

Trial Description

Title

Freiraum im Kopf: A study comparing the efficacy of two online training programs for sustainable recovery from work-related perseverative thinking and stress.

Trial Acronym

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URL of the trial

<https://www.freiraum-im-kopf.de>

Brief Summary in Lay Language

Taking deliberate breaks from work demands is essential for mental health. Regular breaks used for recovery are central to successful stress reduction and thus to the avoidance of longer-term negative consequences of occupational stress.

The aim of the planned study is to investigate the effectiveness of two online training programs to promote recovery processes in the working population. The training programs offer a mixture of scientific background information on the topic of switching off from work and various exercises for recovery in everyday life. Individuals will be randomly assigned to one of four groups. Group A and B will receive access to one of the two training programs two weeks after the start of the study. Group C and D receive access to one of the two training programs ten weeks after the start of the study. To test the effectiveness of the training programs, all participants will be asked to complete online questionnaires (at the beginning of the study, immediately after finishing the training, and three months later). In the course of the study, all participants will be asked to complete short questionnaires focusing on their current stress and well-being several times a day in three different weeks (directly before and directly after the training and three months later) as well as parallel to the training.

Brief Summary in Scientific Language

Low-threshold and evidence-based interventions addressing chronic stress are important for promoting mental health. Previous research has shown that work-related perseverative thinking and a low level of distancing from potentially stressful occupational issues (psychological detachment) mediate the relationship between perceived work demands and measures of stress (e.g., low sleep quality, fatigue, stress symptomatology). In this vein, short-term stress reactions can lead to chronic stress reactions. The aim of the present randomized-controlled trial is to examine the effectiveness of two 6-week online interventions to reduce work-related perseverative thinking. One training is guided by ideas from Behavioral Activation in that planning and performing restorative activities is encouraged. The other training is based on strategies from mindfulness-based approaches that can reduce thoughts revolving around work and affective rumination via awareness of non-work time. The target audience is individuals over 18 years old working at least part-time. Participants are randomly assigned to one of four

groups: Groups A and B start immediately with the training programs, and groups C and D are waitlist control groups that are likewise admitted to one of the two training programs after completion of the posttest in the intervention groups. The present study is based on a so-called "measurement bursts design" in which conventional measurement time points (pretest, posttest, and a 3-month follow-up) are combined with phases of intensive longitudinal assessments.

Do you plan to share individual participant data with other researchers?

No

Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00024933**
- Date of Registration in DRKS: **2021/04/07**
- 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.: **96_2017 , Ethikkommission des Fachbereichs 8, Universität Koblenz-Landau, Campus Landau**

Secondary IDs

Health condition or Problem studied

- Free text: **work-related stress**
- Free text: **Lack of relaxation**

Interventions/Observational Groups

- Arm 1: **Group A receives access to the behaviorally oriented online training approximately two weeks after the pretest. The training first introduces the psychoeducational basics of psychological detachment. In the training, participants receive suggestions for recovery exercises.**
- Arm 2: **Group B receives access to the mindfulness-based online training approximately two weeks after the pretest. Here, too, an introduction to the psychoeducational basics of psychological detachment takes place first. Subsequently, different mindfulness-based techniques are introduced to the participants and practiced with them.**

Arm 2: **Group B receives access to the mindfulness-based online training approximately two weeks after the pretest. Here, too, an introduction to the psychoeducational basics of psychological detachment takes place first. Subsequently, different mindfulness-based techniques are introduced to the participants and practiced with them.**

- Arm 3: **Group C will receive access to the behavioral-based training approximately 10 weeks after the pretest.**
- Arm 4: **Group D will receive access to mindfulness-based training approximately 10 weeks after the pretest.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]*
- Allocation: **Randomized controlled trial**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Other**
- Purpose: **Prevention**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

To evaluate the effectiveness of both training programs, participants answer an online questionnaire at pretest (t1), after completion of the training (t2), and 3 months after completion of the training (t3).

The primary endpoint is determined at t2 with items on work-related perseverative thinking (unpublished)

Secondary Outcome

Psychological detachment

Sonnentag S, Fritz C. The Recovery Experience Questionnaire: development and validation of a measure for assessing recuperation and unwinding from work. Journal of Occupational Health Psychology. July 2007;12(3):204-221. (t1, t2, t3).

State of being recovered

Sonnentag S, Krueger U. Psychological detachment from work during off-job time: The role of job stressors, job involvement, and recovery-related self-efficacy. Eur J Work Organ Psychol. 2006;15:197-217. (t1, t2, t3)

Fatigue

Frone MR, Reis D, Ottenstein C. A German version of the Three-Dimensional Work Fatigue Inventory (3 D - WFI): Factor structure, internal consistency, and correlates. Stress Health. 2018;34:674-80. (t1, t2, t3)

Sleep quality

Görtelmeyer R. Schlafragebogen A und B - Revidierte Fassung [Standardized Sleep Inventory for the SF-A/R and SF-B/R-revised version]. Göttingen: Hogrefe; 2011

Affective well-being

Steyer R, Eid M, Schwenkmezger P. Modeling true intraindividual change: True change as a latent variable. Methods Psychol Res. 1997;2:21-33. (t1, t2, t3)

Negative activation

Yik M, Russell JA, Steiger JH. A 12-point circumplex structure of core affect. Emotion. 2011;11:705-31. doi:10.1037/a0023980. (t1, t2, t3)

Stress

Reis D, Lehr D, Heber E, Ebert DD. The German Version of the Perceived Stress Scale (PSS-10): Evaluation of Dimensionality, Validity, and Measurement Invariance With Exploratory and Confirmatory Bifactor Modeling. Assessment. 2017;;107319111771573

Countries of recruitment

- **DE Germany**

Locations of Recruitment

- other **Saarland University, Saarbrücken**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2021/04/20**
- Target Sample Size: **600**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **99 Years**

Additional Inclusion Criteria

mobile internet access, smartphone

Exclusion criteria

ongoing psychotherapy, unemployed

Addresses

■ Primary Sponsor

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■ **(leading) Ethics Committee**

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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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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.