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**Project Description – Project Proposals**

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**Yellow indicates deviation from Eva's texts**

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# Overview

Brief Title

Preventing Mental Disorders via Self-Efficacy Interventions: A Randomized Controlled Trial (RCT)

Official Title

Preventing mental disorders and promoting favorable development in young adults with low self-efficacy: A randomized controlled trial

# Study Description

Brief Summary

As mental disorders constitute a central health care challenge of the 21st century, increased research efforts on preventive interventions are called for. As suggested by symptom progression models, mental disorders typically evolve gradually from predisposing risk factors over initial minor psychopathological symptoms to full-threshold mental disorders (Wittchen et al., 2014). To prevent such unfavorable trajectories, targeted interventions are needed to modify core high-risk factors as early as possible (Dalgleish et al., 2020). A significant transdiagnostic risk factor is low self-efficacy (SE) (Asselmann et al., 2016; Maciejewski et al., 2000; Schönfeld et al., 2016; Volz et al., 2019). However, to date, there has been limited research on whether self-efficacy training as a preventive intervention in high-risk populations can effectively prevent the development of anxiety, affective, and substance use disorders in young adults at higher risk.

This randomized controlled trial in young adults aims to investigate whether a brief (6 sessions à 70 min) cognitive-behavioral intervention for young adults: (1) increases general SE, (2) lowers the risk for mental disorders, (3) increases domain-specific SE, and (4) improves dimensional mental health symptom outcomes via increased general SE. The intervention group is compared to an active control group, which receives a placebo treatment.

Potential mediators (emotional, cognitive, and behavioral, affectivity, internal locus of control and cognitive/behavioral coping) and moderators (sex, age, symptom severity at baseline and homework adherence during the intervention course) of the training efficacy will be additionally studied. Predictor and outcome measures will be assessed both conventionally (via personal interview and questionnaires during the respective main assessment) and with ecological momentary assessments (EMA, applied via smartphone over a 1-week interval following the respective main assessment) in everyday life.

Detailed Description

*Procedure*

Individuals who meet the inclusion criteria will participate in the baseline assessment. After the baseline assessment, participants will be randomized into either the intervention or control group (1:1 balanced randomization using computer-generated permutated blocks). Following each intervention (6 times), both general and domain-specific self-efficacy will be assessed. Dimensional clinical outcomes will be measured at baseline, post-intervention, and at a 12-month follow-up. Additionally, a 1-week ecological momentary assessment (EMA) will be administered at these three time points.

The self-efficacy intervention will be conducted in an online group format (subgroups with 8-12 participants; 6 sessions à 70 min) and led by an experienced psychologist. Courses will be structured according to well-established self-efficacy interventions with proven efficacy, targeting the 4 key sources of self-efficacy from Bandura (i.e., mastery experience, vicarious experience, verbal persuasion, and physiological/emotional arousal): Each course session will include a theoretical and practical part and be structured as follows: Opening, homework discussion (with a particular focus on participants’ progress and sharing experiences), introduction of the respective topic, practice under supervision, answering open questions, and closing. Course sessions will be accompanied by weekly homework assignments to practice at home. Assignments will be prepared and discussed in each course session. Participants will be additionally asked to keep a homework and success diary (workbook) to document changes in thoughts, feelings, and behaviors, questions/difficulties (to be discussed in the next session), and accumulating accomplishments in daily life over time (to enhance vicarious experiences). The last of the six sessions is held as a booster session. It takes place two weeks after the fifth session (as opposed to the usual one-week interval), with a primary focus on recapitulating the learned concepts, identifying further obstacles, and planning for future implementation in everyday life through behavioral analysis.

To increase intervention adherence, participants will receive weekly short messages with reminders and motivational support. Only participants of the intervention group will be able to contact a psychotherapist between the sessions to ask questions and receive additional support. To ensure that the intervention created has a positive impact on self-efficacy, the intervention is tested in a pilot phase in which self-efficacy is measured at the beginning, during and at the end of the intervention. In addition, feedback interviews on the intervention will be conducted during the pilot phase to assess acceptability, and the intervention will be amended accordingly.

Participants of the control group will meet in small groups (8-12 participants per group; 6 sessions à 60-70 minutes; equivalent to the intervention group). They will receive some theoretical input and discuss it in a non-personal manner. Group meetings will be moderated by an experienced psychologist. Here, the course leader takes on a moderating role to lead the discussion neutrally. They ensure that every participant has an equal say and avoid the use of psychotherapeutic techniques and avoid methods to increase self-efficacy expectations.

*Participants*

Participants of the intervention group are required to not receive any other psychological or psychopharmacological intervention during the training. Participants of the control group are required to not receive any psychological or psychopharmacological intervention at study entry. However, they may or may not engage in any intervention over the study course (usual care). After study completion, they will have the opportunity to receive the same self-efficacy training as the intervention group. Participant compensation: Participants will be compensated with 150€ (~ 17€/h) once they complete their participation in the study.

