trial. Thus, it also provides an opportunity to examine recruitment and retention rates and inform estimates regarding the number of recruiting centres and recruitment period required for the effectiveness trial. We will also examine the viability of primary and secondary outcome

data collection. The researchers will recruit 20 patients aged over 18 with a recently healed diabetic foot ulcer. The trial has
been designed to last 12 months.

Recruitment & eligibility (participants):
Potential participants will be identified and screened by their clinical care team in specialist multidisciplinary diabetes foot clinics at the participating NHS Trusts. Clinical caseloads will be screened against the eligibility criteria at these sites. The researchers hope to recruit 20 eligible patients over a 3 month recruitment period at two participating sites. This would mean a recruitment yield of approximately four participants per site per month, this is comparable to the yield we would require for the main trial. Due to the nature of the intervention blinding of participants and clinicians will not be possible and a procedure for un-blinding is not necessary. However, outcome assessors will be blinded to group allocation. Outcome assessors will be responsible for collecting the outcome data
at 4 months post-randomisation from primary, secondary and community care records. Outcome assessors will not be delivering the intervention, or involved in the participant's usual care. Should the participant inadvertently reveal their allocation to an outcome assessor, or the assessor become un-blinded for any reason, that assessor will no longer continue to assess outcomes for that participant and this will be recorded. Eligible patients will be approached about
the trial by their usual clinical carers and given an information sheet. Participants will be provided with information regarding the trial as soon as possible after healing of all their foot ulcers, but will only be recruited and consented after the ulcer has remained healed for a period of at least 2 weeks.

Patients identified as eligible, interested and willing will have their written informed consent obtained by a suitably qualified and experienced local research nurse, healthcare professional or practitioner according to GCP guidelines. Consenting patients will then have their baseline data collected. This includes clinician recorded data comprising of previous medical history (duration (years) and type of diabetes), most recent HbA1c value, depression, documented peripheral neuropathy, documented peripheral arterial disease (PAD), visual impairment, other relevant conditions, diabetic foot ulcer history (single versus multiple ulcers, most recent episode confirmed healing date, footwear), height, weight and NHS number.

Participant demographics will be collected at baseline (date of birth, sex, ethnicity, marital status, smoking status, highest educational attainment, exposure to COVID-19, income, employment) and they will be asked to complete a range of psychological and behavioural questionnaires and also questions on resource use.
Allocation and Study arms: After obtaining consent and following the completion of all baseline data collection, trial participants will be randomised 2:1 to the intervention to maximize the number of participants receiving REDUCE.

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-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, their website log-in details, two copies of the 'home practice questionnaires' with freepost envelopes and a covering letter with details of when the questionnaires need to be completed and returned (after their week 2 and week 8 sessions).

Follow-up:
All participants will be sent a follow-up questionnaire by post for them to complete and return using a freepost envelope which is provided. Follow up questionnaires will include all the same psychological and behavioural measures that were completed at baseline. Follow up will be at 6 weeks and 12 weeks post
randomisation. For intervention participants they will also be asked to complete home practice questionnaires after their week 2 and week 8 sessions, again freepost envelopes will be provided for the return of these questionnaires.

Four months post-randomisation (16 weeks) blinded outcome assessors will review clinical notes from primary, secondary and community care records to capture clinical outcomes and resource use for all participants. Data captured will include:
1. Ulcer-free days
2. Days to re-ulceration (if re-ulceration occurs)
3. Number of ulcers
4. Days in hospital
5. AEs
6. SAEs
7. Amputations – major and minor
8. Mortality

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 so that adjustments could be made to the intervention programme or to the trial design.

Eligible healthcare professionals 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, data collected includes:
1. Session number
2. Date
3. Attendance
4. Session delivered by
5. Length of session
6. Interventions/modalities delivered
7. Completion of home practice

Qualitative study (participants):
All participants in the intervention arm will be invited to be interviewed at baseline and approximately four months later in order to examine: their understanding and expectations of the intervention and recruitment experience; their likes/dislikes of the initiation and maintenance components of REDUCE; reasons for engagement and non-engagement with these components; and their views about how REDUCE might be further refined to optimize uptake

and engagement. 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 invited to be interviewed after the 'Initiation' phase of the intervention has been delivered to all participants at their site. These interviews will examine their views about: a) the intervention and b) their training, including any improvements which could be made. 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 and will be digitally audio recorded using an encrypted device and transcribed.

