Trial Description

Title

EFFECTIVENESS AND ACCEPTABILITY OF MODERATE CONTINUOUS BED-TIME REDUCTION IN THE SELF-MANAGEMENT OF MILD DEPRESSION

Trial Acronym

GET.UP!

URL of the trial

http://www.deutsche-depressionshilfe.de/stiftung/forschungszentrum.php

Brief Summary in Lay Language

Most patients with depressive disorders suffer from sleep problems: They have problems initiating sleep, experience frequent nocturnal awakenings or awake before the envisioned wake-up time. In most cases they feel exhausted during the day and consider themselves sleepy. Therefore, many tend to go to bed early, remain in bed longer in the morning or try to get additional sleep during the day, all in hope to finally rest-out. However, in most cases longer bed times do not result in less fatigue, but often a deterioration of mood is experienced. This is due to depression being associated with a state of hyperarousal and inner tension, which is increased by inactivity and sleep. Therefore, long bed times lead to a worsening of the situation and, although it seems counter-intuitive for most affected persons, it is recommended to spend the day outside the bed with moderate physical acitivity and reduce bed and sleep times.
The „Get.Up!“-study seeks to investigate the antidepressant effects of a continuous moderate bed-time restriction. The efficacy of such an intervention will be compared to an established relaxation program, which also aims at reducing states of inner tension and hyperarousal. 250 participants and with habitual bed-times above 9 hours per day and mild to moderate forms of depression will be included in the study.
To facilitate the documentation of individual bed-times and mood-ratings as well as to give support in the self-administered modification of bed-times, a smartphone app has been developed that all study participants will receive. By random selection, all study participants will be allocated to one of the two study groups (bed-time restriction or relaxation training), which shall than be performed for 6 weeks. The Get.Up!-App enables a mild to moderate version of the bed-time restriction: Bed-times will be reduced to an amount that still allows sufficient sleep but avoids excessive bed-times and oversleeping. Participants in the relaxation condition will be learn to perform the progressive muscle relaxation by receiving weekly written materials and audio-files for performing the training at home.
Based on the documentations in the smartphone-app and periodic telephone interviews it will be investigated how both self-management conditions affect sleep habits and mood ratings. After 6 weeks both groups will be compared in respect to the amount of depressive symptomatology.

Brief Summary in Scientific Language

Mild depressive syndromes are very prevalent among primary care patients. For this large group of patients, evidence based treatment recommendations (for self-administered forms also) have to be developed. To reduce sleep in patients with depression who mostly suffer from insomnia and exhaustion might seem counterintuitive. However, a variety of arguments indicate that oversleeping can worsen depressive symptoms and that chronic and mild restriction of sleep time can have antidepressant effects.
Therefore, primary aim of the present trial is to prove the antidepressive efficacy of 6 weeks of continuous moderate bed-time reduction (CMBR) in the self-management of mild depression, compared to a self-administered relaxation program (control condition). In Addition, possibly side effects, e.g. gender differences in efficacy and acceptance of this intervention will be explored. Thus, the trial will be a 6-week open randomized controlled clinical trial with 2 arms. All interventions will be performed in a naturalistic setting.
CMBR will be carried out by applying a specially programmed smartphone app ("Get.Up!"-App), which all subjects will use for daily logging of sleeping hours and mood ratings. In the CMBR group, the app also provides assistance to calculate the individual bed time (i.e. the total time spent in bed) and gives recommendations for new bed times (CMBR recommendations will always range from 6.5 to 7.5 hours, thus subjects will not be chronically sleep deprived). Study participants will wear an actigraph during the entire trial, which in the CMBR group is used to monitor compliance with the recommended bed times and changes in sleep patterns.
From about 500 consecutively screened adult participants, 250 participants with mild to moderate depressive episodes (F32.0, F32.1, F33.0, F33.1) will form the intent-to-treat population. 224 participants will be analysed. Primary outcome will be the Inventory for Depressive Symptomatology (IDS-C) total score assessed by blinded raters at the end of intervention. We expect the self-administered CMBR to be superior to the control condition regarding antidepressive efficacy.

