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

Submission date
27/07/2010

Registration date
11/08/2010

Last Edited
09/09/2015

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] 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

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Additional identifiers

Protocol serial number
091410

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

Primary study design
Interventional

Study design
Randomised controlled three-arm study

Study type(s)
Treatment

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 cardiosport 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(s)
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.

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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)

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, European Association for the Study of Diabetes (EASD), EFSD

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Germany

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
	results				

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