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Development of a Cognitive-Behavioural Intervention

Submission date	Recruitment status	[_] Prospectively registered
18/06/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/06/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
29/08/2013	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Angela Beattie

Contact details
Department of Social Medicine
Canynge Hall
Whiteladies Road
Bristol
United Kingdom
BS8 2PR
Angela.Beattie@bristol.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
6299

Study information

Scientific Title
Development of a cognitive-behavioural intervention to reduce the risk of foot re-ulceration in patients with diabetes

Acronym
DRN 279

Study objectives
This is a phase 1 and 2 feasibility study which aims to develop a psychological intervention for people with diabetes. The aim is to delay or prevent the onset of further diabetic foot ulcers recurring. Phase 1 involves a qualitative design incorporating 15 interviews and one patient focus group. Phase 2 involves the exploratory trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Frenchay Research Ethics Committee approved on the 19th December 2007 (ref: 07/HO107/62)

Study design
Single centre randomised interventional prevention and process of care trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Topic: Diabetes Research Network; Diabetic Foot Ulcer Subtopic: Both; Disease: Diabetic Control

Interventions
To deliver a psychological intervention which seeks to modify coping and manage emotional distress in order to reduce the risk of reulceration. This exploratory randomised controlled trial is comprised of two groups:
1. Intervention: receive CBT intervention
2. Control: receive usual care

Total duration of intervention: 13 weeks
Follow up length: anticipated to last up to 6 months (subject to funding extension)
Study entry: single randomisation only

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
To assess the feasibility and acceptability of the psychological intervention, measured in December 2010

Secondary outcome measures
To assess the feasibility and acceptability of the psychological intervention using:
1. Hospital Anxiety and Depression Score (HADS; 0 = not at all to 3 = most of the time)
2. Medical and Coping Modes Questionnaire (MCMQ; 1 = very much to 4 = very little)
3. Brief Illness Perception Questionnaire (BIPQ; 0 = no affect to 10 = severely affects life)
4. Profile of Mood States (POMS; 0 = not at all to 4 = extremely)
5. Work and Social Adjustment Scale (WSAS)
6. Generalised Anxiety Disorder Questionnaire (GAD-IV; 0 = no, 1 = yes)
7. 12-item short form health survey (SF-12; 1 = excellent to 5 = very poor)
8. EQ-5D (1 = no problems to 3 unable to perform usual activities)
9. Embarrassment Questionnaire (EMB-Q; 1 = strongly disagree to 5 = strongly agree)
10. Social Support Questionnaire (SSQ; 1 = never to 7 = always)

Overall study start date
10/02/2009

Completion date
19/04/2010

Eligibility

Key inclusion criteria
1. Patients with one or more previous ulcer, but ulcer free at the time of recruitment
2. Aged 49 - 88 years, either sex

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants

Planned sample size: 30; UK sample size: 30

Key exclusion criteria
Patients diagnosed with charcot foot

Date of first enrolment
10/02/2009

Date of final enrolment
19/04/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Social Medicine
Bristol
United Kingdom
BS8 2PR

Sponsor information

Organisation
University of Bristol (UK)

Sponsor details
Research & Enterprise Development
Senate House
Tyndall Avenue
Bristol
England
United Kingdom
BS8 1TH

Sponsor type
University/education

Website
http://www.bris.ac.uk/

ROR

https://ror.org/0524sp257

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) programme (ref: PB-PG-0906-11179)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2012		Yes	No