Mood treatment with antidepressants or running

Published: 23-05-2012
Last updated: 26-04-2024

1) Are the effects of antidepressant treatment and exercise treatment on depression and/or anxiety symptomatology and general health indicators comparable? 2) Is recovery of depression and/or anxiety after treatment associated with reduced cellular...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON39034

Source
ToetsingOnline

Brief title
MOTAR study

Condition

- Other condition
- Mood disorders and disturbances NEC

Synonym
depression and anxiety, major depressive disorder and anxiety disorder

Health condition

angststoornissen

Research involving
Human

Sponsors and support

Primary sponsor: GGZ inGeest (Amsterdam)
Source(s) of monetary or material Support: VICI subsidie van NWO

Intervention

Keyword: anxiety, depression, physical, running

Outcome measures

Primary outcome

Is SSRI treatment or exercise therapy in depression and/or anxiety comparable

for depression and anxiety symptomatology and physiological stress?

Secondary outcome

Secundary outcome: reduced cellulair aging and metabolic stress after

depression and anxiety treatment and change in brain activity after treatment.

Study description

Background summary

Treatment with an SSRI antidepressant or exercise training have both shown effectiveness in depression and anxiety care but are seldom compared in one trial. Further, whether the influence of these interventions on physiological processes and general health are comparable is unknown. The MOod Treatment with Antidepressants or Running (MOTAR) study is a multi-center clinical trial, partly randomized, to examine whether depression and anxiety treatment reduces physiological stress. Four aims will be investigated: 1) Are the effects of antidepressant treatment and exercise treatment on depression and/or anxiety symptomatology and general health indicators comparable? 2) Is recovery of depression and/or anxiety after treatment associated with reduced cellular aging and metabolic stress? 3) Are antidepressants and exercise intervention similarly effective in reducing cellular aging and metabolic stress? 4) Are changes in depression and/or anxiety related brain activity accompanied by changes in physiological health? 5) To what extent are physiological health status and brain activity different in depressed/anxious patients before and after treatment as compared to healthy controls? The study*s design is a 16-week treatment program with either SSRIs or three times per week running.

The sample consists of 240 participants with current major depressive disorder and/or current anxiety disorder recruited in the mental health care setting. 120 participants will be randomized for treatment arm and 120 participants will receive treatment of their preference. 30 healthy controls without lifetime depressive and anxiety disorders will be included to compare basic characteristics. During the baseline assessment (prior to treatment program) written questionnaires, an interview, medical examination, blood, urine and saliva collection and a cycle ergometer test will be taken and information will be gathered about demographic, (mental) health outcomes, psychosocial, clinical, biological and genetic determinants. In addition, alterations in brain processes in a subsample of minimal 25 patients per treatment arm will be assessed using functional MRI. Assessments will be repeated after 16 weeks of treatment with SSRIs or exercise training and 1 year after starting treatment. The findings of this trial are expected to provide detailed information about the relationship between treatment of depression and/or anxiety and the reduction of physiological stress, which contributes to a better understanding of the biological accomplishments of the two treatment regimens.

Study objective

1) Are the effects of antidepressant treatment and exercise treatment on depression and/or anxiety symptomatology and general health indicators comparable?
2) Is recovery of depression and/or anxiety after treatment associated with reduced cellular aging and metabolic stress?
3) Are antidepressants and exercise intervention similarly effective in reducing cellular aging and metabolic stress?
4) Are changes in depression and/or anxiety related brain activity accompanied by changes in physiological health?
5) To what extent are physiological health status and brain activity different in depressed/anxious patients before and after treatment as compared to healthy controls?

Study design

A clinical trial, partly randomized, with 2 different conditions: SSRI treatment or exercise therapy with also MRI techniques.

Intervention

Antidepressant treatment: Subjects will receive standardized treatment with selective serotonin reuptake inhibitor (SSRI) which has documented efficacy, a rather favorable side effect profile, and is the most commonly prescribed antidepressant. Medication management will be provided by a psychiatrist who meets with each patient at study onset and weeks 2, 6, 10 and 16. At these meetings, the psychiatrist evaluates treatment response and side effects and

titrates dosage according to the evidence-based Dutch multidisciplinary depression/anxiety guidelines until a well-tolerated therapeutic dosage is achieved. Adherence to treatment is evaluated by pill count.

Exercise intervention: During 16 consecutive weeks, subjects will be requested to exercise 3 days per week for 45 minutes, following public health recommendations by CDC/American College of Sports Medicine and its earlier confirmed successful depression/anxiety improvement results. Participants are gradually assigned individual training ranges equivalent to 70% to 85% of heart rate reserve calculated from the maximum heart rate achieved during an initial treadmill test. Exercise sessions will be organized and supervised by qualified staff, starting with a 10-minute warm-up exercise period followed by 30 minutes of jogging at an intensity that will maintain heart rate within the assigned training range, finishing with 5 minutes of cool-down exercises. Routine checks will monitor for the potential occurrence of dangerous depression/anxiety worsening, in which case clinical referral will be sought. Subjects are stimulated to participate in all three organized group exercise sessions per week, but if strongly preferred they are allowed to exercise individually 1 time per week. Subjects will wear heart rate recorders during all exercise sessions and report daily activities on an exercise log. Their data will be uploaded after sessions and used to encourage study compliance.

Study burden and risks

Respondents will have a baseline assessment including interview, questionnaires, cycle ergometer test, collection of blood, saliva and urine samples during 3,5 hours. This assessment will be repeated after 16 weeks to evaluate differences between pre- and post treatment of the depression/anxiety (approximately 3.5 hours). After 6 and 10 weeks depressive symptoms will be measured using a questionnaire (10 minutes per session). 1 year after the baseline assessment a follow up will take place. Alle respondents will receive a self report questionnaire at home (30 minutes).

Duration of MRI assessment will be 2,5 hours and will be repeated after 16 weeks of SSRI or running therapy. It includes cognitive and emotional task inside and outside the scanner and will be taken in a subsample of 50 respondents.

No burden or risks are associated with the treatment of SSRI, exercise training or MRI assessment.

The control group will undergo only a baseline assessment, including a MRI assessment and will not undergo follow up assessments.

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

Clients (aged 18-65) can take part if they meet the DSM-IV criteria for a current major depressive disorder (MDD) and/ or current anxiety disorder.
Healthy persons can take part if they are aged 18-65 years.

Exclusion criteria

Patient-sample: Current use of antidepressants (antidepressants have to be eliminated for at least 4 weeks for participation of this study), current use of psychotropic medication, except for the use of benzodiazepine for which dosage has to be constant, ongoing participation in regular (>1/week) exercise, primary severe, clinically diagnosed psychiatric diagnosis other than depression or anxiety (bipolar disorder, psychosis, addictive disorder), evidence of acute

suicidal risk, medical contra-indications to exercise or antidepressants as confirmed by a physician ;Control-group: lifetime psychiatric disorder, lifetime treatment for psychological symptoms, ongoing participation in regular (>1/week) exercise, medical contra-indications to exercise or antidepressants as confirmed by a physician

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:	Recruitment stopped
Start date (anticipated):	05-07-2012
Enrollment:	270
Type:	Actual

Ethics review

Approved WMO Date:	23-05-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-04-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-08-2013
Application type:	Amendment

Review commission: METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL38203.029.12