ISRCTN58745372 https://doi.org/10.1186/ISRCTN58745372

Effects of psychoeducation on treatment outcomes in depressed diabetic patients

Submission date
25/08/2008

Recruitment status
No longer recruiting

Registration date
04/09/2008

Overall study status
Completed

Last Edited
03/09/2009

Condition category
Mental and Behavioural Disorders

[ ] 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
Dr Mirjana Pibernik-Okanovic

Contact details
Vuk Vrhovac University Clinic
Zagreb
Croatia
10000
+385 1 2353 935
mirjana.pibernik@idb.hr

Additional identifiers

Protocol serial number
045-0450961-0959

Study information

Scientific Title
Effects of a psychoeducational course on treatment outcomes in mildly to moderately depressed diabetic patients

Acronym

EPOT

Study objectives
Screening depressive symptoms in diabetic patients attending their regular medical check-ups, and including those with severe depressive symptoms in a psychoeducational intervention accompanied by a structured follow-up will improve their awareness of the interaction between depression and diabetes, and provide them with necessary support to make an informed decision about self-help and depression treatment. It is also hypothesised that improving patients' activation and their personal competence will positively affect the course of depressive symptoms, diabetes-associated emotional problems, glycaemic control and perceived quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was approved by the Ethics Committee, Vuk Vrhovac Institute in 2006 (ref: No.03-188)

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Diabetes mellitus, depression

Interventions
The intervention comprises 3 interactive small group meetings (8-10 members), each lasting for 90 minutes. The included topics will be:
1. Symptoms of depression; interaction of depression and diabetes
2. Alleviating burden of depression through activities and problem solving
3. Associations between depression and cognitive processes - thoughts, beliefs and attitudes that induce and maintain depression

The first two meetings are held within one week of each other, and the third one after one month. Patients will be provided with a self-help manual for overcoming depressive disturbances, based on the "Coping with depression" course by P.M. Lewinshon (see below for reference). For this study purpose, the programme has been partially modified and adjusted to specific emotional problems related to diabetes. Besides general information (prevalence and cause of depression, interaction with diabetes, treatment modalities, prevention of relapse), exercises to recognise and modify cognitive patterns that contribute to depression maintenance are included.

A run-in period aimed at assessing patients' knowledge and diabetes self-care-related skills will precede the intervention.

The patients in the control group will be given feedback about the severity of their depressive symptoms and receive counselling about appropriate forms of treatment.

Ref: Lewinshon PM, Antonnucio DO, Steinmetz JL et al. The Coping with Depression Course: A Psychoeducational Intervention for Unipolar Depression. Castalia Press, Eugene, OR, 1984.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Depressive symptoms, measured by the Center for Epidemiologic Studies- Depression (CES-D) scale at 6- and 12- month follow-up.

Key secondary outcome(s))
The following will be assessed at 6- and 12-month follow-up:
1. Diabetes-related emotional problems, assessed by the Problem Areas in Diabetes (PAID) scale
2. Diabetes self-care, assessed by the Summary of Diabetes Self Care Activities (SDSCA) questionnaire
3. Long-term glycaemic control as determined by HbA1c
4. Perceived quality of life, assessed by the 12-item short form health survey (SF-12)

Completion date
01/09/2010

Eligibility

Key inclusion criteria
1. Patients with diabetes mellitus
2. Both males and females, aged 18-65 years
3. Patients who have reported elevated depressive symptoms as assessed by the Patient Health Questionnaire-Depression (PHQ-9) and the Center for Epidemiologic Studies-Depression (CES-D) questionnaire

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Key exclusion criteria
1. Poor literacy
2. Drinking problems
3. Co-morbid organic psychiatric disorder
4. Diagnosis of psychosis
5. Severe visual impairment
6. Major depressive disorder

Date of first enrolment
01/09/2008

Date of final enrolment
01/09/2010

Locations

Countries of recruitment
Croatia

Study participating centre
Vuk Vrhovac University Clinic
Zagreb
Croatia
10000

Sponsor information

Organisation
Ministry of Science, Education and Sports (Croatia)

ROR
https://ror.org/0507etz14

Funder(s)

Funder type
Government

Funder Name

Ministry of Science, Education and Sports (Croatia)

Alternative Name(s)
Ministry of Science, Education and Sports, MZOS

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Croatia

Results and Publications

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	26/08/2009		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes