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01_resiLIR_HCP

A Randomized Controlled Study to Evaluate the Feasibility and Efficacy of an Online Resilience Intervention for Healthcare Professionals ("resiLIR Healthcare Professionals")

Document Version History

Version Date	Version	Author	Signature	Change Description	Reason/Comment
17.03.2023	1	Leibniz-Institute for Resilience Research		Initial release.	Not applicable.

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LIST OF ABBREVIATIONS

IG	Intervention group
CG/ WLC	(Waitlist-) Control group
ITT	Intention-to-treat
PP	Per-Protocol
ANCOVA	ANalysis of COVAriance
ANOVA	ANalysis Of VAriance
SD	Standard Deviation
SE	Standard Error

1. STUDY OBJECTIVES

1.1. PRIMARY OBJECTIVE

The goal of this clinical trial is to examine the efficacy of a newly developed online resilience intervention "resiLIR Health Care Professionals" for Health Care professionals and foster resilience in the targeted population.

1.2. SECONDARY OBJECTIVES

Secondary objectives are to find out whether the intervention is effective in increasing the addressed health-related and resilience factors (e.g., optimism) as well as decreasing self-evaluations of psychopathological indicators (e.g., depression, anxiety) in healthcare professionals. Also, the study investigates whether different interventions are effective in changing state-measures of health-related self-evaluations.
Another objective is to investigate these effects in the long term (up to one-year post-intervention).
Additionally, feasibility and usability of the intervention and the newly developed platform resiLIR will be investigated.

Further objectives are to examine exploratorily the influence of the intervention on other resilience-related outcomes, mental health literacy, health seeking behaviour and stigma against mental illness and to conduct network analyses.

2. BACKGROUND/INTRODUCTION

Acute and chronic stress in everyday life plays an essential role in the onset and development of several physical and mental health conditions. The ability to maintain or return to mental health during stress exposure is characterized as resilience. Especially the COVID-19 pandemic emphasized the role of resilience for mental health and pointed to the importance of easily accessible and flexible interventions to improve resilience for vulnerable groups such as healthcare professionals.

2.1. STUDY DESIGN

Randomized Controlled Trial with 240 participants working as healthcare professionals (120 in intervention, 120 in waitlist control group), monocentric study, duration: 14 months, study design chosen to evaluate long-term effects of our training)

2.2. TREATMENT GROUPS

Treatment: Participants in the intervention group will gain access to the 6-week online resilience intervention "resiLIR Healthcare Professionals".
The waitlist control group will receive access to the intervention after the first follow-up assessment (3 months post-intervention).

Randomisation process: Stratified randomization is used, with age and gender as influencing factors. Randomization is performed using randomized numbers generated with Microsoft Excel. Due to the nature of the intervention, no blinding and subject replacements are planned.

Subject replacement: not applicable.

2.3. STUDY POPULATION

Inclusion criteria:

- Age 18 years or older
- Fluent in German language
- Access to web-enabled devices (tablet/laptop/computer)
- Smartphone with internet access
- Trained and employed as health care professionals
    - We used the following definition of healthcare professionals: „Healthcare professionals are specifically trained, often regulated professions that advise on or provide health services. This includes, amongst others, medical doctors, nurses, physiotherapists, speech therapists, psychotherapists, dentists, medical-technical assistants, geriatric nurses,…"

Exclusion Criteria:

- Acute mental health crisis (e.g., suicidality)
- Psychiatric/psychotherapeutic treatment
- Neurodegenerative disease(s)
- Diagnosis of schizophrenia or other psychotic disorders, bipolar disorder, post-traumatic stress disorder

2.4. INTERVENTION

Behavioral intervention delivered via computer/laptop and smartphone

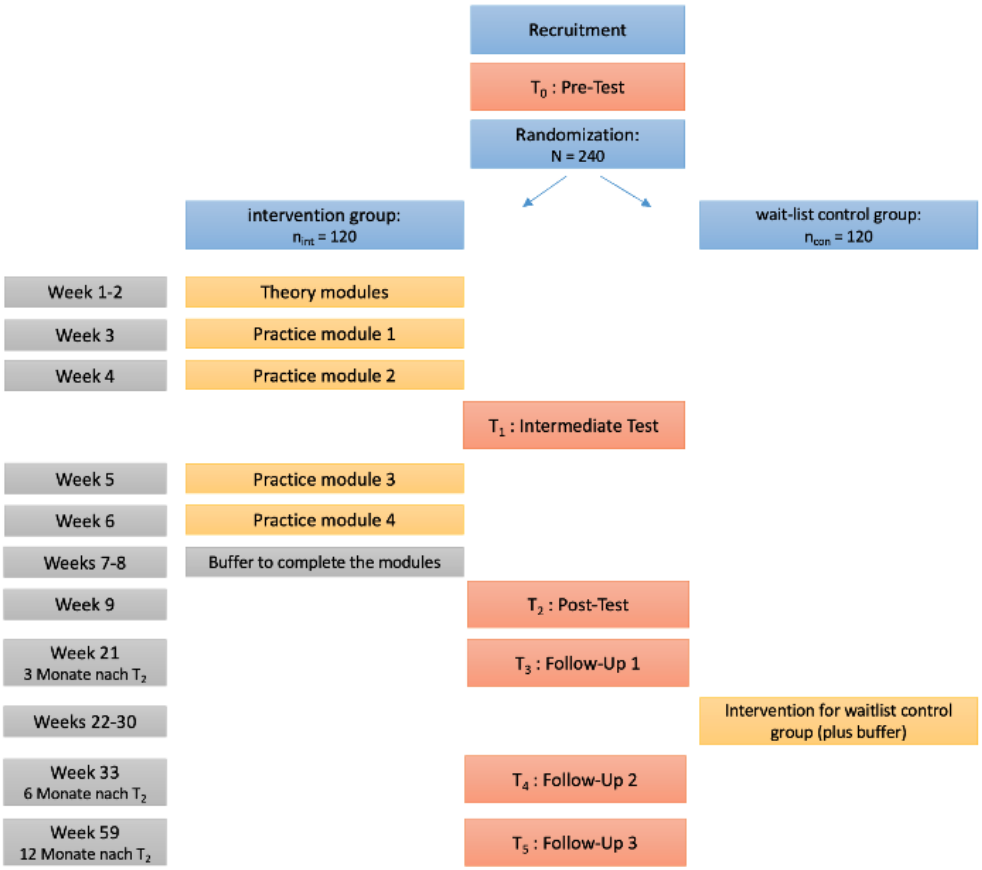
- Weeks 1 and 2 (delivered mainly via computer): Theoretical part on stress, resilience, self-care, and self-compassion
- Weeks 3 to 6 (delivered mainly via smartphone): Training phase of a weekly introduced practical exercise (*weekly training intervention;* topics: reflection on living with ease, self-compassionate body scan, planning of positive activities, self-compassionate letter). This phase additionally includes smartphone reminders to apply the exercises in everyday life *(daily training interventions)*.

