Effectiveness of computerized training of attention and working memory in Post COVID-19 patients with cognitive complaints

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Primary Objective: The aim of this study is to research the effect of a computerized cognitive rehabilitation program (RehaCom) in post COVID-19 patients with cognitive complaints on their sustained and divided attention and their working memory....

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Viral infectious disorders
Study type	Interventional

Summary

ID

NL-OMON53265

Source
ToetsingOnline

Brief title
CO-TRAINER

Condition

- Viral infectious disorders

Synonym
COVID-19, post COVID-19 condition

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

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

Intervention

Keyword: attention, COVID-19, training, working memory

Outcome measures

Primary outcome

Primary outcome measures are sustained and divided attention and working memory which will be measured with objective neuropsychological tests. Change in visual selective attention, processing speed and concentration is measured with the D2 test. Change in visual attention, executive function (divided attention) and processing speed is measured with the TMT A & B. The Stroop Test measures mental speed, executive attention and response inhibition. Attention and working memory are explored with the use of the digit span forward (DSF) and digit span backward (DSB) test. Together with *Rekenen* an index for working memory can be calculated. General cognitive functioning will be measured using the MoCA.

Secondary outcome

Secondary outcome measures are subjective cognitive complaints, mood, fatigue and quality of life which will be measured with standardized questionnaires.

Study description

Background summary

Since 2019, the world has been overwhelmed by COVID-19, a respiratory infectious disease. A few years in the pandemic, the persistence of symptoms after the acute phase is a well-recognized phenomenon. Most people who develop COVID-19 fully recover, but current evidence suggests approximately 10%-20% of

people experience a variety of mid- and long-term effects after they recover from their initial illness. These mid- and long-term effects are collectively known as post COVID-19 condition (PCC) or *long COVID*. According to the World Health Organization PCC is defined as the illness that occurs in people who have a history of probable or confirmed SARS-CoV-2 infection; usually within three months from the onset of COVID-19, with symptoms and effects that last for at least two months. Multiple studies show a variety of symptoms of PCC. Common symptoms include, but are not limited to, fatigue, shortness of breath, cognitive dysfunction and / or subjective cognitive complaints, even after 1 year or more after hospitalization. Patients with PCC have lower general cognition compared to healthy controls. Overall reviews show that attention, memory and executive functions appeared to be affected domains. Detailed research show deficits in attention, both in sustained and executive components. Furthermore, less capacity of working memory, inhibition deficits and lower information processing speed are also frequently reported. These functions are related to fatigue . Fatigue and cognitive impairment have been consistently reported to be some of the most common and debilitating features of PCC. Cognitive dysfunction is associated with anxiety and depression and have an impact on every day functioning, return to work and account for diminished quality of life. Unlike other common symptoms of PCC including dyspnea there are no established and effective treatments yet for post-viral fatigue and cognitive impairment for these patients. Multiple studies already emphasized the urge for (cognitive) rehabilitation programs for post COVID-19 victims. In the Netherlands rehabilitation centers have developed multidisciplinary care pathways without any cognitive rehabilitation elements. Computer-based attention training (a component of RehaCom computerized cognitive therapy software) resulted in significant improvements on attention in acquired brain injury patients, indicating both a direct benefit and generalization of training effects. Also, similar results are found in other patient groups like patients with MS.This study aims to evaluate the effect of computerized cognitive training on attention and working memory in post COVID-19 patients.

Study objective

Primary Objective: The aim of this study is to research the effect of a computerized cognitive rehabilitation program (RehaCom) in post COVID-19 patients with cognitive complaints on their sustained and divided attention and their working memory.
Secondary Objective(s): To evaluate the effect of a computerized cognitive rehabilitation program (RehaCom) on subjective cognitive complaints, psychological outcome measures and HR-QoL.

Study design

Randomized wait-list controlled pilot trial. Patients with persistent cognitive

complaints of the CO-FLOW study, a prospective multi-centre cohort study (NL74252.078.20) will be invited. In this study, the Cognitive Failure Questionnaire (CFQ) was used to measure subjective cognitive complaints. After 1 year 22% (103/468) of the participants showed deviant results on the CFQ . Preliminary results show that these problems did not improve after 2 years, with preliminary results showing deviant results in 24% (67/279). In addition, 53 to 57% of the CO-FLOW participants reported symptoms of concentration and/or memory problems, respectively.

