Randomised Controlled Trial into the Effectiveness of Running Therapy in adult patients on Depression (EFFORT-D)

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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 (...

Ethical review	Approved WMO
Status	Pending
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON32780

Source
ToetsingOnline

Brief title
Effectiveness of Running Therapy on Depression (EFFORT-D)

Condition

- Mood disorders and disturbances NEC

Synonym
depression, mood disorder

Research involving
Human

Sponsors and support

Primary sponsor: Symforagroep (Amersfoort)
Source(s) of monetary or material Support: Stiching De Open Ankh;TNO;Symfora groep;eventueel andere subsidieverstrekkers

Intervention

Keyword: depression, rct, running therapy, treatment

Outcome measures

Primary outcome

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 outcome

Metabolic syndrome will be evaluated by a physical test and blood samples including 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.

Study description

Background summary

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.

Study 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).

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).

Study burden and risks

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.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

age 18 -65 years
DSM-IV diagnosis: unipolar of bipolar depression
baseline score Hamilton Rating Scale of Depresion (HRSD) >= 14
treated for depressive episode

Exclusion criteria

- patients with comorbid psychiatric disorders
- patients in longstay facilities or with complex pathology
- significant cardiovascular disease or other medical conditions which contra-indicates exercise therapy
- contraindications for walking and/or running
- addiction to alcohol and other drugs as a primary diagnosis
- high suicide risk
- 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:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2009
Enrollment:	220
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METIGG: Medisch Ethische Toetsingscommissie Instellingen Geestelijke Gezondheidszorg (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 20278
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL26169.097.08
OMON	NL-OMON20278