

Exercise Enhances

Published: 02-08-2018

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The purpose of our study is to test the augmenting effect and mechanisms of change of exercise provided directly before in total 12 CBT sessions.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Mood disorders and disturbances NEC
Study type	Observational non invasive

Summary

ID

NL-OMON45851

Source

ToetsingOnline

Brief title

Exercise Enhances

Condition

- Mood disorders and disturbances NEC

Synonym

depression, mood disorder

Research involving

Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: augmentation, CBT, depression, exercise, treatment

Outcome measures

Primary outcome

The primary objective of our study is to compare changes in depressive symptoms from pre to post CBT in the different conditions (TAU vs TAU+exercise) .

Secondary outcome

Our secondary aim is to explore psychological processes as mechanisms of change of our intervention.

Explore whether the training transfer to:

- * Anxiety symptoms and stress
- * Self-esteem
- * Sleep
- * Physical activity
- * Functioning
- * Autobiographical memory bias

Explore possible mediating factors:

- * Semantic memory
- * Emotional memory
- * Rumination
- * CBT skills

Study description

Background summary

While cognitive behavioral therapy (CBT) has been proven to be effective in reducing depressive symptoms, 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 (Stathopoulou et al., 2006; Barbour et al., 2007), in preventing relapse (Babyak et al., 2000), and in combination with other therapies e.g. CBT (Abdollahi et al., 2017; Gary et al., 2010). Exercise yields memory improvement (e.g. Blumenthal et al., 1999; Smith et al., 2010), augmenting the learning effect of the post-exercise treatment session (Powers et al., 2015). A recent meta-analysis shows that the combination of psychological intervention (e.g. Cognitive Behavioral Therapy) and exercise is especially effective in reducing depressive symptoms (Sukhato et al., 2017). Hence, exercise is a strong treatment augmentation strategy that is currently being implementing in few but some Dutch mental health care organizations. Its effectiveness is however not yet evaluated in a Dutch setting and the working mechanisms are not well understood thus far.

Study objective

The purpose of our study is to test the augmenting effect and mechanisms of change of exercise provided directly before in total 12 CBT sessions.

Study design

Prospective, cross-over, randomized, multi center study with a cluster-randomized stepped wedge design.

Study burden and risks

The burden is approximately 4 hours of filling out questionnaires and doing computer tasks. Because the institutes are already providing exercise treatment as standard care on some but not all locations, the conditions of the study will be randomized over locations to be able to evaluate the added value of exercise augmentation in the daily care setting. Hence, we are keeping close to practice. There are no known risks associated with filling out the questionnaires or doing the computer tasks.

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

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- Adult: age 18+
- Current depressive episode
- Participation CBT treatment with or without exercise (depending on location)

Exclusion criteria

A potential subject who meets any of the following criteria will not be invited for this study:

- Impossibility to obtain a valid informed consent
- Physical, cognitive, or intellectual impairments interfering with participation
- Lifetime manic episode
- Current psychosis
- Insufficient comprehension of the Dutch language

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	10-01-2019
Enrollment:	240
Type:	Actual

Ethics review

Approved WMO	
Date:	02-08-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	11-12-2018
Application type:	Amendment
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	NL65950.091.18