Sample size calculations are based on the “weakest line” in the analyses: Any incident or recurrent mental disorder from entry exam to follow-up in the intervention vs. control group. Calculations were conducted using data from the baseline and first follow-up assessment of the Early Developmental Stages of Psychopathology Study (EDSP), a community study in adolescents and young adults from Germany (Beesdo-Baum et al., 2015). Based on meta-analytic findings on indicated mental health preventions (Conley et al., 2017), we assume that the intervention group will improve from standardized self-efficacy scores below -1 to scores between -1 and -0.5. In the EDSP, 21% of those with baseline scores between -1 and -0.5 (~ intervention group) and 41% of those with baseline scores below -1 (~ control group) developed any incident anxiety, affective, or substance use disorder until follow-up (considering only individuals without psychopathology at baseline). Setting the statistical power at 0.9, the dropout rate at 20% (from baseline to post and from post to follow-up, respectively), and an incidence rate of 21% vs. 41% in the intervention vs. control group yields 189 individuals required per group at baseline (N=378 in total)

*Acceptability*

Participants of the intervention group will be asked to rate every session directly after completing it using a rating scale (“Stundenbeurteilungsbogen”). After the intervention, they will be asked to complete a questionnaire with closed and open questions to capture their view of the intervention program. Moreover, a subsample of the intervention group (20%, randomly collected) will be invited to (online) face-to-face semi-structured interviews (30 minutes) to determine the acceptability of the intervention.

*Data Exclusion/Missing Data*

To ensure response validity, several control items will be embedded throughout the study. These will include instructed response items and self-assessment items where participants rate their response accuracy on a dimensional scale. If participants rate the accuracy too low, their data will be excluded from the sample.  
Outliers will be identified through visual inspection (e.g., box plots) and statistical methods, including Z-scores (with ±3 SD as the critical threshold) and Mahalanobis distance for multivariate data. Outliers due to data entry errors will be corrected or removed, while genuine outliers will be retained unless they significantly distort the analyses. In such cases, robust methods and sensitivity analyses will be conducted to mitigate their impact, with exclusion only occurring if necessary. Full information maximum likelihood estimation will be applied to handle missing data, where appropriate. All exclusion criteria and decisions regarding outlier handling will be transparently reported.

*Analysis*

Data analyses will be performed with RStudio, Python, Stata (StataCorp, 2021), or Mplus (Muthén & Muthén, 2017). Data from the main assessment will be analyzed using linear (dimensional outcomes) and logistic (binary outcomes) regressions. To test whether outcome changes from baseline to post/follow-up vary by group, the difference of the respective outcome score (post/follow-up minus baseline) will be regressed on a group dummy (0=control, 1=intervention). To test whether rates of incident/recurrent mental disorders from study entry to follow-up vary by group, the diagnostic outcome will be regressed on the group dummy. To test for clinically significant effects, changes in clinical features (e.g., symptom-related burden and impairments) due to the intervention will be additionally assessed using linear/logistic regressions. EMA data will be analyzed using multilevel analyses with measurement occasions (Level 1) nested within persons (Level 2). To test whether outcome changes from baseline to post/follow-up vary by group, the respective outcome will be simultaneously regressed on a timing dummy (0=baseline, 1=post/follow-up), a group dummy (0=control, 1=intervention), and an interaction term (timing\*group). Furthermore, multilevel models will be used to capture time-lagged associations between contextual factors and outcome changes in daily life. For example, the impact of daily hassles on momentary fluctuations in state self-efficacy and psychopathological symptoms in the intervention vs. control group will be examined. Dimensional outcomes with non-normally distributed residuals will be log-transformed (log(x+1)). To allow for comparisons across different measures and groups, all dimensional outcomes will be standardized (M=0, SD=1) based on the pooled standard deviation in the intervention and control group at baseline (to account for potential initial group differences). The analyses will be adjusted for gender and age. The alpha level will be set at .05. The “BY” method will be used to correct for multiple testing of dependent hypotheses (Benjamini & Hochberg, 1995). Spillover effects will be tested using random intercept cross-lagged panel models (RI CLPM). RI-CLPM are a form of structural equation modeling and allow to capture spillover effects by examining time-lagged associations between 2 dimensional variables (cross-lagged paths), while considering their previous levels (autoregressive paths) and concurrent associations. Regarding spillover hypothesis 1, RI-CLPM will be built to assess cross-lagged effects of domain-specific on general self-efficacy from week 1-5 of the self-efficacy training in the intervention group (i.e., 5 time points will be considered per model). Regarding spillover hypothesis 2, RI-CLPM will be built to assess cross-lagged effects of self-efficacy on psychopathological symptoms from baseline to follow-up in the intervention group (i.e., 3 time points will be considered per model). Model fit will be evaluated based on the commonly reported Comparative Fit Index (CFI), Tucker-Lewis index (TLI), and Standardized Root Mean DFG form 53.01 – 09/22 page 13 of max. 17 Square Residual (SRMR). Models with a CFI>0.90, TLI>0.90, and SRMR<0.08 will be considered as acceptable (Bentler, 1990). As a manipulation check, we will test whether participants of the intervention group first increase in the domain of self-efficacy they work on (health, social relationships, or education/work) but not in the other domains. For example, individuals working on their health-related self-efficacy are expected to first increase in their health-related self-efficacy but not in the other 2 domains.

