Working memory training in MCI patients: A pilot study

Published: 22-08-2012 Last updated: 26-04-2024

The aim of this study is to investigate the feasibility of a computer-based cognitive training (working memory training) in a relative old and cognitive impaired population of MCI patients. We will examine the effect of this cognitive training on...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON37054

Source ToetsingOnline

Brief title Working memory & MCI

Condition

• Other condition

Synonym Mild cognitive impairment

Health condition

Mild dementia/Mild cognitive impairment (MCI)

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Maastricht Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Executive functions, MCI, Working memory, Working memory training

Outcome measures

Primary outcome

Feasibility

Feasibility will be evaluated on the basis of (a) age, (b) patient*s abilities/capacity (daily investment, duration and difficulty level of the tasks and questionnaires), and (c) weakly (or daily) telephonic conservations between the researchers and the patient or his/her partner/caregiver. In addition, the (possible) lack of computer skills and the necessity of an involved partner/caregiver are also important factors to consider in regard to the feasibility

Accomplishment of the WMT, excluded subjects and dropouts The number of participants that accomplish the whole WMT (25 days), the number of excluded subjects (e.g. by the researchers) and the number of dropouts will be recorded.

The researchers will try to contact withdrawn subjects, in order to clarify, whether his or her reasons were related to experimental set up. Subjects are not obligated to give the reason why he or she has stopped with the experiment. These outcome measurements can give us crucial information about the applied intervention and the investigated population

Secondary outcome

WM capacity

WM capacity will be measured with using the same tasks that will be used during the WMT. However, the assessment versions of the three tasks will end when participants are unable to reproduce a sequence of two consecutive trials. The outcome measure for each task will be the length of the longest sequences that participants correctly reproduce on two consecutive trials. See section 3 for detailed information about the WM tasks.

WM (equal, but not trained task)

The Backward letter span will be used to function as a control WM task. This means that this task is equal to the other WM tasks, but that it not will be trained. During this backward letter spa task, a sequence of letters will be presented on the computer screen. Participants have to reproduce this sequence in reversed order, using either the computer mouse or the letter keys on the keyboard. This task is added to the present study to see whether the participants show an improved WM performance on only the trained WM tasks or on all WM tasks (including the not trained task). By this way, we can chart the (generalization) effect of WMT.

Consequences of WM deficits in everyday life.

The Working Memory Questionnaire (WMQ) is a self-administered scale, addressing three dimensions of WM: short-term storage, attention, and executive control. 3 - Working memory training in MCI patients: A pilot study 15-05-2025 The WMQ assess the consequences of WM deficits in everyday life (Vallat-Azouvi, Pradat-Diehl & Azvouvi, 2012). The WMQ consist of 30 items and each question will be rated on a five-point Likert-type scale, ranging from 0 (*no problem at all*) to 4 (*very severe problem in everyday life*). Examples of items are: **Do you find it difficult to remember the name of a person who has just been introduced to you?** and Do you feel that fatigue excessively reduces your concentration?**. This questionnaire is added in the present study to monitor the everyday WM problems of our participants.

Executive functioning (non-equal task)

A computerized version of the Stroop task (Stroop, 1935) will be used to measure information processing speed and susceptibility to interfere. Participants have to respond in the first block as fast as possible to four coloured (blue, red, green and yellow) words (**Blue**, **Red**, **Green** and **Yellow**) by using the number keys on the keyboard. During the second block, participants have to respond to the colour (blue, red, green and yellow) of the words (distracters) by using the number keys on the keyboard. This task is included in the present study to chart the executive functioning performance of the participants at pre-test, post-test and follow-up and primarily to see whether executive functioning will improve after WMT.

Cognitive failures

The Cognitive Failure Questionnaire (CFQ; Broadbent et al., 1982; Ponds et al., 2006) is a self-report questionnaire which consists of 25 items measuring the 4 - Working memory training in MCI patients: A pilot study 15-05-2025

frequency of everyday cognitive failures. Each item is rated for frequency in the past 6 months on a four point scale, ranging from *0* (never) to *4* (very often). The maximum score is 100. Examples of items are: ** Forgetting appointments** and ** Forgetting people*s names**. This questionnaire is included in the present study to monitor the cognitive failures of our participants at pre-test, post-test and follow-up.

Sense of control

Mastery, or *the feeling as the extent to which a person perceives himself or herself to be in control of events and ongoing situations* is considered as a psychosocial resource when coping with stressful life events. A high sense of mastery is expected to reduce psychological distress and increase well being. The Mastery-questionnaire (Pearlin, 1978) is used to measure this level of control that people experience. The Mastery scale consist of seven items scored on a 5-point scale from **totally agree** (1) to **totally disagree** (5). Examples of items are: ** Some of my problems I can't seem to solve at all** and ** Sometimes I feel like a play ball of life**. This questionnaire is included to the present study to see whether WM effects are independent of control. One interesting question is for example whether participants with the lowest improvement in WM performance also have a low level of control.

