

Development of a Cognitive-Behavioural Intervention

Submission date 18/06/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 18/06/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 29/08/2013	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

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