2.5. SAMPLE SIZE

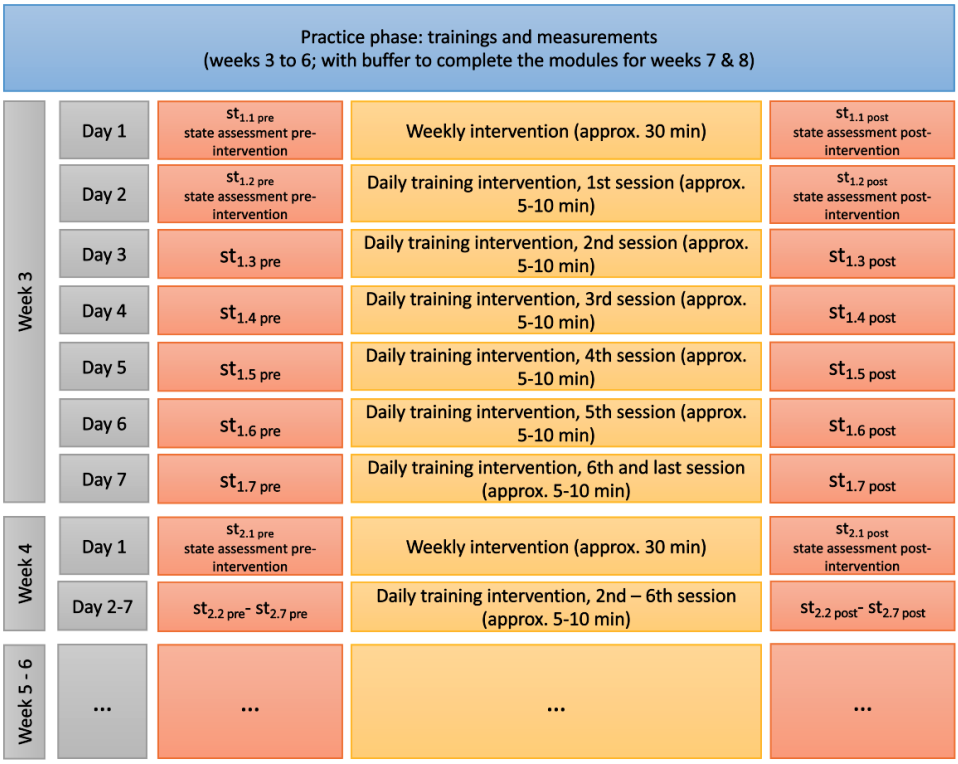
Previous studies from our research groups have shown a medium to large effect size for the stressor reactivity score as a primary outcome measure in online intervention studies for resilience (AG Wessa, unpublished). Because a large effect size was found only in a particularly stressed population, which is not expected in the sample addressed here, we assume a medium effect here (Hedges' g = .50). Therefore, the sample size design was calculated with a medium effect size, a significance level of 0.05 and a power of 0.90 using G*Power (Faul et al., 2007). This results in a required sample size of n = 74 per group (N = 146). As there are high dropout rates for online interventions (van Ballegooijen et al., 2014) we decided to recruit n = 120 individuals per group. This number is based on an assumed dropout rate of 40%.

2.6. STUDY PROCEDURE

Once the desired sample size has been reached, a randomized controlled trial with 6 measurement time points will be conducted in which participants will be randomly assigned to either the intervention group or the waiting control group.
The intervention group receives access to the online training after randomization. The waiting control group receives access only after the first follow-up measurement (3 months after the post-measurement). Two further follow-up measurements follow (6 and 12 months after the post-measurement). The detailed time schedule can be seen in the attached flow chart. The entire data collection and intervention will be online. Neither the participants nor the study team will be blinded.



Within the practice modules, the following interventions and measurements are planned (in weeks 3 and 5, a self-care intervention is planned, in weeks 4 and 6, a self-compassion intervention is planned):



Legend: $st_{x.x\ pre}$ = state assessment pre-intervention; $st_{x.x\ post}$ = state assessment post-intervention

3. POPULATIONS OF ANALYSIS

We will conduct both an intention to treat (ITT) analysis as well as a per protocol (PP) analysis (see also "5.1. Statistical methodology"), with the following criteria:

Inclusion criteria (*included in ITT analysis*):

- All valid data sets

Exclusion criteria:

- *In PP analysis,* Participants will be excluded from respective analyses if
  - they fill in less than 50% of questionnaires at a specific measurement point (e.g., pre-test) which address the primary outcome and secondary outcomes trained in the intervention
  - they fill in less than 50% of a specific questionnaire.
  - they have an implausibly short time for completing the assessments (DEG_TIME in SoSci-Survey).
  - there is an abnormality in data (e.g., rating always the highest/ lowest on several scales).
- Participants will be excluded from the whole analysis if
  - they do not agree with the terms of usage, usage of data and privacy policy.
  - they state that their data cannot be used in a sensible way.

