

# Pilot study: schema mindfulness group training versus self-image module group training

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Objective: primary hypothesis: The level of complaints drops more in patients who have completed module schemafocused mindfulness than in patients who have completed the module self-image. Secondary hypotheses: The Personality Severity Index (PSI)...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Personality disorders and disturbances in behaviour
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON39329

### Source

ToetsingOnline

### Brief title

Pilot study: S-MBCT versus self-image module

### Condition

- Personality disorders and disturbances in behaviour

### Synonym

personality disorder; personality problems

### Research involving

Human

### Sponsors and support

**Primary sponsor:** GGZ Delfland (Delft)

**Source(s) of monetary or material Support:** GGZ Delfland

## Intervention

**Keyword:** personality disorders, Randomised controlled trial, schematherapy

## Outcome measures

### Primary outcome

Main Parameter: The main parameter in this study is the score of the SCL-90.

The expectation is that patients with personality problems benefit more from schemafocused mindfulness training group than in the module self-image training group. The score on the SCL-90 would have to decrease more in the module schemafocused mindfulness training group than in the module self-image group training. This is considered to be a moderate effect: 0.25.

### Secondary outcome

Secondary outcome measures:

scores on the YSQ, SMI I, MAAS and RSES.

The Personality Severity Index (PSI) (part of the SCL-90) during decreases more during module schemafocused mindfulness than during module self-image.

The intensity of the schema modes and schemas decreasesmore during module schemafocused mindfulness than during module self-image.

The degree of mindfulness increases stronger during module schemafocused mindfulness than during module self-image.

The self-image enhances more during module self-image than during module schemafocused mindfulness

## Study description

## **Background summary**

Rationale: It seems important to develop short treatment modules for personality disorders that can be used in a stepped care model. In addition to develop these modules is also important to investigate the effectiveness of these modules. So far there haven't been done researches. This pilot study is the first step of researching the effectiveness of schemafocused mindfulness for patients with personality problems or personality disorders. Clinical experience with this module has already been gained and the results appear favorable for patients. This module will be compared with self-image module that has already been researched with very beneficial effects. The main hypothesis of this research proposal is that schemafocused mindfulness group training has a broader and deeper effect on symptoms than the module self-image group training, since the latter module is focused on the self-image based on the doing-mode and the module schemafocused mindfulness learns patients to adopt a different attitude towards complaints by the mindfulness aspect and thus the being-mode allowing changes in self-image to come from acceptance and not from changes orientation. Because this research is a pilot study, the conclusions about the outcome must be interpreted with care.

## **Study objective**

Objective: primary hypothesis:

The level of complaints drops more in patients who have completed module schemafocused mindfulness than in patients who have completed the module self-image.

Secondary hypotheses:

The Personality Severity Index (PSI) for the module schemafocused mindfulness will drop more than during the module self-image.

The intensity of the schema modes and schemas decreases more during module schemafocused mindfulness than during module self-image.

The degree of mindfulness increases stronger during module schemafocused mindfulness than during module self-image.

The self-image enhances more during module self-image than during module schemafocused mindfulness.

## **Study design**

Study design: In this RCT there will be used a mixed design. We will look for in and between group variables with an ANOVA with repeated measures. The

duration of the study covers three years. The module schemafocused mindfulness group training and module self-image group training will be offered via GGZ Delfland to patients with personality problems.

## **Intervention**

Intervention: Patients are randomly attached to the module schemafocused mindfulness training group or to the module self-image training group. Prior to the module, patients will complete test material, namely SCL-90, SMI I, YSQ, MAAS and RSES. After the group training, patients will re-fill test material. A month after the modules have been completed, patients will re-fill again test material.

## **Study burden and risks**

The degree to which subjects are exposed to hazards, risks or burden: The risk of SAE (serious adverse events) is small because the test material used, is regular. During the diagnostic phase, patients may be confronted with their sensitive strings. This will be discussed afterwards with the patient.

## **Contacts**

### **Public**

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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 need to have as primary diagnosis on axis II a personality disorder. Features of a personality disorder instead of a fullblown personality disorder will also be included.

### Exclusion criteria

psychotic features, substance abuse, untreated ADHD, bipolar I disorder, IQ lower then 80 points.

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	27-03-2012
Enrollment:	36
Type:	Actual

## Ethics review

Approved WMO

Date: 07-02-2012

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO

Date: 21-10-2013

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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## 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	NL37067.098.11