Cognitive rehabilitation therapy in patients with somatic symptom and related disorders.

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

Summary

ID

NL-OMON50112

Source
ToetsingOnline

Brief title
Cognitive rehabilitation therapy in somatic symptom and related disorders.

Condition

- Somatic symptom and related disorders

Synonym
somatic symptom and related disorder

Research involving
Human

Sponsors and support

Primary sponsor: GGZ instellingen / Psychiatrische Ziekenhuizen
Source(s) of monetary or material Support: Herbert Simon Research institute Cross departmental fund

Intervention

Keyword: cognitive rehabilitation, somatic symptom and related disorder

Outcome measures

Primary outcome

The primary outcome of this study is subjective cognitive functioning as measured by the Cognitive Faillure Questionnaire (CFQ) (Broadbent,Cooper, FitzGerald & Parkes, 1982). The CFQ is a self-report questionnaire related to everyday cognitive failure/misstakes related to cognitive functioning. The questionnaire consists of 25 items which are measured using a 5-point scale (0 = never, 4=always). The CFQ has good psychometric properties, include test-retest reliability (Ponds, van Boxtel & Jolles, 2006) and reliability (Bridger, Johnsen& Brasher, 2013). Higher scores are indicative for more subjective congitive symptoms. The CFQ-scores are measured before, during (6 weeks) and after treamtnt to evaluate the course of cognitive functioning during therapy.

Secondary outcome

Neuropsychological assesment (NPA) is conducted twice. Firstly, NPA is conducted to provide a framework for the therapy sessions. The second NPA is conducted to evaluate objective cognitive functioning after therapy. This NPA takes approximately 30 minutes and is considered an (minimal) extra effort for patients. NPA is used to assess the different cognitive domains (e.g., memory, attention, executive functioning).

Scores will be transformed into classificantion 'no cognitive disorders' (equal

to or larger that 20th percentile), 'impaired cognitive functioning' (between 2nd and 20th percentile), and 'cognitive disorder' (smaller than 2nd percentile) based upon the criteria from Lezak, Howiesan, & Loring (2012). The following tests will be conducted: the digit span and symbol substitution from the Wechsler Adult Intelligence Scale (WAIS-IV-NL; Wechsler, 2012) is used to assess working memory and information processing speed, respectively. The Tower test of the DKEFS (Delis et al, 2001) is used to assess planning (Executive functioning), and the rey auditory verbal learning test (15WT; Kalverboer & Deelman, 1986) is used to assess verbal memory processes. The rey osterrieth complex figure test is used to assess visual memory (Osterrieth, 1944) and the d2 is used to assess attention (Brickenkamp, 2002). The psychometric properties of these tests are sufficient and can be found in the manuals (Brickenkamp, 2002;'Delis et al., 2001; Kalverboer & Deelman, 1986; Wechsler, 2012).

Note: to control for possible learning effect, during the second NPA the b-version of the RAVLT will be conducted. The learning effect of the other tests are considered minimal

Study description

Background summary

Somatic symptom and related disorder (SSRD) often coincides with impaired cognitive functioning but has received little attention untill recently.Other studies in the field of depression and anxiety already suggested impaired cognitive functioning. These disorder are often seen comorbidly with SSRD. Regular treatment of SSRD is primarily offered in the form of cognitive behavioral therapy (CBT) but often lacks efficivity. Several case descriptions

suggest that cognitive rehabilitation therapy (CRT) can improve cognitive functioning which in turn may improve the effectivity of CBT (because treatment sessions can, for instance, be remembered better). Whether the combination of CRT before CBT may improve treatment effectivity in patients with SSRD is worthwhile exploring in the future but before such studies can be conducted we first have to explore the effect of CRT on cognitive functioning in patients with SSRD.

Study objective

This study focuses on the the effect of treatment (12 weeks/sessions) on cognitive functioning. Therapy for cognitive functioning exists (regular treatment protocol at the participating clinic) of cognitive behavioral therapy (CBT) and cognitive rehabilitation therapy (CRT). Subjective cognitive functioning is compared between the two therapies before and after therapy. The secundairy outcome measure includes an objective measure of cognitive functioning. To explore the effect on objective cognitive functioning, the results of a neuropsychological assessment before treatment (standard protocol to provide an aim for the therapy) and after treatment will be compared.

