

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

Submission date 25/02/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 23/03/2015	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 16/07/2015	Condition category 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

moritz@uke.de

Contact information

Type(s)

Scientific

Contact name

Dr Steffen Moritz

Contact details

Martinistr. 52

Hamburg

Germany

20246

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

-

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?
Results article	results	01/09/2015		Yes	No