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01_resiLIR_basic

A Randomized Controlled Study to Evaluate the Feasibility and Efficacy of an Online Resilience Intervention in the General Population ("resiLIR Basic")

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 Basic" for the general population 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). 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 in the general population.

2.1. STUDY DESIGN

This intervention study uses a waitlist control design with two arms. 240 adults – 120 in intervention group (IG) and 120 in waitlist-control group (CG) – participate in a randomized controlled trial. Whereas the IG immediately gains access to the 6-week resilience intervention "resiLIR Basic" after the baseline measurement the CG is only enabled to participate in the online intervention after the first follow-up assessment. Further details are specified in the study procedure (2.6.). The online intervention “resiLIR Basic” consists of 8 modules of about 45-60 minutes length using psycho-educational elements and practical exercises to address evidence-based resilience factors, such as optimism or sense of coherence. Participants will complete online surveys on resilience, mental health, and several resilience factors pre-, during and post-intervention as well as 3, 6 and 12 months after completion as follow-up assessments. The main question is whether the intervention is effective in increasing psychological resilience.

2.2. TREATMENT GROUPS

Participants will be randomly allocated to either intervention group or waitlist-control group. Stratified randomization is used, with age and gender as influencing factors. Randomization will be conducted by randomized numbers generated with Microsoft Excel. Due to the nature of the intervention, no blinding and subject replacements are planned.

2.3. STUDY POPULATION

The study population is composed of N = 240 people from the general population.

Inclusion criteria are:

- Age 18 years or older
- Fluent in German language
- Have access to an internet-enabled device with a large screen (tablet / laptop / computer) as well as that they can use at least once a week for 45 min to 1.5 hours during the study period

Exclusion criteria are:

- 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

The intervention combines elements from different psychotherapeutic fields (e.g., Cognitive Behavioral Therapy, Mindfulness-Based Stress Reduction, Acceptance and Commitment Therapy, Compassion Focused Therapy, Positive Psychology). The intervention aims to provide knowledge on evidence-based resilience factors and resilience-promoting life attitudes, and to apply and practice them. Additionally, it includes gamification elements.
In total, the intervention consists of the following eight lessons:

- Introduction (1): This lesson provides a general introduction to the training program and its structure. In addition, the various technical functions are explained to the users. In the further course, the users are guided to reflect on their own goals and expectations regarding the program and then to formulate a concrete goal.
- Resilience and stress (2): The second lesson introduces the topics of resilience and stress. Users learn more about what resilience and stress are and how they are interrelated. Users are encouraged to reflect on their personal experiences and learn how to increase their resilience and reduce their stress (e.g., identifying and planning positive activities into everyday life).
- Optimism (3): In this module, users learn what realistic optimism is, what effects an optimistic thinking style can have on emotions and behaviour, and thus on personal resilience and health. In addition, they will be given various practical exercises (e.g., visualization) that they can use to promote their optimism.
- Mindfulness (4): This lesson is about what mindfulness is, how mindfulness and resilience are related to each other and which (neuro-)scientific findings are behind it. Different mindfulness exercises (e.g., body scan, breathing meditation) are introduced and difficulties and obstacles in mindfulness practice are also discussed.
- Values and sense of coherence (5): The fifth lesson on values and sense of coherence introduces these two topics and explains how they are related to resilience. Furthermore, the users deal with which values are important to them in life and how they can implement more of them in their everyday life. They are also given tips on how to deal with a conflict of values.
- Acceptance (6): In this lesson, users learn what constitutes an accepting attitude in life. This lesson consists of a combination of stories and practical exercises.
- Self-compassion (7): In the lesson on self-compassion, users learn what self-compassion is, how it differs from self-esteem, and what the effects of self-compassion are. In addition, the users learn how self-compassion can be trained and how it can be used to strengthen resilience.

- Conclusion (8): In the last lesson of the training program, users reflect on what they have learned. They plan the future implementation of some strategies in everyday life and identify their own early warning signals for stress. Finally, there is an exercise to appreciate the small and large successes.