4. OUTCOME VARIABLES

4.1. PRIMARY OUTCOME

- Resilience measured with *Stressor-Reactivity-Score* (SR-Score)

4.2. SECONDARY PARAMETERS OUTCOMES

Outcomes related to the intervention and the primary outcome

- Resilience measured with *Brief Resilience Scale* (BRS; Chmitorz et al., 2018)
- Mental Health measured with *General Health Questionnaire* (GHQ-12; Schrnitz et al., 1999)
- Self-Compassion measured with *Self-Compassion Scale Deutsch* (SCS-D; Hupfeld & Ruffieux, 2011)
- Mindfulness measured with *Mindful Attention and Awareness Scale* (MAAS-Short; Höfling et al., 2011)
- Perceived Stress measured with *Perceived Stress Scale* (PSS-2+2; Schäfer et al., in preparation)
- Stressors measured with *Mainz Inventory of Microstressors* (MIMIS; Chmitorz et al., 2020)
- Life Events measured with *Life Events Checklist-5* (LEC-5; Krüger-Gottschalk et al., 2017)
- Anxiety/ Depression measured with *Generalized Anxiety Disorder-7* (GAD-7) and *Patient Health Questionnaire–9* (PHQ-9; Löwe et al., 2002)
- Self-Care measured with *Hamburger Selbstfürsorgefragebogen* (Hamburg Self-Care Survey; Harfst et al., 2009)
- Burnout measured with the German version of the *Maslach Burnout-Inventory* (MBI-D; Büssing & Perrar, 1992)
- Work-Life-Balance measured with the *Trierer Kurzskala zur Messung von Work-Life Balance* (TKS-WLB; Syrek et al., 2017)

Further (exploratory) outcomes

- Optimism measured with *Optimism-Pessimism-Scale* (SOP-2; Kemper et al., 2014)
- Positive reappraisal measured with subscale of *Cognitive Emotion Regulation Questionnaire* (CERQ; Loch et al., 2011)
- Acceptance measured with subscale of *Cognitive Emotion Regulation Questionnaire* (CERQ; Loch et al., 2011)
- Positive (Re-)appraisal measured with *Positive Appraisal Style Scale Content* (PASS-content) and *Positive Appraisal Style Scale Process* (PASS-process; Petri-Romao et al., 2021)
- Social Support measured with *Osloer Social Support Scale* (OSS-3; Kocalevent et al., 2018)
- Control beliefs with *Internal-External Locus of Control Short Scale–4* (IE-4; Kovaleva et al., 2014)
- Meaning measured with subscale of *Comprehensive Inventory of Thriving* (CIT; Hausler et al., 2017)