Self-efficacy

Self-efficacy is defined as the belief that one is capable of performing in a certain manner to attain certain goals. The Dutch General Self-efficacy Scale 5 - Working memory training in MCI patients: A pilot study 15-05-2025

(GSE) consists of 10 statements on a 4-point scale from **totally incorrect** (1) to **totally correct**. The GSE is designed to assess optimistic self-beliefs to cope with a variety of difficult demands in life (Teeuw, Schwarzer & Jerusalem, 1994). An example of an item is: **Whatever happens, I will manage**. This questionnaire is included in the present study to monitor the self-beliefs and goals of our participants at pre-test, post-test and follow-up

Psychological states

The Symptom Check List 90 (SCL-90) will be used as a screening measure of general psychiatric symptomatology (Buckelew et al. 1988). Patients are asked to rate the severity of their experiences with each symptom over the past week on a 5-point scale ranging from 0 (not at all) to 4 (extremely). Examples of items (or symptoms) are: **Headache** and **Thinking about death or dying**. This questionnaire is included in the present study to monitor the psychiatric symptomatology of our participants at pre-test, post-test and follow-up. In addition, it will also be used to measure the progress and outcome of our (neuro) psychological intervention.

Study description

Background summary

Mild cognitive impairment (MCI) is a condition in which a person and their environment experience reduced cognitive functioning at a faster rate than is expected from normal aging. Because the problems do not interfere with daily activities, the person does not meet criteria for dementia. Research has shown that individuals with MCI have an increased risk of developing Alzheimer*s disease (AD) over the next few years. MCI is often found to be a transitional stage between normal aging and dementia. For this reason, the present study will investigate whether working memory training can strengthen working memory and executive control in MCI patients, which may prevent them from further cognitive decline leading to dementia.

Study objective

The aim of this study is to investigate the feasibility of a computer-based cognitive training (working memory training) in a relative old and cognitive impaired population of MCI patients. We will examine the effect of this cognitive training on working memory performance and executive functioning in a small clinical sample of MCI patients. We are especially interested whether this improvement of working memory performance is related to an improvement of other (non-trained) cognitive/executive functions and cognitive functioning in daily living.

Study design

We will use a non-blind observational intervention study. The participants will receive WMT for 25 consecutive days besides the care as usual. Before (pre-test) and after training (post-test) we will measure WM performance and executive functioning. After 3 months, a follow-up measurement will take place.

Intervention

The WMT used in the present study is based on the same tasks used in the study of Houben, Wiers and Jansen (2011). Their WMT was based on the ideas, tasks and studies of Klingberg and associates (e.g. 2002). The daily exercises are designed to train both the visuo-spatial and verbal WM. The participants will perform their WMT program via the Internet on a personal computer (PC). The WMT includes 20-40 minutes of intense training per day. Participants will follow the WMT at their own home for 25 consecutive days. (See section 7.3: Study procedures for further information about the several sessions of the WMT) Participants will be trained during the WMT on three kinds of WM tests: the visuospatial WM span task, the backwards digit span task, and the letter span task (based on Klingberg, Forssberg & Westerberg, 2002).

•Visuospatial WM task: during this task, a certain number of squares in a 4x4 grid changed in colour on the computer screen. Participants have to reproduce this sequence by clicking on the squares that have changed colour in the correct order using the computer mouse.

•Backward digit span: during this task, a sequence of numbers will be presented

on the computer screen. Participants have to reproduce this sequence in reversed order, using either the computer mouse or the number keys on the keyboard.

•Letter span task: during this task, a sequence of letters will be presented on the computer screen in a circle. One of the positions in this circle is to be indicated and participants have to reproduce the corresponding letter using the keyboard.

Participants must follow 30 trials of each of the three WM tasks. This means that they have to solve on a daily basis 90 WM exercises for 25 consecutive days. The difficulty level of all three WM tasks will be automatically adjusted on a trial-by-trial basis. The training is adaptive; WM load is increased according to each individual*s performance levels. Initially, each task involved sequences of three items. The length of the sequences will increase and decrease according to participants* performance. When participants correctly reproduce the sequences on two consecutive trials, one item will be added to the sequence on the next trial. When participants are not able to correctly reproduce the sequences on two consecutive trials, the sequence in the next trial will contain one item fewer. This automatic adjustment makes the training easier or more difficult. Every participant trains on his/her optimal WM capacity.

Study burden and risks

The risk of participating in this study are considered minimal. The working memory training and questionnaires are non-invasive and scarecely stressful, When taken into consideration that the participants have to be mental competent to give informed consent and the risks of participating in this study are minimal, we feel that the burden of approximately 40 minutes for 25 consecutive days are justified, in order to gain more insight in the relationship between working memory and mild cognitive impairment/mild dementia.

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

MCI: diagnosed according to the criteria of the DSM IV-R (American Psychiatric Association, 2000);Age over 18 years;A minimum of 4 years of formal schooling and no history of mental retardation;Native Dutch speaker;Mental competency to give informed consent. Mental competency as defined by the Dutch law (WGBO: Wet of Geneeskundige Behandel Overeenkomst) is determined by the medical specialist (psychiatrist, neurologist).;Participants must have access (preferable at their own home) to a computer with an internet connection. ;Participants must have some experience with computers (preferable with Windows and Internet Explorer).;A partner/caregiver who is willing to help/assist the participant with the daily computerized training.

Exclusion criteria

History of acquired brain injury (e.g. cerebral contusion, cerebrovascular accident)

Study design

Design

Study type: Interventional

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

Recruitment

NL	
Recruitment status:	Will not start
Start date (anticipated):	01-09-2012
Enrollment:	12
Туре:	Anticipated

Ethics review

Approved WMO	
Date:	22-08-2012
Application type:	First submission
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
Other	Nederlands Trial Register (TC = 3476)
ССМО	NL41179.068.12