

Psycho-Education Physical Exercise Effects: does treating subsyndromal depression improve depression- and diabetes-related outcomes?

Submission date 27/07/2010	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 11/08/2010	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 09/09/2015	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

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

A randomised controlled comparison of psycho-education, physical exercise and treatment as usual in patients with diabetes and suffering from subsyndromal depression

Acronym

PEPEE

Study objectives

Early treatment of subsyndromal depression in patients with diabetes is expected to improve the patients' depressive symptoms and health status including indicators of metabolic control, subjectively perceived quality of life, diabetes-related distress and diabetes self-care.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of the Vuk Vrhovac University Clinic, 01/07/2010

Study design

Randomised controlled three-arm study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

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/subsyndromal depression

Interventions

1. Psycho-educational intervention:

The intervention will comprise 6 interactive small-group meetings (4 - 6 members), each lasting for 60 - 90 minutes. The topics will include:

- 1.1. Symptoms of depression, interaction of depression and diabetes
- 1.2. Alleviating burden of depression through activities and problem solving

1.3. Associations between depression and cognitive processes - thoughts, beliefs and attitudes that induce and maintain depression, and developing a personal plan for managing problems in the future

The meetings will be held at weekly intervals. Patients will be provided with a self-help manual for overcoming depressive difficulties based on the "Coping with depression" course by P.M. Lewinsohn. The manual will be given to the participating patients prior to the first session in order to make them familiar with the course and to facilitate reflecting their own experiences. The manual's structure aims to stimulate introducing personal examples and making notes. The "Coping with depression" program is well-evaluated in both general population and medical patients. For the purpose of this study the program has been modified in two ways: it has been adjusted to address specific emotional problems related to diabetes, and also adapted for a shorter format of this intervention. Patients will also receive a workbook containing exercises to recognize depressive symptoms, become aware of daily activities patterns, acquire problem-solving techniques, and to recognize and modify cognitive patterns that contribute to maintenance of depression. The manual was tested for comprehensibility and clarity in a group of diabetic patients (N = 8) with different demographic and disease-related characteristics.

2. Physical activity intervention:

The intervention will comprise 6 small-group weekly sessions. The purpose of these sessions will be to educate patients about the interaction of physical activity, mood and diabetes and to increase their participation in a variety of physical activities with an emphasis on walking. The sessions will combine interactive lectures and exercise techniques (warm up-flexibility, strengthening and stretching exercises) that are considered suitable for the study participants. The educational topics will include:

2.1. Effects of exercise on mood

2.2. Short- and long-term effects of exercise on blood glucose and cardiovascular system

2.3. Strategies to develop and maintain a personal plan for regular exercise. The program has been developed by a professional trainer experienced in working with the diabetic population.

The sessions will be organised in a group format and led by a professional trainer. Exercise intensity will be measured by a cardioport watch. The volume of physical activity will be monitored by a pedometer for one week preceding each point of measurement.

3. Depression screening followed by diabetes treatment as usual:

The patients screened for depression will be given an explanation of their result and informed about available treatment options. Follow-up data will be collected at the same points of measurement as in the treatment groups.

The total duration of the treatments (psycho-education; physical exercise) is six weeks. A one-year follow-up has been planned for all three arms of the trial.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Depressive symptoms, measured after the treatment (i.e. after six weeks for the "diabetes treatment as usual" group), and after six- and twelve-month follow-up periods.

Secondary outcome measures

1. Self-management of diabetes, measured at six weeks for the "diabetes treatment as usual" group, and after six- and twelve-month follow-up periods
2. Metabolic control, measured at six weeks for the "diabetes treatment as usual" group, and after six- and twelve-month follow-up periods
3. Diabetes-related distress, measured at six weeks for the "diabetes treatment as usual" group, and after six- and twelve-month follow-up periods
4. Health-related quality of life, measured at six weeks for the "diabetes treatment as usual" group, and after six- and twelve-month follow-up periods
5. Treatment satisfaction, measured after the treatment

Overall study start date

01/09/2010

Completion date

01/09/2013

Eligibility

Key inclusion criteria

1. Type 2 diabetes
2. Aged 18 - 60 years, either sex
3. Subsyndromal depression as determined by the screenings instruments (Patient Health Questionnaire-2 [PHQ-2], Center for Epidemiologic Studies Depression Scale [CES-D]) and the Structured Clinical Interview for DSM-IV Axis I Disorders (SCID)
4. Willing to participate (signing a written informed consent)

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

59 participants per group

Key exclusion criteria

1. Poor literacy
2. Mobility difficulties
3. Visual impairment
4. Drinking problems
5. Psychosis in personal medical history
6. Medical contraindications for physical exercise (heart attack or stroke in the past six months, chest pain, dizziness, fainting attacks, shortness of breath)

Date of first enrolment

01/09/2010

Date of final enrolment

01/09/2013

Locations

Countries of recruitment

Croatia

Study participating centre

Vuk Vrhovac University Clinic

Zagreb

Croatia

10000

Sponsor information

Organisation

European Foundation for the Study of Diabetes (EFSD) (Germany)

Sponsor details

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Foundation@easd.org

Sponsor type

Charity

Website

<http://www.EuropeanDiabetesFoundation.org>

ROR

<https://ror.org/05tgz4m05>

Funder(s)

Funder type

Charity

Funder Name

European Foundation for the Study of Diabetes (EFSD) (Germany)

Alternative Name(s)

The European Association for the Study of Diabetes, EFSD

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Germany

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?
Protocol article	protocol	21/01/2011		Yes	No
Results article	results	01/07/2015		Yes	No
Results article	results	15/07/2015		Yes	No