The feasibility of working memory training in COPD patients and the efficacy on cognitive performance, self-control, and stress response

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Investigating the efficacy and feasibility of working memory training in COPD patients on cognitive performance, cognitive stress susceptibility and perception, self-control / impulse control, and adherence to physical activity and dietary…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cognitive and attention disorders and disturbances
Study type	Interventional

Summary

ID

NL-OMON47327

Source
ToetsingOnline

Brief title
COGTrain-Trial

Condition

- Cognitive and attention disorders and disturbances
- Bronchial disorders (excl neoplasms)

Synonym
chronic bronchitis, COPD, emphysema

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W,ZonMW subsidie

Intervention

Keyword: COPD, Physical activity, Working memory training

Outcome measures

Primary outcome

Cognitive performance and feasibility of the trial, measured as the number of working memory training sessions completed by the participants (adherence), and their performance therein.

Secondary outcome

Dietary advice compliance, daily physical activity level and pattern, physical performance, self control / impulsivity, motivation, acute and chronic stress

Study description

Background summary

General cognitive impairment is highly prevalent in chronic obstructive pulmonary disease (COPD) patients. Domain-specific cognitive impairments include cognitive flexibility, verbal memory, working memory, planning, and psychomotor speed; which in general are associated with poor lifestyle behaviours, such as infrequent exercising and poor diet. Additional cognitive training may reverse these effects. Recent evidence suggests that working memory training is linked to self-control and, indirectly to improved lifestyle behaviours including increased physical activity. We hypothesise that enhancing cognitive performance through administering specific working memory training not only improves cognitive function but that it facilitates better adherence to a more active lifestyle and a healthier diet in COPD patients.

Study objective

Investigating the efficacy and feasibility of working memory training in COPD

patients on cognitive performance, cognitive stress susceptibility and perception, self-control / impulse control, and adherence to physical activity and dietary guidelines.

Study design

Double-blind, placebo-controlled randomised clinical trial.

Intervention

During the first twelve-week phase, participants receive at least 25 working memory training sessions, which are delivered online on a computer. These sessions take approximately 20-30 minutes. During the second twelve-week phase, participants receive 'booster sessions' once weekly. These also take 20-30 minutes.

Study burden and risks

Participants will be asked to complete a number of tests, taking half a day, on four occasions: before baseline, at baseline, after twelve weeks, and after 24 weeks. Additionally, participants are asked to complete approximately 40 working memory training sessions over the course of the 24 weeks (at least 25 in the first twelve weeks, and once weekly in the second twelve-week phase). These sessions take 20-30 minutes each.
There are minimal risks associated with participating in the current study. No adverse reactions are known about following a working memory training, completing questionnaires, or completing brief physical tests. Participants may feel fatigue after completing the measurements or may lose interest in the training program. With the lung function test, participants might experience short-term dizziness and heart palpitations.

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

Diagnosis of COPD
Motivation to participate in the training

Exclusion criteria

Disease and or disability limiting the ability to undergo a neuropsychological testing battery and/or to follow a working memory training (e.g., blindness)
Neurological disorders (e.g., Alzheimer*s Disease or cerebrovascular disease)
Insufficient mastery of the Dutch language
Individuals who during the study period are or will be participating in an inpatient PR programme
Individuals who during the study period are or will be participating in another interventional study

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-12-2017
Enrollment:	75
Type:	Actual

Ethics review

Approved WMO Date:	21-06-2017
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	14-03-2018
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
ClinicalTrials.gov	NCT03073954
CCMO	NL59883.068.17