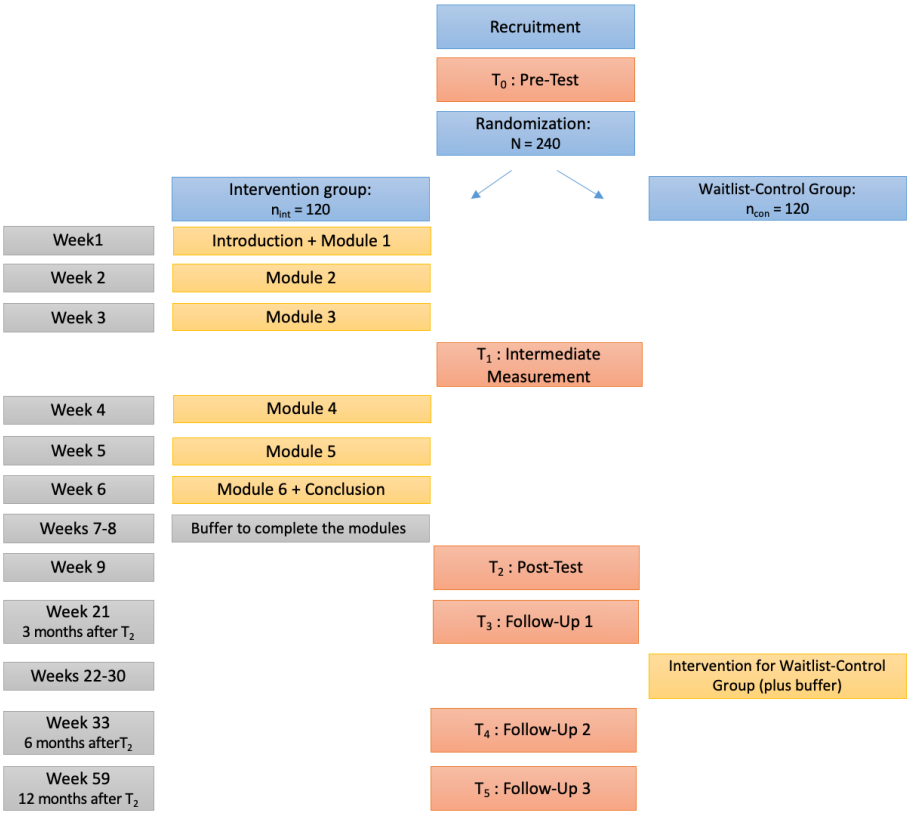
All lessons are approximately 45-60 minutes in length each. Various additional materials are also provided for each lesson. This includes, for example, literature and media recommendations or further exercises to deepen the content already learned.
The individuals in the waiting control group initially receive no intervention. As soon as the participants have completed the first follow-up, the intervention is also activated for the control group.

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 is reached, a randomized controlled trial with six measurement time points will be conducted. There will be a baseline-assessment for both groups. After that, the intervention group will receive access to the online training. The introduction session and the first module can be completed directly one after the other, all further modules are always activated 4 days after the completion of the last module. The concluding session is activated at the same time as the last content-based module. The post-measurement takes place one week after completion of the last module, but no later than eight weeks after the start of the intervention. There will be an intermediate and post-assessment for both groups after the third and sixth module, respectively. The waitlist control group receives access only after the first follow-up measurement (three months after the post measurement). Two further follow-up measurements will be conducted six and twelve months after the post-assessment. The concrete chronological sequence can be seen in the following flow chart.



3. POPULATIONS OF ANALYSIS

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

Inclusion criteria (included in ITT analysis):

- All valid data sets

General Exclusion criteria:

- Participants will be excluded from all analyses 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.

Exclusion criteria 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).

4. OUTCOME VARIABLES

4.1. PRIMARY OUTCOME

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

4.2. SECONDARY OUTCOMES

Related to the intervention and 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)
- 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)
- Sense of Coherence measured with *Sense of Coherence Scale* (SOC-29; Singer et al., 2007)
- Meaning measured with subscale of *Comprehensive Inventory of Thriving* (CIT; Hausler et al., 2017)
- 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)
- 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)

Further (exploratory) outcomes

- 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)
- 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)
- Self-Care measured with *Hamburger Selbstfürsorgefragebogen* (Hamburg Self-Care Survey; Harfst et al., 2009)
- 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)

4.3. OTHER PARAMETERS

DEMOGRAPHY AND BASELINE

Demographic measures:

- Age
- Sex
- Educational background/ status
- Number of persons 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)

USER STATISTICS

Intervention

- Number of processed modules
- 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)
- 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 reduce the perceived stress 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 the optimism 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 the 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 increase the meaningfulness 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 the acceptance 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 increase the self-compassion 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 increase the mental health 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 depressive 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 reduce anxiety 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).

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

5. STATISTICAL METHODOLOGY

5.1. GENERAL METHODOLOGY

Demographics will be reported with a mean and standard deviation in continuous variables (e.g., age) and with frequency and percentage in categorial variables (e.g., sex).

Items of questionnaires will be recoded (if applicable) and a scale mean or sum score will be calculated in data processing. Mean/ Sum score and standard deviation will be reported separately by treatment group.
If applicable, mean, and standard deviation of user statistics will be calculated and reported (e.g., module completion).
T-Tests for independent samples and χ^2-tests will be used to examine whether training groups differ in demographic data or measured variables at baseline.

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 procedures.
- On the other hand, the results are examined in a "per-protocol" analysis, in which only those cases are considered that have gone through the complete study protocol as predicted. We include those subjects who completed the respective content lessons (excluding the introductory and final modules) addressed in the analyses/ hypotheses. To control for influences of usage, usage of intervention will be included as a 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 included.
In all analyses an error probability of α = .05 will be set a priori for all interference statistics calculations.
In addition to statistical significance, descriptive statistics and effect sizes 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. Primary outcome will be resilience (measured with SR Score) and the secondary outcomes will be resilience (measured with BRS), perceived stress, optimism, mindfulness, meaningfulness, acceptance, self-compassion, mental health, depression, and anxiety, respectively.
- If applicable, post-hoc analyses (e.g., t-tests) will be conducted.
- Effect sizes will be calculated.
- In cases of multiple testing, α will be adjusted accordingly.

The analysis plan for H12 is as follows:

- The long-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-test or planned contrasts will be conducted.
- Effect sizes will be calculated.
- In cases of multiple testing, α will be adjusted accordingly.

If assumptions for AN(C)OVAs are violated, appropriate statistical methods will be conducted.

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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