Dynamic Interpersonal Therapy (DIT) in SSD patients: trauma, attachment and the brain

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To evaluate DIT treatment outcome and possible predictors of treatment outcome in patients with MUSS To evaluate brain structure and function related to SSD pre-and post treatment.

Ethical review Not approved **Status** Will not start

Health condition type Somatic symptom and related disorders

Study type Observational non invasive

Summary

ID

NL-OMON46100

Source

ToetsingOnline

Brief title DIT in SSD

Condition

Somatic symptom and related disorders

Synonym

Somatic Symptom Disorder

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit van Tilburg

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

onderwijsgelden afdeling Psychiatrie

Intervention

Keyword: brain, childhood trauma, Somatic symptom disorder, Therapy

Outcome measures

Primary outcome

This study predicts a beneficial effect of DIT therapy on several parameters:

- Compared to a waiting list group, subjects show an increase in mentalization (about oneself and others), a decrease in levels of stress, pain and fatigue, functional disability.
- Associations between childhood trauma and brain structure and function are expected. We expect that structural and functional brain abnormalities realted to trauma play a role in SSD symptoms and that DIT treatment may reverse these abnormalities.

Secondary outcome

we will examine the role of possible moderators in the effect of DIT: childhood trauma, attachment, comorbidity.

Study description

Background summary

The current study aims to examine the effects of Dynamic Interpersonal Therapy (DIT) in patients diagnosed with Somatic Symptom Disorder (SSD). Previous research has shown that patients with SSD experience difficulty in mentalizing about own and others* feelings and that negative childhood experiences and attachment issues can predispose an individual for mentalization difficulties. Furthermore, these patients have been found to be self-critical and perfectionistic which can result in a dysfunctional stress response. Currently, guidelines recommend Cognitive Behavioural Therapy in the treatment of SSD (CBT). However, CBT does not target underlying psychodynamic factors such as mentalization abilities or attachment. Dynamic Interpersonal Therapy (DIT) is

a new treatment that does address psychodynamic factors. Treatment with DIT might result in better outcomes for individuals with MUSS. The proposed study, therefore, aims to examine the effects of DIT in physical and psychological symptoms in patients with SSD.

In addition, the proposed study aims to examine the possible role of structural and functional brain abnormalities in the link between negative childhood experiences and SSD. Previous research has shown that negative childhood experiences result in structural and functional brain abnormalities, but it is unknown how this relates to symptoms in patients with SSD. In the current study, we will examine how structural and functional brain abnormalities in MUSS patients are related to MUSS symptoms, taking into account the role of childhood trauma. In addition, we will examine whether brain abnormalities can be reversed with treatment.

Study objective

To evaluate DIT treatment outcome and possible predictors of treatment outcome in patients with MUSS

To evaluate brain structure and function related to SSD pre-and post treatment.

Study design

Study design: Patients with SSD who are selected for DIT, will be asked to participate in this study to examine the effects of DIT on SSD severity and social functioning. Participants will be asked to fill out online questionnaires measuring attachment experiences, physical symptoms, mentalization of own and others* emotions. Patients will receive Dynamic Interpersonal Therapy, two days per week (total of 10 hours per week) for 24 weeks. A subsample will be invited for an MRI session before and after treatment.

Study burden and risks

There are no benefits for patients or controls when they participate in the current study. Participants will not receive money or other rewards. There is no physical burden associated with participation. Participants might experience emotional burden from filling out questionnaires about negative childhood experiences. Participants will be explained that they can withdraw from participation at any point during the study without consequences for their treatment. They will be given contact information of an (independent) psychiatrist in case they experience any negative emotions as a consequence of completing the questionnaires.

Contacts

Public

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Scientific

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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 SSD: participants (age 18 -65 years) should suffer from medically unexplained somatic symptoms (MUSS) (e.g. chronic somatic unexplained headaches, chronic fatigue syndrome, unexplained dizziness, whiplash-related complaints, fibromyalgia and irritable bowel syndrome) with no or insufficient medical explanation.

Exclusion criteria

MUSS symptoms present for less than 6 months, another psychiatric disorder as main classification, age <18 or >65, insufficient mastery of the Dutch language, and unregistered drug or alcohol abuse. Comorbidity and use of psychopharmaceuticals Patients who agree to participate in the MRI study will be screened for MRI contraindications.

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Contraindications are metal implants or other metal objects that can not be removed, (possible) pregnancy, and claustrophobia.

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled
Primary purpose: Basic science

Recruitment

NL

Recruitment status: Will not start

Enrollment: 120

Type: Anticipated

Ethics review

Not approved

Date: 14-01-2019

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.

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In other registers

Register ID

CCMO NL68529.028.18