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Writing for adults with type 2 diabetes

Submission date 05/10/2009	**Recruitment status** No longer recruiting
Registration date 11/11/2009	**Overall study status** Completed
Last Edited 25/05/2016	**Condition category** Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Miss Kathryn Dennick

Contact details
Warwick Medical School
University of Warwick
Gibbet Hill Road
Coventry
United Kingdom
CV4 7AL
-
K.J.Dennick@warwick.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NA.

Study information

Scientific Title
Written emotional disclosure for adults with type 2 diabetes: a single centre parallel group randomised controlled trial

Acronym
NA.

Study objectives
Milder symptoms of depression in chronic physical conditions such as type 2 diabetes are an important and inadequately addressed problem which has significant negative consequences for the individual's experience, and the course, of the condition. This study is a trial investigating whether an intervention that has been found to improve physical and mental health for individuals with chronic conditions, Written Emotional Disclosure (WED), is similarly effective for adults with type 2 diabetes, specifically UK primary and secondary care patients. The main hypothesis is that participants who receive WED will report lower levels of depressive symptoms, and also improvements in diabetes specific emotional distress, health related quality of life, health care use, self-management behaviours, and glycaemic control (i.e. HbA1c), compared to a control group. Also planned is an assessment of quality assurance, and an investigation of pre-specified mediators and moderators of effects and cost-effectiveness. This is in order to improve understanding of how WED affects health, and identify for whom WED is most effective and whether it is cost-effective.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Warwickshire NHS Research Ethics Committee approved on the 10th December 2008 (ref: 08 /H1211/165). A substantial amendment was approved on the 6th July 2009.

Study design
Single centre parallel group exploratory randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

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
Type 2 diabetes

Interventions
Intervention: Written Emotional Disclosure. This involves writing about personal thoughts and feelings about a stressful event.
Control: A neutral writing condition in which people describe how they use their time.

Both groups write for 20 minutes per day for 3 days over the course of one week.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Symptoms of depression, measured by the CES-D at baseline and then 3 and 6 months post-intervention

Secondary outcome measures
Measured at baseline and 3 and 6 months post-intervention:
1. Diabetes specific emotional distress measured with the Problem Areas in Diabetes (PAID) Scale
2. Health care use measured with the Stanford Patient Education Research Centre Diabetes Health Care Utilisation Questionnaire
3. Diabetes self care behaviours measured with the Summary of Diabetes Self-care Activities Questionnaire (SDCAQ)
4. Glycaemic control (HbA1c) obtained from routine medical records
5. Health related quality of life measured with the EuroQoL

Overall study start date
01/02/2009

Completion date
01/03/2010

Eligibility

Key inclusion criteria
1. Aged 18 years, either sex
2. Have been diagnosed with type 2 diabetes for more than 6 months
3. Have scored below a cut off for significant depressive symptoms in an eligibilty check (Centre for Epidemiological Studies Depression (CES-D) questionnaire less than 16)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
142 (71 per group)

Key exclusion criteria
1. Have received a diagnosis of psychotic or bipolar disorder
2. Are currently receiving treatment for depression
3. Are currently receiving any psychological therapy for any reason
4. Have any history of self harm, suicidal ideation or suicide attempts
5. Have received a care provider assessment as unsuitable (e.g. if they are receiving end of life care, are acutely ill or have any past or present psychological vulnerabilities)

Date of first enrolment
01/02/2009

Date of final enrolment
01/03/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Warwick Medical School
Coventry
United Kingdom
CV4 7AL

Sponsor information

Organisation
University of Warwick (UK)

Sponsor details
c/o Dr P Hedges
Coventry
England
United Kingdom
CV4 8UW

Sponsor type
University/education

Website
http://www2.warwick.ac.uk/

ROR
https://ror.org/01a77tt86

Funder(s)

Funder type
University/education

Funder Name
University of Warwick (UK)

Alternative Name(s)
The University of Warwick, Warwick

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

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:	01/04/2015		Yes	No