

**PLEASE NOTE:** *This trial has been registered retrospectively.*

## Trial Description

### Title

#### **HOLIDAILY - The vacation-coach**

**A smartphone-based application for sustainable recovery from severe occupational stress**

### Trial Acronym

**Holiday**

### URL of the trial

**<http://www.holiday.de>**

### Brief Summary in Lay Language

**Recovery is a crucial component for psychological and physiological health. It is pivotal for primary prevention to reduce stress, thus enabling recovery to being promoted. Occupational stress is core to this issue, resulting in research increasingly focusing on this area.**

**The target audience of this online-based training, in form of the App “Holiday”, are workers dealing with intense occupational strain. The aim of this proposed study is to investigate the effectiveness of an App-based recovery training. Due to the continuous strain placed on workers by occupational stress, recovery activities may have been neglected. Hereby, spending time on vacation provides the ideal environment to reengage and enjoy the application of recovery exercises. This may also provide the stepping stone, where recovery exercises are adopted and maintained on a daily basis, even after vacation. The objective of the examined App “Holiday” is to support users during this process.**

**For this purpose, workers will be randomized into one of two groups. Group A receives access to “Holiday” two weeks prior to their vacation. On a daily basis, participants receive several suggestions for recovery activities. Group B receives access to the App two weeks after returning from their vacation, providing them with the opportunity to engage in recovery activities during their daily life or their next vacation.**

**To evaluate the effectiveness of this training, participants from both groups will be asked to complete five online questionnaires (two weeks prior to their vacation, last working day, middle of vacation, end of first working day, two weeks post vacation). Group A receives four weeks’ post vacation an additional questionnaire (extended Follow-Up).**

### Brief Summary in Scientific Language

**For the purpose of promoting psychological health and preventing issues such as chronic stress, burnout and depression, employing innovative and evidence-based measures are vital. Especially, work related rumination i.e. the lack of mental detachment from work related problems, seems to function as a mediator between acute occupational stress and the development of chronic stress, exhaustion and symptoms of depression. This randomized-controlled trial will evaluate the efficacy of the Holidaily-App to reduce mental rumination concerning work related problems.**

**The App was constructed in line with the findings from research on behavioural activation (Mazzucchelli, Kane & Rees, 2010), whereby the rationale for promoting positive activities has been transferred to recovery activities (recovery behaviour).**

**The experience of these recovery activities has been conceptualized according to the DRAMMA model of recovery (Newman, Tay & Diener, 2016) stating that recovery consists of 6 dimensions (DRAMMA: detachment, relaxation, autonomy, mastery, meaning, affiliation). To promote behaviour change, specific behaviour change techniques from Michie et al (2005) taxonomy have been considered. The target group are workers who are at least 18 years old.**

**Two weeks prior to their vacation, participants will be randomly assigned to one of two groups. Group A receives immediate access to Holidaily, which provides activities to promote recovery. In addition, the App is comprised of playful elements (Gamification) e.g. avatar, scoring-system where different levels can be reached. Group B receives access to the App two weeks after they have returned from their vacation. All participants will be asked to complete questionnaires; two weeks prior to their vacation, last working day, middle of vacation, end of first working day and two weeks post vacation. Group A receives four weeks post vacation an additional questionnaire (extended Follow-Up).**

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

[---]\*

### Description IPD sharing plan

[---]\*

## Organizational Data

- DRKS-ID: **DRKS00013650**
- Date of Registration in DRKS: **2018/01/15**
- 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.: **201606 , EB-Antrag Lehr201606\_holidaily; Ethikbeirat Leuphana Universität Lüneburg**



## Secondary IDs

## Health condition or Problem studied

- Free text: **Occupational Stress**
- Free text: **Burnout**
- Free text: **Lack of relaxation or leisure time (Z73.2)**

## Interventions/Observational Groups

- Arm 1: **Arm 1: Group A: receives two weeks prior to their vacation access to the App “Holidaily”.**  
**On a daily basis participants will be presented with an option of three recovery exercises (Daily’s). Alternatively, within the framework of the presented App, participants can also create their own recovery activity. After completing an activity, participants will be asked to rate their experienced recovery, along several recovery dimensions.**  
**Furthermore, participants will also be asked to rate their wellbeing on a daily basis.**  
  
