ExerciseEnhances+: A prospective cohort study on the synchronization of exercise therapy and cognitive behavioural therapy in depression

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

Summary

ID

NL-OMON57575

Source
ToetsingOnline

Brief title
ExerciseEnhances+

Condition

- Mood disorders and disturbances NEC

Synonym
depression, major depressive disorder, mood disorder

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: NWO VIDI Janna Vrijsen

Intervention

Keyword: Cognitive Behavioral Therapy, Depression, Ecological Momentary Assessment, Exercise Therapy

Outcome measures

Primary outcome

The primary endpoint is clinical improvement (decreases in depressive symptoms and improved CBT skills) from baseline to post-treatment measured weekly, and to 3-month follow-up.

Secondary outcome

Secondary parameters are physical activity, mood states, emotional autobiographical memory, energy, motivation, biomarker levels of endocannabinoids and brain-derived neurotropic factor, genetics, and daily functioning.

Study description

Background summary

Cognitive Behavioural Therapy (CBT) remains a leading first-line treatment for depression, yet it has a non-response rate of around 40%, highlighting a critical need for effective augmentation strategies. Exercise, an accessible and side-effect-free intervention, shows promise in reducing depressive symptoms and enhancing neuroplasticity. Combining exercise therapy with CBT may accelerate skill acquisition and improve treatment outcomes. This study aims to explore the synergistic potential of synchronizing exercise therapy and CBT, with the goal of optimizing therapeutic efficacy for individuals with depression.

Study objective

This study will assess the effect of combining exercise therapy with CBT 12-16

weeks and explore the mechanisms underlying exercise*s mood- and plasticity-boosting effects. The primary question is whether a higher dose of exercise leads to faster or greater CBT skill acquisition and symptom reduction in depressive outpatients compared to a lower dose during and after the program.

Study design

This study is a prospective cohort study. The treatment period is 12-16 weeks with weekly assessments until 1-week post-treatment and 3-month post-treatment; daily assessments with smartphone-based assessment, and continuous physical activity tracking.

Intervention

The 12-16 week intervention encompasses weekly supervised 45-min exercise sessions (moderate intensity aerobic exercise) followed by CBT, both in group setting. Additionally, participants are prescribed two weekly homework exercise sessions.

Study burden and risks

Minimal potential risk is associated with this study. Both interventions are already part of care-as-usual in the Dutch mental health setting. The burden added by this study is the time participants need to invest in the assessments, which is about 20 minutes each treatment week for the ecological momentary assessment, 90 minutes for the baseline assessment and 30 minutes each for the post-intervention and follow-up assessment.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)

Inclusion criteria

• Adult: age 16 +
• Current diagnosis of major depressive disorder, based on the Structured Clinical Interview for DSM-5 (SCID-5-S)(First et al., 1998) flanked with clinical judgement.
• Currently exercising max. once per week, based on telephonic assessment

Exclusion criteria

• Impossibility to obtain a valid informed consent
• Physical, cognitive, or intellectual impairments interfering with participation
• High health risks of physical activity (determined by clinician and/or assessed using the Physical Activity Readiness Questionnaire; Shephard et al., 1981)
• Lifetime manic episode
• Insufficient comprehension of Dutch language
• Current admission to treatment centre

Study design

Design

Study phase: 3

Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2025
Enrollment:	57
Type:	Anticipated

Ethics review

Approved WMO

Date:	03-06-2025
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL88643.091.25