Effectiveness of Running Therapy on Depression.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20278

Source
NTR

Brief title
EFFORT-D

Health condition

Depression

Sponsors and support

Primary sponsor: Symfora groep
Source(s) of monetary or material Support: Onderzoekscentrum Body@Work TNO VUmc Symfora (Stichting Open Ankh)

Intervention

Outcome measures

Primary outcome

Depression symptoms (the Hamilton Rating Scale for Depression). Timepoints: 6 and 12 months.

Secondary outcome

1. Metabolic syndrome: length/weight2 (BMI), waist circumference, systolic and diastolic blood pressure, fasting glucose, triglycerides, total cholesterol, HDL-cholesterol, cholesterol/HDL-ratio, creatinine and Cockroft clearance. Timepoint: 6 and 12 months;

2. Quality of Life (WHO-DAS) at 6 and 12 months;

3. Cost effectiveness (TIC-P, Euroqol, subjective health, VAS) at 6 and 12 months.

Study description

Background summary

Rationale:
Depression is a common disorder in the Dutch society which has negative effects on wellbeing and daily personal and professional functioning. The effectiveness of the current standard treatment by means of antidepressants may be limited because of poor compliance and poor effectiveness in many patients and has additional disadvantages like side effects for the patients and high costs. And although the efficacy of psychotherapy is supported by several studies, much less is known about the effectiveness and efficiency of this treatment. Alternative effective low-cost therapies like exercise therapy are therefore necessary. Exercise is relatively safe, has less negative side effects and beneficial effects on physical health. Although recent reviews and meta-analyses suggest that exercise most likely leads to improvements in depressive symptoms, most of these studies show poor methodological quality. The current study therefore aims to assess the effectiveness of exercise therapy in depressed patients in the clinical psychiatric practice, using a methodological high-quality study design. We postulate that allocation of depressed patients to exercise therapy will lead to reductions in depressive symptoms on the short term as well as on the longer term. In addition, the effects on metabolic problems and quality of life will be monitored and the cost effectiveness will be defined.

Objective:
The objective is to assess the effectiveness of exercise therapy (running therapy or Nordic walking) on depression in adults, in addition to usual care (primary aim) and on metabolic syndrome measures, quality of life and cost effectiveness (secondary aim).

Study design:
Randomized controlled trial (RCT).

Study population:
Adult patients diagnosed with a depression/bipolar disorder who are treated or will be treated at one of the three participating (outpatient) clinics.

Intervention:
Patients in the intervention and control group will receive usual care by their psychiatrists or

psychologists. Additionally patients in the intervention group will be enrolled in a six months (40 sessions, twice a week) supervised, group physical activity program (running therapy or Nordic walking).

Main study parameters/endpoints:
The primary outcome measure is reduction in depressive symptoms as measured with the Hamilton Rating Scale for Depression (HRSD). It is expected that patients in the usual care group will respond with a mean reduction of 6 points compared to 8 points for the intervention group on the HRSD.

Secondary study parameters/endpoints:
Metabolic syndrome will be evaluated by a physical test and blood samples including Body Mass Index (BMI), waist circumference, systolic and diastolic blood pressure, fasting glucose, triglycerides, cholesterol/HDL-ratio, creatinine and Cockroft clearance; Quality of life by the WHO-DAS questionnaire and cost effectiveness by the TIC-P questionnaire, the EUROQOL and a VAS for subjective health.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
After informed consent included patients will be measured four times in 12 months: at baseline, halfway and at the end of the intervention (after 3 and 6 months) and at follow-up (after 12 months). Data will be collected at each measurement in one visit through interviews (depression), digital questionnaire (depression, pain, quality of life, health care use and productivity, life style), physical tests (length/weight, blood pressure, submaximal cycle test, heart rate) and by blood samples (extra visit to a laboratory). For participants in the intervention group, compliance and intensity of running/walking will be monitored by the instructor and heart rate registration equipment.

Study objective

Depression is a common disorder in the Dutch society which has negative effects on wellbeing and daily personal and professional functioning. The effectiveness of the current standard treatment (antidepressants) may be limited because of poor compliance and poor effectiveness in many patients. And although the efficacy of psychotherapy is supported by several studies, much less is known about the effectiveness and efficiency of this treatment. Alternative effective low-cost therapies like exercise therapy are therefore necessary. Exercise is relatively safe, has less negative side effects and has beneficial effects on physical health. Although recent reviews and meta-analyses suggest that exercise most likely leads to improvements in depressive symptoms, most of these studies show poor methodological quality. The current study therefore aims to assess the effectiveness of exercise therapy in depressed patients in the clinical psychiatric practice, using a methodological high-quality study design. We postulate that allocation of depressed patients to exercise therapy will lead to reductions in depressive symptoms on the short term as well as on the longer term. In addition, the effects on metabolic problems and quality of life will be monitored and the cost effectiveness will be defined.

Study design

1. Baseline (T0);

2. Halfway the six month intervention period (T3);

3. At the end of the six months intervention period (T6);

4. At follow up, 12 months after baseline (T12).

Intervention

Besides usual care, patients in the intervention group will be enrolled in a six months supervised, group physical activity program (running therapy or Nordic walking). In total 40 sessions (twice a week) are to be followed within this six months period.

Patients in the control group will receive usual care by their psychiatrists or psychologists. This may include treatment modalities such as cognitive behavioural therapy, interpersonal therapy or mentalisation based therapy and/or the use of antidepressants. In accordance with the 'Multidisciplinaire richtlijn Depressie' (2005) patients are advised to be physically active.

Contacts

Public
Postbus 3015
Frank Kruisdijk
Amersfoort 3800 DB
The Netherlands
+31 (0)33-4609803
Scientific
Postbus 3015
Frank Kruisdijk
Amersfoort 3800 DB
The Netherlands
+31 (0)33-4609803

Eligibility criteria

Inclusion criteria

1. Age between 18-65;

2. Diagnoses of unipolar depression, or bipolar depression, or seasonal depression not responding to light therapy (10 sessions of 1 hour) (using DSM-IV criteria);

3. Baseline Hamilton Rating Scale of Depression (HRSD) score of 14 or higher;

4. (Will be) treated for depression.

Exclusion criteria

1. Patients with comorbid disorders (including depression due to another comorbid condition, psychotic disorder, schizophrenia, schizoaffective disorder or obsessive compulsive disorder, anxiety disorder as primary diagnosis);

2. Patients in longstay facilities (including day care) or with complex pathology, treatment resistant depression and multiple hospital admissions with little effect on the depressive state;

3. Significant cardiovascular disease or other medical conditions which contra-indicates exercise therapy;

4. Contraindications for walking and/or running;

5. Pregnancy;

6. Addiction to alcohol and other drugs as a primary diagnosis (DSM-IV criteria Substance Depence);

7. High suicide risk;

8. Regular physical exercise (2-3 times a week on a high-intensity).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2009
Enrollment:	220
Type:	Anticipated

Ethics review

Positive opinion

Date:	02-07-2009
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 32780
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1784
NTR-old	NTR1894
CCMO	NL26169.097.08
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON32780

Study results

Summary results
N/A