

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

Trial Description

Title

A randomized controlled pilot study of a brief web-based mindfulness training

Trial Acronym

[---]*

URL of the trial

<http://www.psychologie.uzh.ch/achtsamkeit>

Brief Summary in Lay Language

This study examined the effect of a brief web-based mindfulness (meditation) training. Since there have been various web-based psychotherapeutic programmes which included mindfulness techniques it is not yet known whether meditation can be taught over the internet and whether it is an effective intervention by itself. In a non-clinical sample, persons with a broad age range are instructed in different mindfulness techniques over the internet to reduce distress and perceived stress, and to improve mood and emotion regulation over the period of 13 days. They practice 20 minutes a day. Persons with suicidal ideation, psychotic symptoms, high distress and minors could not participate. The study was designed and conducted as master thesis study.

Brief Summary in Scientific Language

The training consisted of two 6 day modules which were delivered via the internet. Participants log on to a secure homepage at the university of Vienna and listened to the exercises which were provided as audiofile in the first week. In the second week participants practice the techniques with a flash-animated surrounding to support the affect labelling aspect of the training.

Organizational Data

- DRKS-ID: **DRKS00003209**
- Date of Registration in DRKS: **2011/07/27**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***



Secondary IDs

Health condition or Problem studied

- ICD10: **Z73 - Problems related to life-management difficulty**
- ICD10: [---]* - [---]*

Interventions/Observational Groups

- Arm 1: **Mindfulnessstraining, 13 days, 2 Modules a 6 days. Module 1: Audiofiles with guided mindfulness techniques. Module 2: flash-animated exercise to improve affect labelling and support exercising the techniques learned in M1.**
- Arm 2: **Waitlist, started training when treatment-group finished the training.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]*
- Allocation: **Randomized controlled trial**
- Blinding: **Open (masking not used)**
- Who is blinded: [---]*
- Control: **Active control**
- Purpose: **Other**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): [---]*

Primary Outcome

Distress and perceived stress were measured at baseline and after 13 days, when the training had ended. There was also a 3-month follow-up. Distress was measured with the BSI (Brief Symptom Inventory, Franke, 2000) and perceived stress with the PSQ (Perceived Stress Questionnaire, Fliege et al., 2005). It was expected that an improvement of both parameters could be documneted after the training.

Secondary Outcome

Mindfulness, mood and emotion regulation skills were measured at baseline, after 13 days and at a 3-month follow-up were measure with the FMI (Freiburg



Mindfulness Inventory, Walach et al., 2006), emotion regulation with the EMO-CHECK/SEK-27 (Berking & Znoj, 2008) and mood with the PANAS (Positive Affect Schedule Negative Affect Schedule, Crawford & Henry, 2004), which was included in the EMO-CHECK. It was expected that mindfulness, emotion regulation and positive affect would improve. Negative affect was expected to decrease.

Countries of recruitment

- AT **Austria**
- DE **Germany**
- CH **Switzerland**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2010/02/16**
- Target Sample Size: **50**
- Monocenter/Multicenter trial: [---]*
- National/International: **International**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **75 Years**

Additional Inclusion Criteria

Internet access

Exclusion criteria

Psychotic, suicidal ideation, current psychotherapeutic treatment

Addresses



■ **Primary Sponsor**

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

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2010/07/10**

Trial Publications, Results and other documents

- Trial results **A randomized controlled pilot study of a brief web-based mindfulness training.**

* 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.