Retraining the Fatigued Brain (REFAB): A randomized controlled trial evaluating personalized cognitive rehabilitation treatment in somatic symptom and related disorders

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In the current study, the subjective and objective effectiveness of cognitive rehabilitation therapy for people with somatic symptom and related disorders will be investigated. Additionally, the effects of this treatment on brain activity in the...

Ethical review	Approved WMO
Status	Pending
Health condition type	Somatic symptom and related disorders
Study type	Interventional

Summary

ID

NL-OMON56516

Source
ToetsingOnline

Brief title
REFAB

Condition

- Somatic symptom and related disorders

Synonym
persevering somatic complaints, somatic symptom disorder, somatoform disorder

Research involving
Human

Sponsors and support

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

Intervention

Keyword: cognitive complaints, cognitive rehabilitation treatment, somatic symptom and related disorders

Outcome measures

Primary outcome

The main study parameter is the suspected change in subjective and objective

cognitive functioning after the treatment, as measures using questionnaires and

neuropsychological tests, respectively.

Secondary outcome

Secondary outcomes include (possible changes in) brain activity, stress system

activity and immune system activity.

Study description

Background summary

Somatic symptom and related disorders (SSRD) are disorders that involve significant distress due to and impairment caused by (anticipated) physical complaints. These disorders are often accompanied by cognitive complaints which to date are not treated with targeted evidence-based therapy.

Study objective

In the current study, the subjective and objective effectiveness of cognitive rehabilitation therapy for people with somatic symptom and related disorders will be investigated. Additionally, the effects of this treatment on brain activity in the frontal cortex, the neuroendocrine system, the autonomic nervous system and the immune response will be researched.

Study design

Randomized controlled trial

Intervention

The experimental group will receive personalized cognitive rehabilitation treatment, whereas the control condition will receive treatment as usual (cognitive behavioral therapy).

Study burden and risks

The risks of participation are minimal. Both experimental and control treatments are already given in the target population, and the experimental treatment has already been proven to be effective in other patient populations. The burden associated with participation includes taking part in a non-invasive psychophysiological assessment (i.e., fNIRS, cortisol and heart rate variability measurements), once before and once after the treatment. In addition, participants are asked to fill in additional questionnaires pre and post treatment, as well as at six months follow up. In case patients take part in the experimental condition, they are able to receive treatment tailored to their cognitive complaints. In addition, patients in this condition still have the possibility to receive the treatment as usual upon completion of the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- SSRD diagnosis
- Subjective cognitive complaints
- Age: 18 years or older

Exclusion criteria

Acute psychosis
Addiction that requires treatment first
Insufficient mastery of the Dutch language
Blindness, deafness
Severe cognitive disorder (e.g. aphasia, dementia)

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:	Pending
Start date (anticipated):	01-01-2024
Enrollment:	150
Type:	Anticipated

Ethics review

Approved WMO Date:	22-02-2024
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL84822.028.23