- Self-Efficacy measured with *German Version of Self-Efficacy Short Scale* (Allgemeine Selbstwirksamkeit Kurzskala, ASKU; Beierlein et al., 2014)
- Coping measured with *Coping Orientation to Problems Experienced Inventory* (Brief-COPE; Knoll et al., 2005)
- Self-Esteem measured with *German Single-Item Self-Esteem Scale* (G-SISE; Brailovskaia & Margraf, 2020)
- Positive Affect measured with subscale of *Positive and Negative Affect Schedule (*PANAS; Breyer & Bluemke, 2016)
- Life Satisfaction measured with *Satisfaction with Life Scale* (SWLS; Janke & Glöckner-Rist, 2012)
- Well-Being measured with *WHO-5 Well-Being Index* (Brähler et al., 2007)
- Functionality measured with *World Health Organization Disability Assessment Schedule* (WHODAS 2.0; Üstün et al., 2010)
- Coping Flexibility measured with *Coping Flexibility Questionnaire Revised* (CFQ-R; Kato, 2012)
- Satisfaction with Intervention measured with *Client Satisfaction Questionnaire-Intervention* (CSQ-I; Boß et al., 2016)
- Adverse Effects measured with *Inventory for the Assessment of Negative Effects of Psychotherapy* (INEP; Ladwig et al., 2014)
- Relationship to Intervention measured with *Mobile Agnew Relationship Measure* (mARM; von Wulffen et al., 2022)
- Sense of Coherence measured with *Sense of Coherence Scale* (SOC-29; Singer et al., 2007)
- Mental Health Literacy measured with *Mental Health Literacy Questionnaire* (MHLQ, Dias et al., 2018), *Mental Health Literacy Scale* (MHLS; O'Connor & Casey, 2015), *Mental Health Knowledge Schedule* (MAKS; Evans-Lacko et al., 2010), *Health Literacy Survey EU 16* (HLS EU 16; Jordan & Hoebel, 2015), *eHealth Literacy Scale* (eHEALS; Soellner et al., 2014), *Well-being Literacy Scale* (Hou et al., 2021), *STRESS K-10* (Giesinger et al., 2008), *Fragebogen zur Erhebung des Wissens über psychosoziale Versorgungsstrukturen* (Questionnaire to survey knowledge of psychosocial care structures; Fritz, 2021)
- Belief Towards Mental Illness Scale (Hirai & Clum, 2018)
- Help-seeking behaviour measured with *General Help Seeking Scale* (GHSS; Rickwood et al., 2005) and *Attitudes Toward Seeking Professional Psychological Help* (ATSPPH; Kessler et al., 2015)
- Work engagement measured with the *Utrecht Work Engagement Scale* (UWES-9; Schaufeli et al., 2006)
- Perceived work stress measured with a German translation of the *Perceived Occupational Stress Scale* (Marcatto et al., 2022)

4.3. OTHER PARAMETERS

DEMOGRAPHY AND BASELINE

Demographic measures:

- Age
- Sex
- Educational background/ status
- Number of persons living in the household
- Number of children living in the household
- Household net income
- Individual net income

Baseline variables

- Attitudes towards psychological online interventions measured with Attitudes towards Psychological Online Interventions Questionnaire (APOI; Schröder et al., 2015)
- Personality measured with Big Five Inventory-10 (BFI-10; Rammstedt et al., 2017)

Work-related variables

- Type of healthcare profession
- Number of overtime hours
- Contractually agreed working hours (full-time / part-time -> %)
- Working night shifts yes/no
- Leadership responsibility yes/no

USER STATISTICS

- Intervention
- Number of processed modules (in the theory phase) and weekly and daily interventions in the practice phase
- Processing time of the individual contents as well as of the entire intervention
- Contents from the feedback questionnaire, e.g., how well the last module was liked
- Self-care, self-compassion, stress and resilience history / state queries
- Days of usage

Survey

- Response times, namely
  - Per questionnaire (how long the user spent on each questionnaire)
  - Total processing time for all questionnaires (after adjustment for interruptions)
- Percentage of missing answers in the questionnaires (absolute and relative to total length of the survey)
- "DEG_TIME" as normalized indicator for extremely fast completion of questionnaires

