Trial Description

Title

DEVELOPMENT AND PILOTING OF AN ONLINE-BASED INTERVENTION FOR ONCOLOGICAL STAFF TO PROMOTE MENTAL HEALTH

Trial Acronym

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URL of the trial

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Brief Summary in Lay Language

The burden on employees in oncology is increasingly becoming the focus of preventive health studies. In addition to work intensification, specific stress factors include dealing with the deaths and deaths of patients as well as the stress of relatives of cancer patients. These stresses increase the risk of clinical phenomena such as burnout (BO), anxiety, depression and compassion fatigue (CF). CF is a concept that has not yet been sufficiently considered. It involves a state of mental emergency as a result of secondary traumatization characterized by diminishing compassion over time. Oncology staff are particularly affected by this condition. The maintenance of Compassion Satisfaction (CS) is a prerequisite for the appropriate care of the above-mentioned groups.
To date, there have been only a few interventions to maintain CS among oncology staff. These are mostly face-to-face services, where regular, scheduled participation in clinical routine often seems difficult. As a result, online intervention approaches have become increasingly established in recent years. Previous evaluation studies of mobile and web-based training for nurses and physicians in a non-oncological setting provide indications that they are effective in reducing burnout and compassion fatigue. However, it has not yet been possible to successfully implement an intervention tailored to the needs of oncology staff that produced empirically significant results. According to systematic reviews, online-based procedures with a focus on mindfulness-based therapy approaches showed the largest effects on mental health and stress symptoms, while cognitive-behavioural therapy and stress management procedures showed the smallest effects. A combination of the three methods, especially for the target group of oncology staff, within the framework of an online intervention has not yet been carried out. The development and evaluation of such an intervention with a view to reducing mental stress and promoting CS, which can be carried out flexibly at any time by the target group of oncology staff, is still pending.
The planned study project comprises a preliminary study in which quantitative and qualitative data are collected from oncology staff. The quantitative survey is carried out using validated questionnaires, the qualitative preliminary study using individual interviews and focus groups. In the pilot study, qualitative interviews and quantitative questionnaires are carried out before and after the online intervention. The online intervention will provide the participants with six modules for processing over a period of seven weeks.
The project presented here is intended to meet the demand to develop a measure tailored to the specific requirements of oncology and thus to reduce stress

symptoms and compassion fatigue.

Brief Summary in Scientific Language

The aim of this study is the development and piloting of an online training course that will be geared to the specific stresses and strains of oncological employees. A needs analysis will first collect quantitative and qualitative data on the exposure of up to one hundred physicians and nursing staff in oncology. On the basis of these results, online training will be developed in which participants will have the opportunity to develop cognitive and behavioural strategies and improve resilience. For evaluation purposes, qualitative interviews will be conducted before and after participation in the online training and participants will complete questionnaires on anxiety, depression, compassion satisfaction, burnout and work ability.

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

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Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00018851**
- Date of Registration in DRKS: **2019/10/10**
- 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.: **S-615/2019 , Ethik-Kommission I der Medizinischen Fakultät Heidelberg**

Secondary IDs

Health condition or Problem studied

- Free text: **Compassion Satisfaction**
- Free text: **Depression, anxiety, burnout, resilience, workability,**

Interventions/Observational Groups

- Arm 1: **After inclusion of the test persons, an explanatory discussion takes place in which the intervention is presented and its treatment explained. This is followed by a qualitative and quantitative survey. A total time requirement of 90 minutes per participant is expected for the clarification interview and the subsequent survey. The initial and final interviews take place as semi-structured surveys in which qualitative and quantitative data are collected. The interviewer categorises the responses of the participants on the data collection form and documents them in keywords.**
  Following the information interview, the study participants begin to work on the intervention. A processing time of approx. seven weeks is assumed for the processing of a total of six modules of max. 60 minutes each. After the last module has been completed, a final discussion takes place with each individual participant and concludes with the completion of a questionnaire. The final interview and the processing of the questionnaire are expected to take about 90 minutes.
  Depending on the preliminary study, the intervention comprises up to 6 modules of max. 60 minutes each over approx. 7 weeks). The internet-based intervention includes psychoeducation to compassion fatigue, coping strategies according to the Lazarus model, a training-oriented mindfulness module, grief work in general and personal experiences. In addition, the participants are taught various coping strategies in the form of relaxation exercises/techniques (mindfulness exercises, fantasy trips, PMR).
  Once all participants have completed the intervention, the data collected will be evaluated.

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Prevention**
- Assignment: **Single (group)**
- Phase: **I-II**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

As soon as all n=20 study participants have completed the online training (pilot study), the data collection will be completed. If this is not achieved within one year after the start of the study, the study will be completed with the number of participants available at that time. The quantitative survey is carried out online and comprises the following validated questionnaires: Workability Index (Hasselhorn & Freude, 2007), PHQ-4 (Löwe et al., 2010), Oldenburger Burnout Invententar (Demerouti & Bakker, 2008), the scales `Compassion Satis-faction´ and `secondary traumatic Stress´ from the Proqol-5 (Stamm, 2010) as well as the resilience scale RS-13 (Leppert, Koch, Brähler & Strauß, 2008).

Secondary Outcome

Revocation of the participant's consent to study participation, whereby the participant's consent to study participation may be revoked at any time and without giving reasons.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Klinik für Allgemeine Innere Medizin und Psychosomatik II, Heidelberg**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2019/10/17**
- Target Sample Size: **120**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **100 Years**

Additional Inclusion Criteria

Participation requires cooperation in oncology as a nurse or physician. The study participants must be 18 years of age or older, have access to a smartphone or the Internet, have German as their mother tongue or very good German language skills, and have the technical prerequisites for carrying out the intervention. All persons who agree to participate in the study will receive the information leaflet and the declaration of consent, which will also be explained orally. The participation in the study requires the receipt of a written consent documented by a signature or, in the case of an online survey, confirmation of the consent by clicking on the corresponding button.

Exclusion criteria

Not included in the study are participants with cognitive or physical impairments that complicate online program processing, severe mental illness, age < 18 years,

and lack of written consent to participate.

Addresses

■ **Primary Sponsor**

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Sources of Monetary or Material Support

■ **Institutional budget, no external funding (budget of sponsor/PI)**

Universitätsklinikum Heidelberg

Institutional budget, no external funding (budget of sponsor/PI)

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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.*