The total group will be divided randomized 1:1, to the intervention or control group. First, both group will have a baseline measurement. Both groups of patients will receive the computerized training, using a waiting list procedure. 1 group will directly after the baseline measurement start the online (at home) computerized cognitive training for 10 weeks, 3 times a week, each session 15-30 minutes (RehaCom). Directly after the intervention this group will be retested. Also, follow-up 3 months after the intervention will be performed to study preservation of training effects. The other group also receives the same intervention, after a 3 months waiting period, starting after the second measurement. This group will also be tested after the intervention.

Intervention

Investigational product/treatment
RehaCom is a software program consisting of 29 different therapy modules in multiple cognitive domains (attention, memory, executive functioning, visual field and visual motor coordination. Each domain has several subtasks. The cognitive domain **attention** for example, consists of therapy modules about alertness, vigilance, selective attention, sustained attention, visuospatial attention and visuoconstruction. Each module has different levels of difficulty. Starting at a low level of difficulty, the patient can progress to solve increasingly complex tasks. RehaCom is an auto-adaptive program which adapts the complexity of each task automatically to the patients actual performance. The computer operates as a neutral observer making objective comments on the patient performance and gives, if necessary, error-specific feedback.

RehaCom saves all training results. A new training session starts where the last one has been finished. The therapist has the ability to monitor all data to further develop the therapy strategies.

In this study the following training modules will be used as intervention:
Attention:
* The module **Sustained Attention** (SUSA) aims to train the ability to maintain the focus and level of attention during high frequencies of stimuli and high demands on the selection process for longer periods. This module has 9 levels.
* The module **Attention and Concentration** (AUFM) is based on the principle

of pattern comparison. The client has to find one picture in a matrix that matches exactly the *comparison picture*. This is used to train selective attention and concentration. This module has 24 levels.
* In the module **Divided Attention** (GEAU) several stimuli have to be observed simultaneously as often demanded in everyday life. Like a train driver, the patient has to monitor the driver*s cab, regulate the speed, and react to different signals during the train run. This module has 14 levels.
* In the module **Divided Attention 2** (GEA2), patients have to pay attention to several external stimuli whilst driving a car (divided attention). They have to observe the landscape passing in front of them as well as the car dashboard and react to acoustic information in a differentiated way. This module has 22 levels.
* The module **Working Memory** (WOME) is a training that exercises the ability to remember information and to manipulate it. Maintaining attention and the resistance to interference play a central role. Depending on the level of difficulty, the patient has to remember an increasing number of playing cards (memory system), select them from different distractors (selective attention) and later mentally manipulate them (central executive). This module has 70 levels.
* The module **Memory Strategy Training** (LEST) introduces and consolidates a learning strategy and thus improves the memorization and retrieval of Information. This module has 18 levels.
* The module **Verbal Memory** (VERB) aims to improve the short-term memory of verbal information. For this purpose, short stories are displayed on the screen. The patients have to memorize all details in the story. Afterwards, they must reproduce them when asked by the program. This module has 10 levels.
Patients will be trained with Rehacom 3 times a week 15-30 minutes for 10 weeks.

Study burden and risks

The intervention is an online cognitive rehabilitation program, 3 times a week 15-30 minutes per session during 10 weeks. Participants can choose what time of the day is most convenient for them to engage in the program, so they can optimize their circumstances as much as possible. Participating in the computerized training program might lead to temporary fatigue. Patients will be advised to rest before and after the training. There are no extra risks involved in participating in the intervention.

In 3 visits assessments will be performed using short tests and questionnaires. Questionnaires and neuropsychological tests (pen and papertasks) are minimally physically demanding and have a maximum duration of 60 minutes per session, including regular breaks.

We expect that after the computerized training patients will be able to better concentrate and divide their attention. We hypothesize that this will decrease subjective cognitive and psychological complaints and improve quality of life.

By repeating the tests in the long term, participants will gain more insight in their recovery after COVID-19.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

* aged 18 years and older;
* patient has sufficient knowledge of Dutch language;
* participated in the CO-FLOW study (NL74252.078.20)
* cognitive complaints (CFQ> 43 at 2 years after hospital discharge);
* no cognitive complaints before COVID-infection
* computer and internet-access.

Exclusion criteria

* Incapacitated subjects like patients diagnosed with dementia;
* Patients should not be involved in any concurrent rehabilitation program for COVID-19, cognitive behavioural therapy or psychotherapy targeting cognition, anxiety and/or depression.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2023
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	RehaCom
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	05-09-2023
Application type:	First submission

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NCT05831839
CCMO	NL84105.078.23