4.4. Hypotheses

1. The intervention will significantly increase resilience, measured with the SR Score, in the intervention group (IG) compared with a waitlist control (WLC) group at t_2 and t_3 compared to t_0.
2. The intervention will significantly increase resilience, measured with the Brief Resilience Scale, in the intervention group (IG) compared with a waitlist control (WLC) group at t_2 and t_3 compared to t_0.
3. The intervention will significantly increase self-care in the intervention group (IG) compared with a waitlist control (WLC) group at t_2 and t_3 compared to t_0.
4. The intervention will significantly increase self-compassion in the intervention group (IG) compared with a waitlist control (WLC) group at t_2 and t_3 compared to t_0.
5. The intervention will significantly increase mindfulness in the intervention group (IG) compared with a waitlist control (WLC) group at t_2 and t_3 compared to t_0.
6. The intervention will significantly reduce perceived stress in the intervention group (IG) compared with a waitlist control (WLC) group at t_2 and t_3 compared to t_0
7. The intervention will significantly increase mental health in the intervention group (IG) compared with a waitlist control (WLC) group at t_2 and t_3 compared to t_0.
8. The intervention will significantly reduce depressive symptoms in the intervention group (IG) compared with a waitlist control (WLC) group at t_2 and t_3 compared to t_0.
9. The intervention will significantly reduce anxiety symptoms in the intervention group (IG) compared with a waitlist control (WLC) group at t_2 and t_3 compared to t_0.
10. The intervention will significantly reduce burnout symptoms in the intervention group (IG) compared with a waitlist control (WLC) group at t_2 and t_3 compared to t_0.
11. The intervention will significantly increase work-life-balance in the intervention group (IG) compared with a waitlist control (WLC) group at t_2 and t_3 compared to t_0.
12. In the intervention group, the intervention will lead to improved resilience by the end of the intervention (at t_2) and these improvements should be maintained at the respective follow-ups (at t_3, t_4, t_5; probably to a lesser degree).
13. Self-compassion interventions (weekly intervention and daily training intervention) in the practice modules:
    A) For the weekly interventions, the state self-compassion measure will be significantly higher after the interventions (comparison of $st_{2.1pre}$ vs. $st_{2.1post}$ and $st_{4.1pre}$ vs. $st_{4.1post}$).
    B) For the first session of the daily training interventions, the state self-compassion measure will be significantly higher after the interventions (comparison of $st_{2.2pre}$ vs. $st_{2.2post}$ and $st_{4.2pre}$ vs. $st_{4.2post}$).
14. Self-care interventions (weekly intervention and daily training intervention) in the practice modules:
    A) For the weekly interventions, the state self-compassion measure will be significantly higher after the interventions (comparison of $st_{1.1pre}$ vs. $St_{1.1post}$ and $st_{3.1pre}$ vs. $st_{3.1post}$).
    B) For the first session of the daily training interventions, the state self-compassion measure will be significantly higher after the interventions (comparison of $st_{1.2pre}$ vs. $St_{1.2post}$ and $st_{3.2pre}$ vs. $st_{3.2post}$).
15. For the intervention group, the number of weekly interventions and daily training interventions completed will result in a significant
    A) increase of self-care at t_2
    B) increase of self-compassion at t_2
    C) increase of resilience measured with SR score at t_2
    D) decrease of burnout symptoms at t_2

Further longitudinal effects, intervention effects at intermediate measurements (t_1), other resilience-related outcomes as well as moderator and mediator analyses will be examined exploratorily. Therefore, no specific hypotheses are stated.

5. STATISTICAL METHODOLOGY

5.1. GENERAL METHODOLOGY

Demographics and work-related variables will be reported with means and standard deviations for continuous variables (e.g., age) and as frequencies for categorial variables (e.g., gender).
Items of questionnaires (e.g., Sense of Coherence Scale) will be recoded (where applicable) and a scale mean or sum score will be calculated in data processing. Means/sum scores and standard deviations will be reported separately by treatment group.
If applicable, means and standard deviations of user statistics will be calculated and reported (e.g., means among the subgroup of users who completed a specific module).
For continuous outcomes, we will use *t*-tests for independent samples and for categorical outcome we will employ χ^2-tests to examine baseline differences between training and control group in demographic data or measured variables.

HANDLING OF MISSING DATA

- On the one hand, the data will be analysed according to the "intention-to-treat" principle, with missing values being replaced using appropriate imputation methods.
- On the other hand, the results will be reported as "per-protocol" analysis, in which only those cases are considered that have gone through the study procedure as defined by protocol. We consider the intervention to be completed for participants who, in addition to the theory modules, completed at least 50% of the weekly interventions and the daily training interventions. To note, a maximum of 4 weekly interventions with 6 daily interventions can be reached. In the per-protocol analysis, only these participants will be included. To control for influences of compliance, usage of intervention will be examined as covariate in an exploratory analysis.

