PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Sustained Attention as Mediator in Mindfulness-Based Cognitive Therapy for Depression

Trial Acronym

8YZ

URL of the trial

http://uni-tuebingen.8yz.de/

Brief Summary in Lay Language

In this study, we investigate the healing mechanisms of two new interventions for prevention of depressive relapse. The two therapies have a similar structure and the same duration of 8 weeks. The effectiveness of both interventions has already been proved empirically. The existing studies showed a similar effectiveness of both therapies especially with clients who had suffer 3 or more episodes of major depression in the past. A short 8-week long group therapy can help such clients to reduce their risk for relapse by 40% to 50%. We are conducting a comparative investigation of these two different forms of therapy with a special focus on their respective working mechanisms ("How do the the interventions work?", "Which are the most important healing factors?"). The central therapeutic goal of our study is to help our clients to develop mindful awareness and insight into the nature of their own cognitions. Both interventions facilitate the development of such insight into the nature of one's own depressive thoughts, memories, expectations and beliefs. The two interventions differ, however, in their therapeutic methods and techniques. It is assumed that the training of sustained attention by formal meditation exercises is crucial for the first form of therapy but certainly not for the second form. The main goal of our research is to investigate the role of sustained attention as a therapeutic factor in both therapies.

Brief Summary in Scientific Language

**Mindfulness-based cognitive therapy (MBCT) effectively prevents relapse/recurrence
in major depression. The ability to deploy and maintain attention on a particular focus
is considered a prerequisite for 'mindful', 'metacognitive' awareness, and hence crucial
for therapy success. Accordingly, sustained concentration, is the skill most extensively taught
in MBCT. In a previous DFG-funded study, we tested whether this ability increases after MBCT
as assumed. The late contingent negative variation (LCNV), an event-related**

**brain potential (ERP),
known to reflect the allocation of attentional resources in real-time, was used as a measure
of concentration ability. The LCNV was significantly increased after MBCT compared to both
pre-therapy baseline and no-treatment control group. Since our 'mindfulness LCNV task'
included sad mood induction and rumination challenge, we interpreted this result as reflecting
the patients' improved ability to shift their attention toward current moment experience
and away from potentially depressogenic thinking or rumination during mild dysphoric states
(a known risk factor for depressive relapse/recurrence). However, the clinical and discriminating
relevance of the LCNV effect and, consequently, of the measured concentration ability still
remains unclear, which is the reason for the present grant proposal. We intend to validate
further the LCNV as a measure of sustained mindful attention by comparing the LCNV in a group
treated with MBCT with the LCNV in a group treated with cognitive therapy (CT) without mindfulness,
and also by investigating the relationship between LCNV and a newly developed self-report measure
of sustained mindful attention. The ultimate goal of the proposed project, however,
is to investigate the relationship between LCNV and the presence and severity of symptoms
and/or relapse/recurrence of depression during a one-year follow-up period after treatment.
We intend to recruit 100 recurrently depressed patients in remission and to assign them
randomly to MBCT or CT. Patients' LCNV will be measured immediately before, immediately after,
and one year after treatment. Presence and severity of depressive symptoms and/or
relapse/recurrence will be assessed retrospectively for the year preceding the treatment
and both retrospectively and continuously (via internet-assisted self-report)
for the follow-up year. To the best of our knowledge, this will be the first study
to test the hypothesis that increased mindful concentration ability predicts reduction
in frequency and severity of symptoms and/or relapse/recurrence of major depression.**

Organizational Data

- DRKS-ID: **DRKS00006014**
- Date of Registration in DRKS: **2014/12/19**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **173/2013BO2 , Ethik-Kommission an der Medizinischen Fakultät der Eberhard-Karls-Universität und am**

DRKS-ID: **DRKS00006014**
Date of Registration in DRKS: **2014/12/19**
Date of Registration in Partner Registry or other Primary Registry: **[---]***
Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
Ethics Approval/Approval of the Ethics Committee: **Approved**
Universitätsklinikum Tübingen

Secondary IDs

Health condition or Problem studied

- ICD10: **F33 - Recurrent depressive disorder**

Interventions/Observational Groups

- Arm 1: **MBCT (mindfulness-based cognitive therapy) comprises eight weekly two-and-a-half-hour group sessions (eight to twelve participants) and at least 45 min of daily homework (six days a week) over the eight weeks. Participants are first trained in sustained focused attention to the breath and to other bodily sensations. Later, still using the breath as an anchor for concentration, they are taught to include thoughts and emotions as objects of mindful attention and learn to perceive them as mental events and not as absolute truth, self or reality (metacognitive awareness).**
- Arm 2: **This particular group CT (cognitive therapy) protocol is particularly suitable for comparison with MBCT, because of the almost identical format (group size, number, frequency and length of sessions, homework load, etc.). It contains all CT elements included in MBCT (teaching the relationship between thoughts, feelings and behavior, cognitive restructuring, pleasure and mastery activities, etc.), but NO meditation exercise. The CT groups meet weekly for 8 weeks. Each session lasts about two-and-a-half hours with 10-12 group member.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

Allocation: **Randomized controlled trial**

- Blinding: **[---]***
- Who is blinded: **assessor, data analyst**
- Control: **Active control (effective treament of control group)**
- Purpose: **Basic research/physiological study**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Patient's electroencephalogram (EEG) is measured during two meditation tasks at 3 time points: pre-therapy, post-therapy, and at follow-up, 1 year after the end of therapy. Event-related brain potentials (ERP) are obtained from the EEG, especially the contingent negative variation (CNV), a component elicited by a simple stimulus and reflecting the allocation of attentional resources during meditation. The quality of mindfulness and sustained attention during the two meditation tasks is assessed also by the Toronto Mindfulness Scale (TMS), a self-report measure administered immediately after each task at the same 3 time points as the CNV.

Secondary Outcome

**Presence and severity of depressive symptoms is monitored weekly by the Center for Epidemiologic Studies Depression Scale (CES-D) administered via internet, starting with the first week of therapy and ending 1 year after the end of therapy (i.e. 60 measuring points: 8 during therapy, 52 during follow-up).
Relapse/recurrence of Major Depression during the 1-year follow-up period is assessed retrospectively by the Longitudinal Interval Follow-up Evaluation (LIFE).**

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- other **Psychologie, psychotherapeutische Ambulanz, Tübingen**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2014/07/01**
- Target Sample Size: **100**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **65 Years**

Additional Inclusion Criteria

(a) age between 18 and 65 years, right-handedness, normal hearing ability;
(b) history of recurrent major depression with three or more previous episodes
(c) commitment to homework compliance and to not initiating any changes in medication
(starting, suspending, changing dosage) unless a relapse made it necessary.

Exclusion criteria

(a) current major depressive episode, or presence of dysthymic disorder;
(b) presence of substance abuse, eating disorder, or obsessive-compulsive disorder;
(c) presence or history of one or more of the following: bipolar disorder, borderline personality disorder, schizophrenia or schizoaffective disorder, epilepsy or other neurological disorder, organic mental disorder, pervasive developmental delay;
(d) significant experience with any kind of practice including mindfulness and/or concentration as important element
(e.g. meditation, meditative prayer, autogenic training, meditative yoga, etc.).

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Sources of Monetary or Material Support

■ **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

Deutsche Forschungsgemeinschaft (DFG)

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E-mail: **postmaster at dfg.de**
URL: **http://www.dfg.de/**

Status

- Recruitment Status: **Recruiting complete, follow-up continuing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*