Trial Description

Title

Online sleep training for stressed employees

Trial Acronym

[---]*

URL of the trial

http://www.geton-training.de/Regeneration.php

Brief Summary in Lay Language

The recovery training is for employees, who have sleep problems and problems with mentally detaching from work. After stress at work we mentally and physically seek for recovery. Many employees experience rather loose boundaries between work and private life. Due to Internet and smartphones, many employees are nonstop available for work and private spaces for recovery are experienced less. Some stress factors are then seen as inevitable. Esspecially then, phases of successful recovery are very important to prevent chronic stress reactions. Chronic stress reactions are developed, when it is repeatedly not possible to establish recovery. Recovery means: a)mental detachment from work, because worrying and rumination about problems at work can lead to the same strain as work itself. b) recovery activities, that are important to promote mental detachment (to "switch off") and c) restaurative sleep. This is the most important element of recovery. Occupational stress and esspecially corresponding rumination and worrying lead to increased strain and tension, which is one cause for sleep disorders. 10 % of the population suffer from problems falling asleep, sleeping through or waking to early in the morning.
Aim and hypotheses: the online training which is to evaluate was already evaluated in two randomized controlled trials successfully. the samples consisted of teachers. the primary aim of this study is to make conclusions on the generalizability of the previous results on employees in general. Also, we aim to investigate a previously not tested format of the training. while in study 1, an online coach gave feedback after each lesson and in study 2, participants went through the training on their own as pure self-help, now in this study, the format tested is "feedback on demand".

Brief Summary in Scientific Language

Insomnia and work-related stress often co-occur. Both are associated with personal distress and diminished general functioning, as well as substantial socio-economic costs. Internet-based CBT-I interventions (ICBT-I) could potentially reduce the given supply gap and are proven to be effective. There is less known about the efficacy of ICBT-I in populations affected by work-related stress. The present training specifically addresses those employees who have problems with seperating work and private life, e.g. because of anticipated expectation of 24/7 availability. Given a complicated seperation between work and private life,

**detachment from work and recovery in general becomes more difficult.
In a two-arm randomized controlled trial (N = 128), the effects of a guided ICBT-I training ("GET.ON Recovery") will be compared to a waitlist-control condition, pre-treatment, post-treatment and at 6-months follow-up.German teachers with clinical significant insomnia complaints and work-home interference are included. Apart from classic CBT-I elements (e.g. sleep hygiene, sleep restriction) GET.ON Recovery accentuates the promotion of recreational activities and cognitive detachment. The primary outcome is insomnia severity.**

Organizational Data

- DRKS-ID: **DRKS00006223**
- Date of Registration in DRKS: **2014/11/24**
- 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.: **Eb-Antrag-Lehr201403_Schlaftraining , Ethikbeirat der Leuphana Universität Lüneburg**

Secondary IDs

Health condition or Problem studied

- ICD10: **F51 - Nonorganic sleep disorders**
- ICD10: **Z73 - Problems related to life-management difficulty**

Interventions/Observational Groups

- Arm 1: • **Arm 1: six week online training with consisting of 6 modules which each take about 1 hour. Format: feedback on demand. Feedback on single online exercises is only given when participants asks for it. Nevertheless, during the training, the primary study investigator is available for technical questions. Half of the total sample (N=128, n = 64) is randomised in Arm 1. this group gets "GET.ON Recovery", a sleep training based on Cognitive Behavioral Therapy, that is specifically designed for employees with occupational strain. This training aims to reduce insomnia severity, measured by the Insomnia Severity Index (ISI). Insomnia Severity as well as secondary outcomes like rumination or depressive symptoms will be measured pre-treatment, post-treatment (8 weeks) and at 6-months follow-up.**
- Arm 2: • **Arm 2: waitlist-control-group (receives online-training without feedback on demand following the 6-months follow-up). Before Arm 1 gets access to the online training (GET.ON Recovery), both groups, Arm 1 and Arm 2,fill in the Baseline questionnaires (online). After Arm 1 worked through the online training (8 weeks), Arm 1 and Arm 2 fill in the post-questionnaires**

(online). At 6-months follow-up, again online questionnaires are to be filled in. The questionnaires assess insomnia severity, rumination, depressive symptoms, etc. After the last assessment, 6 months after randomization, Arm 2 receives access to GET.ON Recovery. During the traning, Arm 2 does not receive regular e-mail support, but the primary study investigator is available when a participant has a question regarding technical problems.

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **No treatment**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Insomnia Severity, measured with the Insomnia Severity Index (ISI; Morin, 2011) at Baseline, after the training (8 weeks) and at 6-months follow-up

Secondary Outcome

depressive Symptoms (CES-D): pre-treatment, post-treatment and at 6-months follow-up; worrying (Penn State Worry Questionnaire, PSWQ): pre, post, 6 months follow-up; - psychological strain in the work context (Irritation Scale, IS): pre, post, 6-months Follow-up; - segmentation supplies scale (by Kreiner, 2006), pre, post, 6-months-follow-up; - work-home interference (SWING), pre, post, 6-Months-Follow Up;
- restorativeness of the sleep(Schlaffragebogen B): pre, post, 6 months follow-up;
recovery experience (Recovery Experience Questionnaire): pre, post, 6-months follow up;
frequency of recovery activities (Recreation experience and activity questionnaire, ReaQ): pre, post, 6 months follow up;
Health-Related Quality of Life (Short Form SF-12 Health Survey Questionnaire): pre, post, 6 months follow-up;
costs associated with nonorganic insomnia (for cost-effectiveness analyses) (German adaptation of the Trimbos/iMTA questionnaire for costs associated with psychiatric illness (TiC-P)): pre, 6-months follow-up;
work-related stress (Effort Reward Imbalance, short version, ERI-S): pre, post;
side effects of the online training (adaptation of the German Inventary for the Assessment of negative side effects of psychotherapy, INEP): 6 months follow-up;
satisfaction with the online training (german adaptation of the ZUF 8, which is the german version of the Client Satisfaction Questionnaire, CSQ): post

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2014/12/01**
- Target Sample Size: **128**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **70 Years**

Additional Inclusion Criteria

**- clinic significant insomnia complaints (Insomnia Severity Indey≥15); - occupation which complicates the separation of work from private life (segmentation supplies scale < 2.25); - currently employed/in work (not unemployed)
; - access to the internet; - valid e-mail address**

Exclusion criteria

- at Baseline slightly suicidal (BDI II item 9 >1); - currently in psychotherapy or in a waitlist for psychotherapy; not willing to sign informed consent

Addresses

- **Primary Sponsor**

  **Leuphana Universität Lüneburg GET.ON Gesundheitstraining.Online / Innovations-Inkubator
  Mr. Dr. Dirk Lehr**

Primary Sponsor

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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.)**

European Union (finanzielle Förderung organisiert über NBank bzw. Niedersächsisches Ministerium für Wirtschaft, Arbeit und Verkehr
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URL: **http://www.nbank.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.*