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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

## Study design
Randomised controlled three-arm study

## Primary study design
Interventional

## 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
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# 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 |