

Trial Description

Title

Otium in the hospital? A mindfulness-based intervention for resident physicians

Trial Acronym

MDA

URL of the trial

<https://www.sfb1015.uni-freiburg.de/en/subprojects/p-practices#p3>

Brief Summary in Lay Language

Background and Purpose: Work-related mental health problems are considerably more prevalent in hospital doctors during residency than in the general population. Residents suffer more often from burnout, depression or substance abuse and are at a higher risk to commit suicide than other academic professionals. Work factors contributing to ill health are a high work load, long working hours, a neglect of self-care and a widespread performance mentality.

Our intervention aims at enabling residents to meet their exceptional work challenges with more serenity and autonomy. The intervention consists of an eight-week mindfulness-based program that considers strategies especially relevant to the needs of hospital residents as well as a four-month maintenance phase consisting of monthly meetings.

Hypotheses:

We hypothesize that (1) the mindfulness intervention will have positive effects on resident's self reported burnout, empathy, experience of stress, depression, anxiety, jobstrain, mindfulness, work satisfaction, self-worth, thriving, flourishing, life satisfaction, self-efficacy, emotional sensation, mental health, self-compassion, feeling loved, subjective passage of time, treatment errors, Muße (2) the mindfulness intervention will have positive effects on external assessments of residents through patients and colleagues; (3) the mindfulness intervention will have positive effects on implicit, behavioural, and physiological measures (hair cortisol).

Brief Summary in Scientific Language

Background and Purpose: Work-related mental health problems are considerably more prevalent in hospital doctors during residency than in the general population. Residents suffer more often from burnout, depression or substance abuse and are at a higher risk to commit suicide than other academic professionals. Work factors contributing to ill health are a high work load, long working hours, a neglect of self-care and a widespread performance mentality.

Our intervention aims at enabling residents to meet their exceptional work challenges with more serenity and autonomy. The intervention consists of an eight-week mindfulness-based program that considers strategies especially relevant to the needs of hospital residents as well as a four-month maintenance



phase consisting of monthly meetings.

Method: This is a randomized-controlled trial. 178 residents will be allocated to either an 8-week mindfulness intervention followed by a 4-month maintenance phase or the control group which receives a course book about mindfulness for self-study.

Hypotheses:

We hypothesize that (1) the mindfulness intervention will have positive effects on resident's self reported burnout, empathy, experience of stress, depression, anxiety, jobstrain, mindfulness, work satisfaction, self-worth, thriving, flourishing, life satisfaction, self-efficacy, emotional sensation, mental health, self-compassion, feeling loved, subjective passage of time, treatment errors, Muße (2) the mindfulness intervention will have positive effects on external assessments of residents through patients and colleagues; (3) the mindfulness intervention will have positive effects on implicit, behavioural, and physiological measures (hair cortisol).

Organizational Data

- DRKS-ID: **DRKS00014015**
- Date of Registration in DRKS: **2018/05/24**
- 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.: **361/16 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

Health condition or Problem studied

- Free text: **Subjects of the present study are a non-clinical sample that faces high work loads, long working hours, a neglect of self-care and a widespread performance mentality.**

Interventions/Observational Groups

- Arm 1: **Residents randomly allocated to the intervention group will take part in an eight-week mindfulness course consisting of weekly sessions. Specifically, participants will learn a variety of mindfulness exercises (e.g. body scan, mindfulness of breath, mindful movements, walking meditation). Moreover, thematic emphasis have specifically been adapted to residents needs, including topics such as: otium, dealing with barriers, experience of time, desidentification, dealing with stress in a mindful way, self-care, and experiencing meaning in daily life. A central aspect of the intervention is the**



application and integration of mindfulness into ones work-routine and everyday life. After the eight-week intervention participants will take part in a four-month maintenance phase, consisting of monthly sessions aiming at refreshing the skills learned during the eight-week course.

- **Arm 2: Residents randomly allocated to the control group will receive a course book about mindfulness for individual study. The individual chapters will be sent to participants on a weekly basis over the course of eight weeks.**

Characteristics

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

Primary Outcome

Self-rated burnout using the Copenhagen Burnout Inventory will be assessed before the eight-week course (t0), after the course (t1), after the four-month maintenance phase (t2) as well as six months after the end of the maintenance phase (t3).

Secondary Outcome

Participants will be assessed before the eight-week course (t0), after the course (t1), after the four-month maintenance phase (t2) as well as six months after the end of the maintenance phase (t3).

