

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

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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.

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

Samenvatting

ID

NL-OMON24898

Bron

NTR

Verkorte titel

Exercise Enhances

Aandoening

depression

Ondersteuning

Primaire sponsor: ZonMW: Doelmatigheidsonderzoek

Overige ondersteuning: ZonMW: Doelmatigheidsonderzoek

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Depressive symptoms: Inventory of Depressive Symptomatology-Self Report (IDS-SR), assessed at each time point.

Toelichting onderzoek

Achtergrond van het onderzoek

While there are many effective treatment options for depression, only appr. 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?

Doel van het onderzoek

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.

Onderzoeksopzet

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)

Onderzoeksproduct en/of interventie

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 be 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>.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Adult: Age 16+
- Current depressive episode

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-03-2020
Aantal proefpersonen:	120
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies	
Datum:	06-03-2020
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	NL8432
Ander register	METC Arnhem/Nijmegen : 2019-5958

Resultaten