**Participants receive points for each completed recovery activity and rating of their wellbeing. Within the framework of the App “Holidaily”, participants receive a weekly email summarising the amount of completed activities and their “recovery” process.**
- Arm 2: **Arm 2: Group B: receives access to the App “Holidaily” two weeks post their vacation. Participants can employ the App during their daily life or during their next vacation or weekend trip. The usage of the App does not differ to that of Arm 1.**

## Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]\*
- Allocation: **Randomized controlled trial**
- Blinding: [---]\*
- Who is blinded: [---]\*
- Control: **Control group receives no treatment**
- Purpose: **Prevention**
- Assignment: **Parallel**
-

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Who is blinded: [---]\*

Control: **Control group receives no treatment**

Purpose: **Prevention**

Assignment: **Parallel**

Phase: **N/A**

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

### Primary Outcome

**The primary endpoint will be work related perseverative thinking (work related rumination). This will be assessed by the means of a validated questionnaire, the irritation scale.**

**To assess the efficacy of the application, participants are asked to answer two weeks prior to their vacation= t1, last working day=t2, middle of vacation=t3, end of first working day=t4, two weeks' post vacation=t5 online questionnaires. Participants from Arm 1. receive an additional questionnaire four weeks' post vacation=t6\*. The primary comparison between study conditions will be conducted two weeks' post vacation (t5).**

**Employed questionnaire:**

**Mohr, G., Müller, A., Rigotti, T., Aycan, Z., & Tschan, F. (2006). The assessment of psychological strain in work contexts. *European Journal of Psychological Assessment*, 22(3), 198-206.**

### Secondary Outcome

**Mental health:**

**- Symptoms of Depression:**

**The PHQ-8 as a measure of current depression in the general population. (PHQ-8 Kroenke K, Strine, Spitzer, Williams, Berry & Mokdad, 2009): Measures depressive symptoms (t1, t4, t5, t6\*).**

**- Emotional exhaustion:**

**Schaufeli, Leiter, Maslach, Jackson. Maslach Burnout Inventory - General Survey (MBI-GS). In: Maslach, Jackson, Leiter, eds. Maslach Burnout Inventory. 3rd ed. Palo Alto, CA: Consulting Psychologists Press; (1996) (t1, t4, t5, t6\*).**

**- Sleep disorder:**

**Validation of the insomnia severity index as an outcome measure for insomnia research. (Bastien CH, Vallières A, Morin CM: 2001): (t1, t2, t3, t4, t5, t6\*).**

**Recovery**

**Recovery in accordance with the DRMMA-Model by Newman DB, Tay L, Diener E.**

**Leisure and Subjective Well-Being: A Model of Psychological Mechanisms as Mediating Factors.** *J Happiness Stud* 2014; 15(3):555-78. (t1, t2, t3, t4, t5, t6\*).

The sum scores and individual components will be considered:

- **Mental detachment and recovery:**

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, t4, t5, t6\*)

- **Autonomy, Mastery and Affiliation:**

Johnston MM, Finney SJ. Measuring basic needs satisfaction: Evaluating previous research and conducting new psychometric evaluations of the Basic Needs Satisfaction in General Scale. *Contemporary Educational Psychology.* October 2010;35(4):280-296. (t1, t2, t3, t4, t5, t6\*).

- **Meaning:**

Hackman JR, Oldham GR. *The Job Diagnostic Survey: An instrument for the diagnosis of jobs and the evaluation of job redesign projects.* New Haven: Yale University; 1974. (t1, t2, t3, t4, t5, t6\*).

**Further measures of recovery:**

- **Need for recovery:**

Measurement quality and validity of the "need for recovery scale"; *Occupational and Environmental Medicine* (van Veldhoven & Broersen, 2003) (t1, t2, t4, t5, t6\*).