Self-report measures:

Burnout (Copenhagen Burnout Inventory - CBI), Empathy (Jefferson Scale of Physician Empathy - JSPE), Stress (Perceived Stress Scale - PSS), Depression (PHQ-4), Anxiety (PHQ-4), Jobstrain (Irritation), Mindfulness (Freiburger Fragebogen zur Achtsamkeit - FFA), Work Satisfaction (Kunin's Faces Scale), Self-Esteem (Single Item Self-Esteem Scale), Thriving (Thriving Scale), Flourishing (Flourishing Scale), Life Satisfaction (Kurzskala zur Erfassung der allgemeinen Lebenszufriedenheit - L1), Self-Efficacy (Allgemeine Selbstwirksamkeit Kurzskala - ASKU), emotional well-being (SAM face scale), mental health (General Health Questionnaire - GHQ-12), Self-Compassion (Self-Compassion Scale - SCS), Feeling Loved (Feeling Loved Scale), Subjective Passage of Time (Subjective Time Questionnaire - STQ), Treatment Errors and Muße.

Qualitative Interviews:



Semi-structured interviews will be held between t1 and t2 with a subgroup of subjects. Topics of the interview will be: Mindfulness, personal understanding of otium, relationship between otium and mindfulness, effects of mindfulness on stress, effects of mindfulness on the implementation and experience of leisure time and recreation, experience of meaning at work, and the effects of mindfulness on dealing with patients.

External assessments:

External assessment by colleagues regarding the following dimensions: tension, hurry, serenity, empathy, being mindfully present. External assessment by patients regarding the following dimensions: satisfaction with treatment, being mindfully present, competence, empathy, being caring. Additionally sick leave will be assessed.

Implicit and objective measures: attitude to work with the single-category Implicit Association Test (Bluemke & Friese, 2008; Leavitt, Fong, & Greenwald, 2011), emotional state using the Implicit Positive and Negative Affect Test (IPANAT; Quirin, Kazen, & Kuhl, 2009), emotional state using the word fragment test (Gilbert & Hixon, 1991; Johnson et al., 2010), self-esteem using the Full-Name Name-Liking (Gebauer et al. 2008), attitude to work using the Affect Misattribution Procedure (AMP; Payne, Cheng, Govorun, & Stewart, 2005). Additionally, indices of stress will be assessed by tracking movement of mouse and keyboard. Finally, cumulated haircortisol of the past month using a 1 cm long hair sample will be examined.

Countries of recruitment

- **DE Germany**

Locations of Recruitment

- **other Individuelle Ansprache von Assistenzärzt*innen im Raum Freiburg - Individual sample recruiting in the Freiburg area, Freiburg im Breisgau**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2018/09/10**
- Target Sample Size: **178**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **45 Years**

Additional Inclusion Criteria

residents employed at a clinic with a minimum employment of 40%, regular contact with patients, good knowledge of German language

Exclusion criteria

Lack of willingness to fulfill the requirements of the study, participation in other work related studies, psychological and psychiatric condition impairing people-to-people contact, addiction

Addresses

■ **Primary Sponsor**

**Klinik für Psychosomatische Medizin und Psychotherapie
Mr. Prof. Dr. Stefan Schmidt
Hauptstraße 8
79104 Freiburg
Germany**

Telephone: **0761 27069280**

Fax: [---]*

E-mail: **stefan.schmidt at uniklinik-freiburg.de**

URL: [---]*

■ **Contact for Scientific Queries**

**Klinik für Psychosomatische Medizin und Psychotherapie
Mr. Prof. Dr. Stefan Schmidt
Hauptstraße 8
79104 Freiburg
Germany**

Telephone: **0761 27069280**

Fax: [---]*

E-mail: **stefan.schmidt at uniklinik-freiburg.de**

URL: [---]*

■ **Contact for Public Queries**

**Albert-Ludwigs-Universität Freiburg
Ms. M.Sc. Vanessa Aeschbach
Rheinstraße 10
79104 Freiburg
Germany**

Telephone: **0761 203 67697**

Fax: [---]*

E-mail: **mda at sfb1015.uni-freiburg.de**



Contact for Public Queries

Albert-Ludwigs-Universität Freiburg
Ms. M.Sc. Vanessa Aeschbach
Rheinstraße 10
79104 Freiburg
Germany

Telephone: **0761 203 67697**

Fax: [---]*

E-mail: **mda at sfb1015.uni-freiburg.de**

URL: [---]*

■ Collaborator, Other Address

**Albert-Ludwigs-Universität Freiburg, Institut für Psychologie,
Wirtschaftspsychologie**
Ms. Prof. Dr. Anja Göritz
Engelbergerstraße 41
79085 Freiburg
Germany

Telephone: **0761 2035686**

Fax: [---]*

E-mail: **goeritz at psychologie.uni-freiburg.de**

URL: [---]*

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.)**

Deutsche Forschungsgemeinschaft e.V.
Kennedyallee 40
53175 Bonn
Germany

Telephone: [---]*

Fax: [---]*

E-mail: [---]*

URL: [---]*

Status

- Recruitment Status: **Recruiting complete, follow-up continuing**
- Study Closing (LPLV): [---]*

DRKS-ID: **DRKS00014015**

Date of Registration in DRKS: **2018/05/24**

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

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.*