

Exercise Enhances: A randomized controlled trial on aerobic exercise as depression treatment augmentation strategy

No registrations found.

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

Summary

ID

NL-OMON24898

Source

Nationaal Trial Register

Brief title

Exercise Enhances

Health condition

depression

Sponsors and support

Primary sponsor: ZonMW: Doelmatigheidsonderzoek

Source(s) of monetary or material Support: ZonMW: Doelmatigheidsonderzoek

Intervention

Outcome measures

Primary outcome

Depressive symptoms: Inventory of Depressive Symptomatology-Self Report (IDS-SR),

assessed at each time point.

Secondary outcome

Depressive remission (T4-T8): Structured Clinical Interview for DSM-5 (SCID-5-S)

Fitness:

- Self-rated physical activity level: The International Physical Activity Questionnaire (IPAQ; Vandelandotte, et al., 2005), assessed at each time point
- Objective physical activity level and heart rate: A non-invasive activity-tracker ('FitBit') will be used in the adjunct exercise intervention arm to track exercise frequency, duration and intensity from three days before T0 (or as soon after informed consent) till T5. The FitBit is an important feature of the intervention, as it allows self-dosing during the at-home exercise sessions, and helps patients motivate themselves hence contributing to adherence
- Objective fitness: Fitness tests at T0 and T4 in 15 % of the patients (randomly selected). The main endpoint is improvement in cardiorespiratory fitness. The tests will be performed by a trained psychomotor therapist with a physician nearby and on call. An electrocardiogram and blood pressure will be assessed before each test and during testing at the end of every minute, at peak, and immediately post exercise; after minute 2 of active recovery; and at 1, 3, 5, and during seated recovery. Values will be calculated based on body weight as ml/kg/min and categorized according to standardized values for men and women in different age categories.

Mood: Patients will fill out a positive and negative mood rating (Visual Analogue Scales) directly before and after each supervised exercise session. They are stimulated to also use the mood ratings at home to monitor direct mood benefits. This is a technique to self-empower patients to motivate themselves and hence contributes to adherence and long-term exercise use. This is already part of usual psychomotor therapy care.

At-home exercise: At the end of each supervised exercise session, patients fill out a brief questionnaire on the type, frequency, duration and intensity (mean and peak heart rate, as measured by the FitBit) of the two weekly at-home sessions. The psychomotor therapist will discuss how the week went and adapt the personalized exercise plan if needed.

Additional positive outcomes (T0, T4 and T8):

- Functioning: World Health Organization Disability Assessment Schedule, WHODAS 2.0; WHO, 2000)
- Motivation: Motivation and Energy Inventory-Short Form (Fehnel et al, 2005)

Economic evaluation (T0, T4-T8):

- Quality of the health status using the EuroQol-5D (EuroQoL Group, 1995).
- The Trimbos Institute and iMTA Cost questionnaire for Psychiatry (Tic-P; Hakkaart - van Roijen et al. 2002) will be used for measuring health care usage (costs), patients' and their family's out-of-pocket costs, and productivity losses

Possible cognitive mechanisms of change:

- Rumination: Ruminative Response Scale (RRS; Raes et al., 2003) (T0-T8)

- Memory bias (Self-Referent Encoding Task; SRET; Dobson & Shaw, 1987) (T0, T4 and T8)

Study description

Background summary

While there are many effective treatment options for depression, only approx. 60% of depressed patients respond sufficiently to treatment (DeRubeis et al., 2005; Dimidjian et al., 2006) and relapse rates are high (e.g. Hardeveld et al., 2010). Exercise is effective as monotherapy for depression, with comparable effects to psychological treatment and antidepressant medication in outpatient and community-based populations, but also in inpatients (Cooney et al, 2013; Rimer et al, 2012; Stanton et al, 2014; Stathopoulou et al, 2006). It is also effective in preventing relapse (Babyak et al, 2000). Unlike most other treatment options, exercise is inexpensive, universally accessible, and without side effects (Wright & Cattan, 2009). Exercise treatment also augments the effectiveness of psychological and pharmacological treatment (e.g. Abdollahi et al, 2017; Blumenthal et al, 1999; 2007; Garry et al, 2010; Trivedi et al, 2011; Veale et al, 1992), making it an attractive adjunct treatment. Hence, exercise is a strong treatment augmentation strategy that is currently being implemented in few but some Dutch mental health care organizations. However, although a prescription for exercise treatment has been formatted (see: National Institute for Health and Clinical Excellence, NICE, 2009; Rethorst & Trivedi, 2013), this is currently not used in depression care. Moreover, the mechanisms of change are not well understood so far, requiring further research to successfully implement exercise as an augmenting treatment for depression.

The present study tries to fill this gap in the literature and investigates the augmenting effect of exercise provided alongside care as usual (CAU) for depression for 12 weeks. Moreover, we aim to examine mechanisms of change. The primary research question is: Is CAU with adjunct evidence-based prescription of exercise more effective than CAU alone in reducing depressive symptoms in patients with major depressive disorder in the specialised mental health service setting?

Study objective

We expect that CAU with adjunct evidence-based prescription of exercise is more effective than CAU alone in reducing depressive symptoms in patients with major depressive disorder.

Study design

Assessments take place at baseline (T0), after session 3, 6, and 9, and at 3, 6, 9, 12, and 15-months follow-up (T1-T8)

Intervention

The intervention condition receives CAU combined with physical exercise according to

prescription: 12 weeks with one supervised and two at-home moderate-intensity sessions. The supervised weekly exercise sessions consist of 45 min of moderate intensity aerobic exercise. Heart rate will be measured using a heart rate monitor (FitBit). The local psychomotor therapist (mostly one per location) supervises the exercise sessions and provides coaching.

Care as usual is guideline concordant psychological and pharmacological treatment of depression in the specialised outpatient mental healthcare services. CAU will conform the 'Multidisciplinaire richtlijn Depressie' (2013), which is integrated in the recently published 'Zorgstandaard Depressieve Stoornissen' (Akwa GGZ, 2018), see <https://www.ggzstandaarden.nl/zorgstandaarden/depressieve-stoornissen>.

Contacts

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Eligibility criteria

Inclusion criteria

- Adult: Age 16+
- Current depressive episode

Exclusion criteria

- Impossibility to obtain a valid informed consent
- Physical, cognitive, or intellectual impairments interfering with participation
- High health risks of physical activity (assessed using the Physical Activity Readiness Questionnaire; Shephard et al, 1981)
- Lifetime manic episode
- Current psychosis

- Insufficient comprehension of the Dutch language

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-03-2020
Enrollment:	120
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion	
Date:	06-03-2020
Application type:	First submission

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
NTR-new	NL8432
Other	METC Arnhem/Nijmegen : 2019-5958

Study results