CLASSIFICATION OF PROTOCOL VIOLATION

Exclusion of participants due to protocol violations will be reported in the methods / results section. To examine outliers in the questionnaire data, boxplots will be created.

5.2. PRIMARY AND SECONDARY DATA ANALYSES

In primary and secondary data analyses, all stated hypotheses will be tested. In all analyses an error probability of α = .05 will be set a priori for interference statistics calculations. In cases of multiple testing, α will be adjusted accordingly. In addition to statistical significance, descriptive statistics and effect sizes (e.g., Cohen's d) will be reported. Publication of results will follow CONSORT guidelines for transparent reporting of randomized trials.

Cronbach's α and McDonald's ω will be calculated as measure of reliability of the respective questionnaires.

Before data analysis, assumptions of statistical methods (e.g., variance of homogeneity, normal distribution) will be tested with suitable procedures (e.g., Levene-tests, Box's M, histograms, QQ-plots, and Shapiro-Wilk-Test). Zero-order correlations between study variables will be reported. Non-parametric correlation calculation will be based on results of (non-)normality, etc. Variables will be standardized where applicable.

The analysis plan for H1 to H11 is as follows:

- Differences between study groups in primary and secondary outcomes before (t_0) and after the intervention (t_2) and at the time of the first follow-up (t_3) will be examined using mixed analyses of covariance (ANCOVA), with group (intervention vs. waitlist-control) as a between-subjects factor, time (t_0, t_2, t_3) as a within-subjects factor and pre-measurement (t_0) included as a covariate to increase test power. Outcomes will be the primary outcome resilience (measured with SR Score) and the secondary outcomes resilience (measured with BRS), perceived stress, self-care, self-compassion, mindfulness, mental health, depression, anxiety, burnout, and work-life-balance, respectively.
- If applicable, post-hoc *t*-tests will be conducted.
- Effect sizes will be calculated for the ANCOVA (i.e., Eta^2) as well as for between-group differences (i.e., Cohen's *d*) at post-intervention assessment (t_2) and the first follow-up assessment (t_3). Also, the effect size of the intervention effect will be calculated (i.e., Cohen's *d*).

The analysis plan for H12 is as follows: term effect over the follow-up measurements (t_0 to t_5) within the intervention group will be tested using a repeated measures ANOVA.

- If applicable, post-hoc *t*-tests and planned contrasts will be conducted.
- Effect sizes will be calculated.
- Eta^2 will be calculated as measure for effect size for the ANOVA.

The analysis plan for H13 and H14 is as follows:

- In order to test whether the changes in the state measurements (pre- to post-intervention in state self-compassion and state self-care) are significant, we will conduct within-group *t*-tests. We will perform separate tests for state self-compassion and state self-care, each for (1) the weekly training interventions and (2) the first practice of daily interventions, respectively.
- Cohen's *d* will be calculated as measure for effect size.

The analysis plan for H15 is as follows:

- Linear regressions will be conducted with the following predictor and criterion variables:
    - Predictor variables:
        - baseline-values of self-care (and, in separate models, self-compassion / resilience / burnout, respectively) at t_0
        - amount of interventions completed (number of weekly training interventions and daily interventions)

- Criterion variables:
  - Post-intervention values of self-care (and, in separate models, self-compassion / resilience / burnout, respectively) at t_2

If assumptions for the mentioned statistical methods are violated, appropriate non-parameteric statistical methods will be chosen.

5.3. EXPLORATORY DATA ANALYSES

All other outcome measures mentioned above and not directly addressed in the intervention will be evaluated exploratively.

In addition, changes will be examined in correlative network analyses of the variables. Moderator and mediator analyses are intended as exploratory analyses to examine the influence of mediating/ moderating variables (e.g., gender, personality, intervention usage, attitudes toward online psychological interventions, coping styles) of the primary correlations.

The intermediate survey (t_1) will be exploratively included in the analyses.

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