## Trial Description

### Title

**Comparative efficacy and cost-effectiveness of  Internet-based Stressmanagment with and without guidance.**

### Trial Acronym

**GET.ON Stress Role of Support?**

### URL of the trial

**https://geton-training.de/stressbewaeltigung.php**

### Brief Summary in Lay Language

**Occupational stress constitutes a risk factor for a variety of psychological and physical disorders. In general, stress is associated with unfavourable health behaviours and leads to loss of productivity at work and affects private life. The "Flexible Internet Training for managing work-related stress" aims to reduce perceived stress and depressive symptoms. It targets employees who are seeking help for coping with personal problems and dealing with difficult emotions. The aim of the study is to evaluate the efficacy of the online training, which can support participants in recognizing their personal stressors, choosing effective coping strategies and strengthening their abilities to solve personal and work-related problems in a systematic and effective manner. Furthermore, it aims to improve their way of dealing with stress and difficult emotions in occupational and private life. This study will compare three study arms: pure self-help, guided self-help, and a 6-month waiting list control group.**

### Brief Summary in Scientific Language

**Work-related stress is associated with a variety of mental and emotional problems, such as symptoms of depressions, anxiety, and sleep disturbances. This can lead to substantial economic costs due to loss of productivity, absenteeism or inability to work. There is a considerable amount of evidence on traditional face-to-face stress management interventions; however, they are costly, time-consuming and only available for a certain number of people. The aim of the study is to assess the comparative efficacy and cost-effectiveness of an internet-based self-help stress managment program and a guided self-help version of the same program. N=396 employees experiencing high levels of stress (Perceived Stress Scale ≥ 22) will be randomly allocated into one of three groups: pure self-help, guided self-help or a 6-month waiting list control group. The intervention is based on problem- and emotion-focused stress management according to Lazarus and contains systematic problem solving as well as effective strategies for emotion regulation.  Data is collected in a baseline survey, seven weeks and six months after randomization. Primary Outcome is perceived stress.**

## Organizational Data

- DRKS-ID: **DRKS00005687**
- Date of Registration in DRKS: **2014/06/06**
- 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.: **Aktenzeichen 2014-05k , Marburg - Ethik-Kommission des Fachbereichs Psychologie der Philipps-Universität Marburg**

## Secondary IDs

## Health condition or Problem studied

- Free text: **work-related stress**

## Interventions/Observational Groups

- Arm 1: **intervention group A: Online Training consisting of 7 sessions. Each session will be completed in approximately 45-60 minutes. Four weeks after finishing the training, participants complete an additional booster session. Questionnaires are completed at pre- and posttest (7 weeks), as well as at 6 months follow up.**
- Arm 2: **intervention group B: Online Training consisting of 7 sessions. Each session will be completed in approximately 45-60 minutes. Participants receive feedback on demand via e-mail from an online coach. Four weeks after finishing the training, participants complete an additional booster session. Questionnaires are completed at pre- and posttest (7 weeks), as well as at 6 months follow up.**
- Arm 3: **waitlist control group: After 6 months, participants obtain access to the same training as participants of the intervention group A. Questionnaires are completed at pre- and posttest as well as 6 months follow up.**

## Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **data analyst**
- Control: **Active control, No treatment**
- Purpose: **Prevention**
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Study Type: **Interventional**

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Blinding: **[---]***

Who is blinded: **data analyst**

Control: **Active control, No treatment**

Purpose: **Prevention**

Assignment: **Parallel**

- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

## Primary Outcome

**Perceived Stress, measured with the Perceived Stress Scale (PSS-10; Cohen, 1983) at Baseline, after the training (7 weeks) and at 6-months follow-up (6-M-FU).**

## Secondary Outcome

**• Emotional exhaustion (Maslach Burnout Inventory, MBI-GS-D, emotional exhaustion scale, Maslach & Jackson, 1981): pre, post (7 weeks), 6-M-FU**
**• Depressive symptoms (CES-D, Hautzinger & Bailer, 1993): pre, post, 6-M-FU**
**• Self-assessed emotional competences (SEK-27, Berking & Znoj, 2008): pre**
**• Dimensions of personality (Big Five Inventory, BFI-10, Rammstedt & John, 2007): pre**
**• Volitional competences (Short Form of the Volitional Components Questionnaire, SSI-36, Forstmeier & Rüddel, 2008; subscales of attentional focusing, self-motivation, goal recollection, forgetfulness prevention, impulse control and initiation control): pre**
**• Self-efficacy (SWE, Schwarzer & Jerusalem, 1999): pre**
**• Self-Regulation Scale (SRQ, Schwarzer, 1999): pre**
**• Self-Control Scale (SCS-K-D. Bertrams & Dickhäuser, 2009): pre**
**• Therapy motivation questionnaire (FPTM-23, Schulz, Lang, Nübling, & Koch, 2003): pre**
**• Task-related motivational and volitional factors in line with the Health Action Process Approach (HAPA, according to guidelines by Schwarzer et al., 2003): pre**
**• Effort-Reward Imbalance, short version (ERI-S, Siegrist, Wege, Pühlhofer, & Wahrendorf, 2009): pre, post, 6-M-FU**
**• Work engagement (Utrecht Work Engagement Scale, UWES, Schaufeli, Salanova, González-Romá, & Bakker, 2002): pre, post, 6-M-FU**
**• Quality of life and subjective functioning (Short form health survey, SF-12, Morfeld, Kirchberger, Bullinger): pre, post, 6-M-FU**
**• Quality of life for economic evaluation (EuroQol, Graf, Claes, Greiner, & Uber): pre, post, 6-M-FU**
**• Current occupation (self-development): pre**
**• Cost related to mental and physical impairment (German adaption of Trimbos / iMTA questionnaire for Costs associated with Psychiatric Illness, TiC-P, Van Roijen Hakkaart, 2002): pre, post, 6-M-FU**
**• Dropout reasons (self-development): post**

**• Training satisfaction: self-development based on participants´satisfaction questionnaire (ZUF 8, Schmidt, Lamprecht, Wittmann, 1989) and the Client Satisfaction Questionnaire (CSQ, Attkisson & Zwick, 1982): post**
**• Work Limitations Questionnaire (WLQ-8, Lerner, Amick, Rogers, Malspeis, Bungay, & Cynn, 2001), measuring the on-the-job impact of chronic health problems (pre)**
**• Connor-Davidson Resilience Scale (CD-RISK, Campbell-Sills & Stein, 2007), measuring the abil- ity to cope with adversity (pre)**
**• Internet Affinity Scale (Papacharissi & Rubin, 2000), measuring internet affinity (pre)**

## Countries of recruitment

- DE **Germany**

## Locations of Recruitment

- other **Leuphana Universität Lüneburg (Teilnehmer werden über die Forschungswebsite www.geton-training.de rekrutiert/participants are recruited via the research website www.geton-training.de), [---]***

## Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2014/09/24**
- Target Sample Size: **408**
- 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

**distinct level of perceived stress (Perceived Stress Scale [PSS-10] ≥ 22), access to the internet, valid e-mail-adress, employed**

### Exclusion criteria

**- at baseline slightly suicidal (BDI II item 9 > 1),**
**- not willing to sign informed consent,**
**- diagnosed psychosis or dissociative symptoms in the past**

## Addresses

- **Primary Sponsor**

  **Leuphana Universität Lüneburg GET.ON Gesundheitstraining.Online / Innovations-Inkubator**
  **Mr. Dr. David Daniel Ebert (Ansprechpartner des Sponsors)**
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- **Contact for Scientific Queries**

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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 planned**
- 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.*