- **Recreational activities**

Lehr, D. (2014). *Recreation Experience and Activity Questionnaire (ReaQ).* In Koch, S, Lehr, D. & Hillert, A. *Burnout und chronischer beruflicher Stress.* Göttingen: Hogrefe. (t1, t5, t6\*).

- **Work related rumination:**

Shortened Work-related rumination questionnaire (Querstreet & Croyley, 2012). Affective rumination (items 1, 3, 6), Problem-solving pondering (items 2, 4, 5) (t1, t2, t3, t4, t5, t6\*).

**Resilience factors:**

- **Resilience:**

Leppert, K., Koch, B., Brähler, E., Strauß, B. (2008). Die Resilienzskala (RS) - Überprüfung der Langform RS-25 und einer Kurzform RS-13. *Klinische Diagnostik und Evaluation*, 2, 226-243 (t1,t5,t6\*)

- **Creativity:**

Tierney, P., Farmer, S. M., & Graen, G. B. (1999). An examination of leadership and employee creativity: The relevance of traits and relationships. *Personnel Psychology*, 52, 591-620 (t1,t2,t4,t5,t6\*)

- **Vitality:**

Crawford, John R, & Henry, Julie D. (2004). The Positive and Negative Affect Schedule (PANAS): Construct validity, measurement properties and normative data in a large non-clinical sample. *British Journal of Clinical Psychology*, 43(3), 245-265. (t1, t2, t3, t4, t5, t6\*).

**Occupational factors:**

- **Work-Engagement:**

Seppälä, P., Mauno, S., Feldt, T., Hakanen, J., Kinnunen, U., Tolvanen, A., & Schaufeli, W. B. (2009). The construct validity of the Utrecht Work Engagement Scale: Multisample and longitudinal evidence. *Journal of Happiness Studies*, 10(4), 459-481 (t1,t2,t4,t5,t6\*).

- **Work-Life-Balance:**

Syrek, C. J., Bauer-Emmel, C., Antoni, C. & Klusemann, J. (2011). Entwicklung und Validierung der Trierer Kurzskala zur Messung von Work-Life Balance (TKS-WLB). *Diagnostica*, 57 (3), 134-145 (t1,t2,t5,t6\*).

- **Unfinished tasks:**

**Syrek, C. J., Weigelt, O., Peifer, C., & Antoni, C. H. (201-). Zeigarnik's sleepless nights: How unfinished tasks at the end of the week impair employee sleep on the weekend through rumination. Journal of Occupational Health Psychology. (t1,t2,t4,t5,t6\*).**

- **Work performance:**

**Staufenbiel, T. & Hartz, C. (2000). Organizational Citizenship Behavior: Entwicklung und erste Validierung eines Meßinstruments. Diagnostica, 46, 73-83 (t1,t2,t4,t5,t6\*).**

- **Time pressure:**

**Semmer, N.K., Zapf, D., & Dunckel, H. (1998). Instrument zur streßbezogenen Tätigkeitsanalyse ISTA. In H. Dunckel (Hrsg.). Handbuch der Instrumente zur Arbeitsanalyse. Zürich: Verlag der Fachvereine Hochschulverlag (t1,t2,t4,t5,t6\*).**

## Countries of recruitment

- DE **Germany**

## Locations of Recruitment

- University Medical Center **Leuphana Universität Lüneburg , Lüneburg**

## Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2017/07/06**
- Target Sample Size: **788**
- 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

- **Vacation in foreseeable future**
- **Internet Access**
- **Smartphone**
- **Occupational Stress**

## Exclusion criteria



- **Participation in other training programs**
- **Participation in a psychotherapeutic treatment**
- **Unemployment**
- **Unstable medication usage**

## 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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## **Status**

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): [---]\*

## **Trial Publications, Results and other documents**

DRKS-ID: **DRKS00013650**

Date of Registration in DRKS: **2018/01/15**

Date of Registration in Partner Registry or other Primary Registry: [---]\*



Deutsches Register  
Klinischer Studien

German Clinical  
Trials Register

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\* *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.*