Mood treatment with antidepressants or running.

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N/A

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27941

Bron
NTR

Verkorte titel
MOTAR

Aandoening

Depressie en angststoornissen

Depression and anxiety

Ondersteuning

Primaire sponsor: B.W.J.H. Penninx, GGZ inGeest/ VUmc
Overige ondersteuning: VICI, NWO

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Changes in physical health after antidepressants or runningtherapy, especially in metabolic syndrom and cellular aging.

Toelichting onderzoek

Achtergrond van het onderzoek

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 randomized clinical trial 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? 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. 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 MRI. Assessments will be repeated after 16 weeks of treatment with SSRIs or exercise training. 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.

Doel van het onderzoek

N/A

Onderzoeksopzet

Bofore and after 16 weeks of treatment. Further after 6 and 10 weeks after start of the treatment, depression and anxiety symptoms will be inventoried.

Methods of measurement are oral intervieuws, questionnaires, blood pressure, blood withdrawal, saliva- and urinecollection, length, weight and a fitness test.

Onderzoeksproduct en/of interventie

Antidepressants:

Subjects will receive standardized treatment with selective serotonin reuptake inhibitor (SSRI) which has documented efficacy, a rather favorable side effect profile, is recommended as first-step treatment in both the GP (NHG Standardized depressive disorder and anxiety disorder (in Dutch)) and psychiatry treatment guidelines (Multidisciplinary guidelines depression and anxiety (in Dutch)), and is one of the most commonly prescribed antidepressant. Dosage of 10 mg per day of escitalopram will be used. Medication management will be provided by a psychiatrist who meets 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 (to a maximum of 20 mg) according to the evidence-based Dutch multidisciplinary depression/ anxiety guidelines until a well-tolerated therapeutic dosage is achieved. If the initial SSRI is poorly tolerated, the psychiatrist can switch prescription to another SSRI drug (sertraline, dosage of 50 mg to a maximum of 150 mg). Adherence to treatment is evaluated by pill count.

Runningtherapy:

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 and anxiety improvement results. Participants are gradually assigned individual training ranges equivalent to 70% to 85% of heart rate reserve calculated from the heart rate achieved during an cycle ergometer test with the formula of Karvonen. This intensity level was confirmed to be effective to decrease depressive symptoms and will be used to reduce anxiety symptoms as well.

Exercise sessions will be organized and supervised by qualified staff, starting with a 10-minute warming-up exercise period followed by 30 minutes of jogging at an intensity that will maintain heart rate within the assigned training range (starting in first 4 weeks at 50-70% of heart rate reserve and in the subsequent 12 weeks 70-85% of heart rate reserve), finishing with 5 minutes of cooling-down exercises. During the exercise sessions, all subjects will wear a heart rate monitor. Heart rate will be monitored for three times per session to ensure that the clients are exercising within the prescribed exercise training ranges.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Current depressive disorder or a current anxiety disorder as ascertained by the DSM-IV criteria.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Current use of antidepressants (antidepressants have to be eliminated for at least four weeks for participation of this study);

2. Current use of psychotropic medication, except for the use of benzodiazepine for which dosage has to be constant;

3. Ongoing participation in regular (>1/week) exercise;

4. Primary severe, clinically diagnosed psychiatric diagnosis other than a depressive or anxiety disorder (bipolar disorder, psychosis, addictive disorder);

5. Evidence of acute suicidal risk;

6. Medical contra-indications to exercise or antidepressants (current heart problems) as confirmed by a physician.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	15-06-2012
Aantal proefpersonen:	160
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	31-05-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3313

Register	ID
NTR-old	NTR3460
Ander register	METC VUmc : 12-064
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A