# De rol van emotionele factoren op het hebben van lichamelijke klachten

No registrations found.

**Ethical review** Positive opinion **Status** Recruiting

Health condition type -

**Study type** Observational non invasive

# **Summary**

#### ID

NL-OMON22895

Source

NTR

**Health condition** 

Symptom somatic disorder

## **Sponsors and support**

**Primary sponsor:** Zuyderland Medisch Centrum Afdeling klinische en medische psychologie

Source(s) of monetary or material Support: Zuyderland Medisch Centrum, RVE7

#### Intervention

#### **Outcome measures**

#### **Primary outcome**

The dependent variables are post-task negative affect and level of SSD complaints.

#### **Secondary outcome**

Manipulation check: the effectiveness of the mood manipulation is tested with a paired samples t-test for pre- and post-task levels of NA.

# **Study description**

#### **Background summary**

A considerable number of patients with medically unexplained somatic symptoms keep on searching for a conclusive explanation for their symptoms, even after repeated medical examination by different medical specialists. This maladaptive response contains maladjustment in thoughts, beliefs, negative emotion and behavior, and is defined as Somatic Symptom Disorder (SSD) according to the Diagnostic and Statistical Manual for Mental Disorders, fifth edition (DSM-5; 2013). Up to this moment, little is known about psychological vulnerability factors in the development of SSD.

An interesting study is done by Bardeen (2015) who found that experiential avoidance is moderating the effect of anxiety sensitivity on negative affect, and anxiety sensitivity on posttraumatic stress symptoms in an undergraduate student population that experienced a traumatic event in lifetime. Anxiety sensitivity predicted increases in negative affect after completing an emotionally evocative task, but only for those with lower levels of experiential avoidance. On the other hand, posttraumatic stress symptoms were also positively related to anxiety sensitivity, but only when experiential avoidance was high. In analogy with Bardeen's study, in the current study we are interested we therefore aim to explore the role of the following concepts in the development of SSD: health anxiety (e.g. anxiety-sensitivity (AS)), experiential avoidance (EA) and, more explorative, self-compassion (SC) on negative affect and the development of SSD-symptoms in the presence of shortly developed unexplained somatic symptoms.

Anxiety sensitivity refers to a personality trait in which anxiety-related bodily sensations are misattributed as a harmful experience causing more intense anxiety or fear (Reiss & McNally, 1985). experiential avoidance refers to avoiding, controlling or changing certain unpleasant internal experiences such as thoughts, feelings and physical sensations, as well as memories and situations that evoke these experiences (Hayes, Wilson, Gifford, Follette, & Strosahl, 1996). Self-compassion (SC) entails being kind toward oneself in instances of pain or failure; perceiving one's experiences as part of the larger human experience; and holding painful thoughts and feelings in balanced awareness (Neff, 2003a; Neff, Rude, Kirkpatrick, 2007; Neff & Germer, 2013).

### **Study objective**

The primary objective of the current study is to examine the moderating effect of EA on the relationship between health anxiety and SSD-symptoms after inducing negative emotions in a general population who suffers from somatic symptoms. More specifically, it is hypothesized that...

1. There is a positive relation between AS and post task negative affect and between health anxiety and SSD-symptoms.

- 2. There is a negative relation between EA and post task negative affect, and a positive relation between EA and SSD-symptoms.
- 3. Health Anxiety like Anxiety Sensitivity may only be a vulnerability factor for the development of negative affect and SSD-symptoms among those who are unwilling to experience emotional distress (Experiential Avoidance is high). Among individuals with relatively higher Health Anxiety (Anxiety Sensitivity), those with higher experiential avoidance would experience less short-term increases in negative affect in the face of an emotionally evocative situation, but relatively worse long-term SSD-symptoms outcomes in comparison to those with lower experiential avoidance.

A secondary objective has an exploratory character and aims to study the relation between self-compassion, SSD-symptoms and negative affect. More precisely, it is explored whether . Higher levels of SC may have a protective effect on levels of post task negative affect and SSD-symptoms in a population with somatic symptoms by inspecting correlations between the variables of interest.

#### Study design

T0: pre- and post-task levels of NA.

T1: after 6 months

#### Intervention

The study has a cross-sectional research design using self-report questionnaires, a semi structured interview and an emotionally evocative task (view pictures with negative content while listening to sad music). Negative affect is induced by an emotionally evocative task to register the effects of Experiential Avoidance on negative affect in the short term.

## **Contacts**

#### **Public**

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# **Eligibility criteria**

#### Inclusion criteria

- participants of this study are required to be at least 18 years of age
- fluent knowledge of the Dutch language
- who experience somatic symptoms
- duration at least one month

#### **Exclusion criteria**

- psychosis or bipolar disorder in medical history
- current alcohol or drug abuse
- cognitive impairment
- problems in understanding Dutch language

# Study design

## **Design**

Study type: Observational non invasive

Intervention model: Factorial

Allocation: Non controlled trial

Masking: Open (masking not used)

Control: N/A, unknown

## Recruitment

NL

Recruitment status: Recruiting
Start date (anticipated): 01-04-2017

Enrollment: 90

Type: Anticipated

# **Ethics review**

Positive opinion

Date: 21-03-2017

Application type: First submission

# **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

NTR-new NL6315 NTR-old NTR6490

Other METC Zuyderland : 17-N-16

# **Study results**