

Trial Description

Title

Online self help for better sleep in teachers with high occupational strain

Trial Acronym

[---]*

URL of the trial

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

Brief Summary in Lay Language

The recovery training is for teachers, who have sleep problems and problems with mentally detaching from work. After stress at work we mentally and physically seek for recovery. Especially for teachers, who experience rather loose boundaries between work and private life, successful recovery is very important. Some stress factors are even inevitable. Especially 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) restorative sleep. This is the most important element of recovery. Occupational stress and especially 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.

The aim of the present study is to evaluate an online self help training, that is specifically designed to help teachers find restorative sleep and to mentally detach from work. For this evaluation, participants are randomly allocated into one of two groups: One half gets immediate access to the training, the other half following a waiting period of 8 weeks.

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. Thus, the aim of the present study is to evaluate an ICBT-I training tailored to teachers affected by occupational stress.

In a two-arm randomized controlled trial (N = 128), the effects of a self help ICBT-I training ("GET.ON Recovery") will be compared to a waitlist-control condition pre-treatment and post-treatment. German teachers with clinical significant insomnia complaints and work-related strain 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: **DRKS00004984**
- Date of Registration in DRKS: **2013/05/16**
- 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.: **2013-10-K , Marburg- Ethikkommission des Fachbereichs Psychologie der Philipps Universität Marburg**

Secondary IDs

Health condition or Problem studied

- ICD10: **F51.0 - Nonorganic insomnia**

Interventions/Observational Groups

- Arm 1: • **Arm 1: six week online training (pure self-help). Training consists of 6 modules, each taking circa 1 h to work through. During the training, the primary study investigator is available in case problems or questions occur. 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 teachers 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 and post-treatment (8 weeks)**
- Arm 2: • **Arm 2: waitlist-control-group (receives online-training without supporting e-mails 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). The questionnaires assess insomnia severity, rumination, depressive symptoms, etc. After that last assessment, 8 weeks after randomization, Arm 2 receives access to GET.ON Recovery (self-help). During the training, the primary study investigator is available in case problems or questions occur.**

Characteristics



- Study Type: **Interventional**
- Study Type Non-Interventional: [---]*
- Allocation: **Randomized controlled trial**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Control group receives 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 and after the training (8 weeks)

Secondary Outcome

depressive Symptoms (CES-D): pre-treatment, post-treatment (8 weeks); worrying (Penn State Worry Questionnaire, PSWQ): pre, post; - psychological strain in the work context (Irritation Scale, IS): pre, post; sleep effort (Glasgow Sleep Effort Scale): pre, post (8 weeks); - restorativeness of the sleep (Schlaffragebogen B): pre, post; subjective quality of sleep (one item of the Pittsburgh Sleep Quality Index, PSQI): pre, post; recovery experience (Recovery Experience Questionnaire): pre, post; frequency of recovery activities (Recreation experience and activity questionnaire, ReaQ): pre, post; Health-Related Quality of Life (Short Form SF-12 Health Survey Questionnaire): pre, post; 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, post; work-related stress (Effort Reward Imbalance, short version, ERI-S): pre 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: **2013/05/16**
- 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: **no maximum age**

Additional Inclusion Criteria

clinic significant insomnia complaints (Insomnia Severity Index ≥ 15); - occupational strain/problems with mentally detaching from work (irritation scale, subscale "cognitive Irritation" ≥ 15); - currently employed/in work as a teacher; - 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

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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.)**

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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.)**

Unfallkasse NRW



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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2014/11/24**

Trial Publications, Results and other documents

- Paper **Ebert et al. (2015). Restoring depleted resources: Efficacy and mechanisms of change of an internet-based unguided recovery training for better sleep and psychological detachment from work. Health Psychology, Vol. 34, Supplement, 1240-1251**

* 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.