Organizational Data

- DRKS-ID: **DRKS00009031**
- Date of Registration in DRKS: **2015/08/07**
- 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.: **245-14-14072014 , Ethikkommission an der Medizinischen Fakultät der Universität Leipzig**

Secondary IDs

Health condition or Problem studied

- ICD10: **F32.0 - Mild depressive episode**
- ICD10: **F32.1 - Moderate depressive episode**

- ICD10: **F33.0 - Recurrent depressive disorder, current episode mild**
- ICD10: **F33.1 - Recurrent depressive disorder, current episode moderate**

Interventions/Observational Groups

- Arm 1: **6 weeks of self-administered continuous moderate bed-time reduction (CMBR).**

  Individual specifications for CMBR-goals (ranging from 6.5 to 7.5 hours) according to individual sleep habits recorded in the baseline phase of the study will be given by a smartphone app ("GET.UP!"-App) specifically designed for the trial. Feedback on achivement of CMBR-goals will be given daily by the smartphone app.
- Arm 2: **6 weeks of self-administred progressive muscle relaxation training according to Jacobson. Each week participants in the control group will receive a new lecture in form of written information forms and audio-files for practice.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **assessor**
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Inventory of depressive symptomatology clinician version (IDS-C) total score assessed by blinded raters at the end of the intervention (6 weeks)

Secondary Outcome

Clinical Global Impressions (CGI) total score (non-blinded rating) after intervention;
Inventory of Depressive Symptomatology self-rating version (IDS-SR) total score after intervention;
Change in IDS-C and IDS-SR total scores from baseline

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Department of Psychiatry, University Hospital Leipzig, Leipzig**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/10/23**
- Target Sample Size: **250**
- 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

diagnosis of current mild or moderate depressive episode (F32.0, F32.1, F33.0, F33.1); IDS-C score between 12 and 23 points; habitual average bed time >= 9 hours; availability of a smartphone with android OS (due to utilisation of GET.UP!-App throughout the study)

Exclusion criteria

ICD-10 diagnoses: dementia, schizophrenia, mania and bipolar affective disorders, OCD (F0, F2, F30, F31, F42); known personality disorder (F60.2, F60.31); acute suicidality (MADRS item 10 ≥ 4); Bochumer Screnning Bipolar (BSB) Mania Scale Score ≥ 12; ongoing psychotherapy or pharmacotherapy (exeption: stable treatment with max.1 substance since more than 3 weeks before randomisation; known alcohol- or drug misuse within 6 month before randomisation; pregnancy, lactation period or newborn child in household; shiftwork, professional driver or work with heavy machinery

Addresses

■ **Primary Sponsor**

Universitätsklinikum Leipzig
Liebigstr. 18
04103 Leipzig
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **www.uniklinikum-leipzig.de**

■ **Contact for Scientific Queries**

Klinik und Poliklinik für Psychiatrie und Psychotherapie, Universitätsklinikum Leipzig / Forschungszentrum Depression der Stiftung Deutsche Depressionshilfe
Mr. Professor Ulrich Hegerl
Semmelweisstraße 10
04103 Leipzig
Germany

Telephone: **0341-97 24 530**
Fax: **[---]***
E-mail: **Ulrich.Hegerl at medizin.uni-leipzig.de**
URL: **http://psychiatrie.uniklinikum-leipzig.de/psychiatrie.site,postext,stiftung-deutsche-depressionshilfe.html**

■ **Contact for Public Queries**

Klinik und Poliklinik für Psychiatrie und Psychotherapie, Universitätsklinikum Leipzig / Forschungszentrum Depression der Stiftung Deutsche Depressionshilfe
Mr. PhD Christian Sander
Semmelweisstraße 10
04103 Leipzig
Germany

Telephone: **0341-97 24 558**
Fax: **[---]***
E-mail: **Christian.Sander at medizin.uni-leipzig.de**
URL: **http://psychiatrie.uniklinikum-leipzig.de/psychiatrie.site,postext,stiftung-deutsche-depressionshilfe.html**

■ **Contact for Public Queries**

Forschungszentrum Depression der Stiftung Deutsche Depressionshilfe
Ms. M. Sc. Psychologie Mandy Rogalla
Semmelweisstraße 10
04103 Leipzig
Germany

Contact for Public Queries

Forschungszentrum Depression der Stiftung Deutsche Depressionshilfe
Ms. M. Sc. Psychologie Mandy Rogalla
Semmelweisstraße 10
04103 Leipzig
Germany

Telephone: **DE 0341 97 24 550**
Fax: **[---]***
E-mail: **mandy.rogalla at medizin.uni-leipzig.de**
URL: **[---]***

Sources of Monetary or Material Support

- **Private sponsorship (foundations, study societies, etc.)**

Stiftung Deutsche Depressionshilfe
Semmelweisstraße 10
04103 Leipzig
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting ongoing**
- 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.*