Study design

This study follows a 2x3 mixed model randomized design with cognitive rehabilitation therapy (CRT) vs. standard of care cognitive behavioral therapy (CBT) as between-subjects factor and repeated measures of the outcome measures (pre-intervention, 6 weeks, and 12 weeks = end intervention) as within-subjects factor. A questionnaire used to asses subjective cognitive functioning is used for the repeated measures variable. The study will take place from 1st of january 2021 until 1st of september 2021 at the clinic of excellence for body mind and health, GGz Breburg. At this clinic, CRT is offered in the standard care based on studies regarding its effecitivity in patients with acquired brain injuries. Cognitive symptoms are also treated using CBT at this clinic (primarily due to the lack of trained psychologists in CRT) while focussing on dysfunctional thoughts regarding these symptoms (in short). The neuropsychological assessment (NPA) is part of (standard) clinical practice since the NPA and CFQ are used to select the kind of intervention (standard CBT or CRT) that is offered (focusing on specific cognitive domains).The additional burden related to this scientific study is considered minimal and primarily involves completion of study-related questionnaires (approximately 5 minutes per assessment and an end-intervention neuropsychological assessment (30 minutes); total 40 minutes).

Intervention

Cognitive rehbailitation therapy (CRT) aims to learn a compensatory strategy to overcome cognitive symptoms in a broad range of cognitive domains. For

instance, the protocol for impaired mental speed (Winkens & Fasotti, 2010) offers a strategy to overcome impairments within the domain of information processing speed. This protocol contains three stages. The first stage focuses primarily on increasing awareness of the deficits and the relationship between mental slowness and perceived problems in daily life. In the second stage, the main focus is on acceptance and acquisition of the strategy. Besides relating the (poor) performance of the patient and the concept of time pressure, the strategy will be explained and taught to the patient. The final stage focuses on strategy application and maintenance. This stage mainly involves real-life application of the strategy by the patient, evaluating the results of its application and improving the strategy during the treatment session. Other protocols target improving executive functioning and memory but we expect to use the protocol for mental speed based on our prior findings that information processing speed is most frequently impaired in patients with SSRD (De Vroege et al., 2018).

Cognitive behavioral therapy (CBT)
CBT centers on identifying and changing or modifying inaccurate or distorted thoughts concerning ones symptoms. These symptoms may be psychiatric, for instance depression, for which a depression CBT protocol is available. During CBT in the control condition, automatic negative thoughts regarding cognitive failures or cognitive symptoms will be identified, challenged and replaced with objective, realistic thoughts. In this way, CBT contributes to feeling less stressed about cognitive failures or symptoms and improves patients* wellbeing. Due to the fact that no other therapy focuses on cognitive symptoms, CBT is regularly used in therapy at CLGG for targeting these negative thoughts regarding cognitive failures/symptoms.

Study burden and risks

Patients are treated with care as usual. Baseline assessments with NPA and CFQ are part of (standard) clinical practice since the NPA and CFQ are used to select the kind of intervention (standard CBT or CRT) that is offered (focusing on specific cognitive domains).The additional burden related to this scientific study is considered minimal and primarily involves completion of study-related questionnaires (approximately 5 minutes per assessment and an end-intervention neuropsychological assessment (30 minutes); total 40 minutes). Participants can leave the study at any time for any reason if they wish to do so without any consequences. Furthermore, if patients do not wish to participate in this study, data gathered during intake will not be used for this purpose and their treatment trajectory continues as per usual. Withdrawal has no consequences for treatment selection at CLGG.Patients whom are offered CBT and for which cognitive symptoms remain after treatment, CRT is offered as well. Psychologists at the clinic are trained in CRT and supervision during treatment is provided (already provided, not specifically set up for this study),
Benefits for the patients contain the insights we would like to obtain with regards to treatment of cognitive symptoms in patients with SSRD, which is

frequently reported but not treated for.

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

patients with SSRD, >= 18 years, cognitive symptoms.

Exclusion criteria

Exclusion criteria: direct risk of suicide, dementia, usage of illicit drugs within the past 6 months, consumption of more than 21 units of alcohol per week, illiteracy, insufficient knowledge of Dutch language or short-term risk

of psychoses, and refusal to informed consent .

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:	Recruitment stopped
Start date (anticipated):	04-10-2021
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	03-03-2021
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	NL75852.028.20