# Eligibility Criteria

*Inclusion Criteria:*

* (1) age 18-30 years and
* (2) low scores (<24) on the German version of the General Self Efficacy Scale (i.e., more than one standard deviation (5.4) below the mean score (29.4) in the German norm sample (Hinz et al., 2006)(treshhold might be lowered, if to few participants are to be found)
* (3) ability to participate in the courses (German language proficiency, availability during the intervention period)

*Exclusion Criteria:*

* (1) 12-month anxiety, affective, or substance use disorder (excluding nicotine dependence)
* (2) current psychological/psychopharmacological intervention or treatment seeking for psychological problems and
* (3) acute suicidality. Individuals who report acute suicidality will be withdrawn from the study and referred to treatment.

# Outcome Measures

Unfortunately, there I found no table function in clinicaltrials.gov, that is why the following is formatted like this

See for a legend of assessment timepoints below

*A Self-Efficacy (Instrument: GSE and* ASKU (Allgemeine Selbstwirksamkeit Kurzskala for EMAs))

General Self-Efficacy (Assessment timepoints: S, B, C, P, FU: see legend below for description)

Domain Specific Self-Efficacy (Assessment: B, P, FU)

*B Clinical outcomes (categorical) (Instrument: SCID-5-CV (module A,D,E,F)) (Assessment: E, FU)*

Anxiety disorders

Affective disorders

Substance use disorders

Because a 12-month follow-up period is a relatively short time frame to evidence group differences in onset rates of full-threshold mental disorders, also incident/recurrent sub threshold disorders will be considered. Sub-threshold disorders are defined as disorders falling short of one diagnostic criterion (e.g., the time criterion). In these analyses, incidences of subthreshold disorders not being present at entry exam will be additionally counted.

*C Clinical outcomes (dimensional) (Instrument: DSM-5 CCSM) (Assessment: B, P, FU)*

Depressive symptoms

Anxiety symptoms

Anger symptoms

Somatic symptoms

Sleep disturbances

*Further Assessments, no direct outcome measures*

*D Demographics (Instrument: Individual items) (Assessment: S or E)*

*E Adherence (Instrument: Short scale) (Assessment: C)*

*F Acceptability (Instrument: Stundenbeurteilungsbogen, short scale, interview) (Assessment: C)*

*G Fidelity (Instrument: Individual item) (Assessment: B, P, FU)*

Legend of assessment timepoints

S=screening; E=entry exam; B=baseline assessment; C=course assessment; P=post assessment; FU=12-month follow-up assessment. GSE=General-Self-Efficacy Scale. CCSM=Cross-Cutting Symptom Measure. SCID-5-CV=Strukturiertes Klinisches Interview für DSM-5-Störungen – Klinische Version. 1 Domain-specific self-efficacy (i.e., regarding health, social relationships, and school/university or work) will be additionally assessed at the respective main assessment (but not EMA) to test for generalization and spillover effects across different domains.

# Interventions

*Behavioral: Cognitive-Behavioral Intervention to increase Self Efficacy*

Description: Participants receive a brief (6 sessions à 70 min) cognitive-behavioral intervention. The self-efficacy intervention will be conducted in online group-format (subgroups with 8-12 participants). Courses will be structured according to well-established self-efficacy interventions with proven efficacy (Bresó et al., 2011; Cieslak et al., 2016; Luszczynska et al., 2007), targeting the 4 key sources of self-efficacy from Bandura (i.e., mastery experience, vicarious experience, verbal persuasion, and physiological/emotional arousal). Each course session will include a theoretical and practical part and be structured as follows: Opening, homework discussion (with a particular focus on participants’ progress and sharing experiences), introduction of the respective topic, practice, answering open questions, closing. Course sessions will be accompanied by weekly homework assignments to practice at home. The

*Behavioral: Group Discussion on Psychological Experiments as active Control*

Description: Participants of the control group will meet in small groups (8-12 participants per group; 6 sessions à 60-70 minutes; equivalent to the intervention group). They will receive a short introduction to popular psychological experiments and findings (e.g. Asch experiment, selective attention), and discuss their views on them. Personal implications of the experiments and concepts of self-efficacy ar explicitly avoided. Group meetings will be moderated by an experienced psychologist.

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