Intervention fidelity tool:
It is the aim that all intervention sessions will be audio-recorded, this will be discussed at consent with both intervention participants and Healthcare Professionals; consent will be checked verbally at the beginning of each session. To ensure the sensitivity of the fidelity tool an assessment of the fidelity tool will be conducted at the individual level and will focus on randomly selected sessions, whilst ensuring that all eight treatment sessions are covered to ensure all components of the treatment, and all items of the scale, are examined. The selected sessions will be rated using the fidelity tool by two skilled observers.

Intervention Type
Behavioural

Primary outcome(s)
1. Participant's perception of their illness measured using the Brief Illness Perception Questionnaire (B-IPQ) at baseline, 6 weeks and 12 weeks
2. Participant's beliefs about their symptoms measured using the Cognitive and Behavioural Responses Questionnaire (CBRQ) – short version at baseline, 6 weeks and 12 weeks
3. Anxiety assessed using the Generalised Anxiety Questionnaire (GAD-7) at baseline, 6 weeks and 12 weeks
4. Depression assessed using the Patient Health Questionnaire-9 (PHQ-9) at baseline, 6 weeks and 12 weeks
5. Participant physical activity assessed using the International Physical Activity Questionnaire - Elderly (IPAQ-E) – short form at baseline, 6 weeks and 12 weeks
6. Emotional, psychological and social well-being assessed using the Mental Health Continuum Short Form (MHC-SF) at baseline, 6 weeks and 12 weeks
7. Foot self-care behaviours assessed using the Nottingham Assessment of Functional Footcare (NAFF) at baseline, 6 weeks and 12 weeks
8. Positive feelings assessed using the Scale of Positive And Negative Experience (SPANE-P) - positive items only: Examines at Baseline, 6 weeks and 12 weeks
9. Social relationships and support assessed using the Social Provisions Scale (SPS) at baseline, 6 weeks and 12 weeks.
10. Capability including attachment, stability, achievement, enjoyment and autonomy measured using the ICEpop CAPability measure for Adults (ICECAP-A) at baseline and 12 weeks
11. Mobility, self-care, usual activities, pain/discomfort and anxiety/depression measured using the EQ5D-5L consisting of the EQ5D descriptive system and the EQ Visual Analogue Scale (EQ VAS) at baseline and 12 weeks
12. Ulcer-free days collected from patient records at 4 months post randomisation

13. Days to re-ulceration (if re-ulceration occurs) collected from patient records at 4 months post randomisation
14. Number of ulcers collected from patient records at 4 months post randomisation
15. Days in hospital collected from patient records at 4 months post randomisation
16. Adverse events (AEs) collected from patient records at 4 months post randomisation
17. Serious adverse events (SAEs) collected from patient records at 4 months post randomisation
18. Amputations (major and minor) collected from patient records at 4 months post randomisation
19. Mortality collected from patient records at 4 months post randomisation
20. Resource use data collected from patient records at 4 months post randomisation

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
07/01/2022

Eligibility

Key inclusion criteria
1. Has diabetes (according to World Health Organization [WHO] criteria)
2. 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 of 2 weeks
5. Has the cognitive capacity to provide informed consent, to engage with the study intervention (both as digital and written handbook versions), to take part in interviews (if randomised to the intervention), and to provide follow-up data
6. Has sufficient command of English language to engage with the intervention and to provide follow-up data

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
20

Key exclusion criteria

1. Has active Charcot Neuro-osteoarthropathy
2. Presence of active diabetic foot ulceration
3. Diagnosis of a current severe mental illness which could hinder engagement with the trial and /or intervention (e.g., psychosis)
4. Has previously been randomised to this pilot trial
5. 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
24/05/2021

Date of final enrolment
03/09/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Derby Hospital
University Hospitals of Derby and Burton NHS Foundation Trust
Uttoxeter Road
Derby
United Kingdom
DE22 3NE

Study participating centre
Norfolk and Norwich University Hospital
Norfolk and Norwich University Hospitals NHS Foundation Trust
Colney Lane
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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); Grant Codes: RP-PG-0618-20001

Results and Publications

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol file	version 1.1	25/05/2021	13/03/2023	No	No