

# Effect of mindfulness training and progressive muscle relaxation as a self-help technique on obsessive-compulsive, psychotic and depressive symptoms

<b>Submission date</b> 25/02/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 23/03/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 16/07/2015	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Many patients with obsessive compulsive disorder (OCD), depression, as well as patients with schizophrenia go untreated. This is due to a lack of accessible treatment options and the reluctance of patients to engage in face-to-face treatment. Even though cognitive behavioral therapy with stimulus exposure and response prevention is the most effective psychotherapeutic treatment for OCD only a small number of patients actually receive psychotherapy and many therapists trained in cognitive behavioral therapy do not practice evidence-based techniques. A quarter of individuals with OCD fail to initiate cognitive behavioral therapy and another 30% who initiate treatment drop out prematurely, stating fear of engaging in cognitive behavioral therapy as one of the main reasons. The situation is similar for patients with schizophrenia or depression. Even though cognitive behavioral therapy serves as a standard treatment for schizophrenia it is rarely applied, and patients with depression often experience a relapse. Thus alternative and accessible interventions are needed for patients with obsessive compulsive disorder, schizophrenia and depression. This study investigated the effectiveness of mindfulness-based training in comparison to progressive muscle relaxation, delivered as a bibliotherapeutic self-help approach.

### Who can participate?

We are asking volunteers to take part in this research project who have either been diagnosed with obsessive compulsive disorder, schizophrenia or depression in the past. Only participants between the age of 18 and 65 are allowed to participate and they should be fluent in German language.

### What does the study involve?

You will be asked to take part in two online assessments. The second one is scheduled six weeks after the first. The assessments will include a number of questionnaires. You will be randomly

allocated to receive either a manual for mindfulness training or for progressive muscle relaxation training after the first assessment. Both manuals are conceptualized as self-help manuals and are accompanied by (an) audio file(s).

What are the benefits and risks of taking part?

Participants will benefit from the study by receiving two self-help manuals. The results will help to improve treatment for patients with obsessive-compulsive disorder, schizophrenia and depression. There are no risks associated with participation.

Where is the study run from?

This study is run from the Department of Psychiatry and Psychotherapy University Medical Center Hamburg-Eppendorf (Germany).

When is the study starting and how long is it expected to run for?

From April to May 2013.

Who is funding the study?

Universitätsklinikum Hamburg-Eppendorf (Germany).

Who is the main contact?

Prof. Dr Steffen Moritz

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## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Steffen Moritz

**Contact details**

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

N/A

## Study information

**Scientific Title**

Self-help mindfulness training leads to a greater reduction in obsessive-compulsive or psychotic as well as depressive symptoms compared to self-help progressive muscle relaxation in patients with obsessive-compulsive disorder or schizophrenia

**Study objectives**

Obsessive-compulsive disorder is characterized by intrusive, recurring and disturbing thoughts causing distress (obsessions) usually followed by ritualized behaviors (compulsions) that are aimed at neutralizing the obsessive content and negative emotions. Schizophrenia is often characterized by abnormal social behavior and failure to recognize what is real including symptoms of false beliefs, unclear or confused thinking, auditory hallucinations, reduced social engagement and emotional expression, and inactivity. Both disorders are accompanied by depressive symptoms. Depression is characterized by a pervasive and persistent low mood that is accompanied by a loss of interest or pleasure in normally enjoyable activities

Participants learning mindfulness will show a greater decrease in obsessive-compulsive, psychotic and depressive symptoms compared to the participants exercising progressive muscle relaxation at the 6 weeks post-assessment. A secondary aim was to assess the hypercorrection bias in psychosis, that is, whether patients with psychosis are less able to correct their judgment in view of counterevidence.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Ethics Committee of the German Psychological Society, 19/09/2012, ref: SM 09\_2012

**Study design**

Single-center randomised controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Internet/virtual

**Study type(s)**

Treatment

**Participant information sheet****Health condition(s) or problem(s) studied**

Obsessive compulsive disorder, schizophrenia, depression

**Interventions**

We prepared two self-help manuals for the study. Participants were randomized to receive either a manual including a description of mindfulness and exercises or a manual describing progressive muscle relaxation. One of the manuals can be downloaded at the end of the

baseline survey and the respective other after the second assessment. Both manuals are available as pdf versions and include audio files giving instructions for the relaxation tasks.

Mindfulness is defined as a process of deliberately focusing attention on the present moment in a non-judgmental and non-reactive way. The mindfulness manual consists of 15 pages and comprises an introduction into the concept of mindfulness and its effectiveness, including ten exercises. Four exercises (e.g. body scan) are accompanied by self-spoken audio files to support participants in performing the tasks.

Progressive Muscle Relaxation (PMR) according to Jacobson is a standard relaxation procedure. Certain muscle groups are first tensed or tightened and then deliberately relaxed and released of tension. The PMR manual consists of three pages and gives information on the background, the content of the exercises and how to deal with problems that might arise while practicing PMR. An audio-file providing instructions, is also available for download.

### **Intervention Type**

Behavioural

### **Primary outcome measure**

Obsessive-compulsive symptoms, psychotic symptoms and depressive symptoms as measured with items from: Obsessive-Compulsive Inventory-Revised, Paranoia Checklist and Center for Epidemiologic Studies-Depression Scale at the baseline assessment and post-assessment (6 weeks later)

### **Secondary outcome measures**

1. Feasibility and acceptance of self-help manuals for mindfulness and progressive muscle relaxation measured by items asking for use of the manual and number of practice day and subjective appraisal of the manuals
2. We investigated whether schizophrenia patients are less prone to the hypercorrection bias that is commonly observed in nonclinical controls

### **Overall study start date**

27/03/2012

### **Completion date**

26/07/2014

## **Eligibility**

### **Key inclusion criteria**

1. Age between 18 and 65
2. Either participants with a diagnosis of obsessive-compulsive disorder, depression or schizophrenia or healthy participants, who have never been diagnosed with any psychiatric disorder
3. Access to internet
4. Sufficient German language ability
5. Consent to participate in two anonymous (internet-based) surveys that were scheduled 6 weeks apart

### **Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

60 patients with schizophrenia, 60 patients with obsessive-compulsive disorder and 60 patients with depression

**Key exclusion criteria**

1. Lifetime occurrence of a manic episode or diagnosis of bipolar disorder
2. Known neurological disorder (e.g. stroke, MS, epilepsy)
3. Current alcohol or drug dependence
4. Current suicidal ideation or suicidal intent
5. Current severe symptoms of psychosis

**Date of first enrolment**

18/02/2013

**Date of final enrolment**

06/05/2013

**Locations****Countries of recruitment**

Germany

**Study participating centre**

University Medical Center Hamburg-Eppendorf

Germany

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**Sponsor information****Organisation**

University Medical Center Hamburg-Eppendorf

**Sponsor details**

Martinistr. 52

Hamburg

Germany  
20246

**Sponsor type**

Hospital/treatment centre

**Website**

clinical-neuropsychology.de

**ROR**

<https://ror.org/01zgy1s35>

## Funder(s)

**Funder type**

Hospital/treatment centre

**Funder Name**

Universitätsklinikum Hamburg-Eppendorf

## Results and Publications

**Publication and dissemination plan**

To be confirmed at a later date

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not expected to be made available

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/09/2015		Yes	No