

INPLASY PROTOCOL

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None declared.

Efficacy of internet-based Self-Management Interventions for Depression in German: Protocol for a systematic Review and Meta-Analysis

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Review question / Objective: The aim of this systematic review and meta-analysis is to examine the effectiveness of internet-based self-management interventions for depressive symptoms in adults, which are available in German and have been tested via randomized controlled trials. The interventions must be either available for free or covered by public health insurance.

Information sources: The electronic database PubMed will be used for systematic literature search. Additionally, the “DiGA-Verzeichnis” of the “Bundesinstitut für Arzneimittel und Medizinprodukte” as well as the manufacturers' websites of the identified interventions will be searched for relevant studies. The knowledge of an expert on digital interventions for mental disorders also serves as a source of information.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 11 May 2022 and was last updated on 11 May 2022 (registration number INPLASY202250070).

interventions must be either available for free or covered by public health insurance.

Rationale: To the authors' knowledge there are currently no reviews or meta-analysis addressing all of the digital self-management interventions for depression that are available for free or covered by public health insurance in Germany. This

INTRODUCTION

Review question / Objective: The aim of this systematic review and meta-analysis is to examine the effectiveness of internet-based self-management interventions for depressive symptoms in adults, which are available in German and have been tested via randomized controlled trials. The

review shall help healthcare providers in identifying which of these interventions can be recommended in terms of the quality of the literature supporting them and also the reported effectiveness.

Condition being studied: The condition being studied is depression - either as formal diagnosis, as rated on validated questionnaires, or as amount of symptoms in diagnostic manuals. The depression may be comorbid to another disease as long as the intervention that is studied focuses primarily on reducing depressive symptoms.

METHODS

Search strategy: The search strategy is comprised of three steps:

(1) A systematic literature search of PubMed.

(2) Searching through manufacturers' websites of interventions identified in step 1 to find any studies the literature search might have missed; Searching through the "DiGA-Verzeichnis" of the "Bundesinstitut für Arzneimittel und Medizinprodukte" to find additional interventions that meet the inclusion criteria and then searching through those manufacturers' websites to find any suitable studies.

(3) Consult an expert on digital interventions for depression in German to check if any intervention was missed.

The search string in step 1 is: ("Depression"[Mesh] OR "Depressive Disorder"[Mesh] OR "Dysthymic Disorder"[Mesh] OR "Depressive Disorder, Major"[Mesh] OR "depress*"[tiab] OR "dysthymi*"[tiab]) AND ("Internet-Based Intervention"[Mesh] OR "Telemedicine"[Mesh]) OR "online deliver*"[tiab] OR "online intervention*"[tiab] OR "online treat*"[tiab] OR "online therap*"[tiab] OR "online psychotherap*"[tiab] OR "digital intervention*"[tiab] OR "digital treat*"[tiab] OR "digital therap*"[tiab] OR "digital psychotherap*"[tiab] OR "mobile intervention*"[tiab] OR "mobile treat*"[tiab] OR "mobile therap*"[tiab] OR "mobile psychotherap*"[tiab] OR "mobile deliver* intervention*"[tiab] OR "mobile deliver*

treat*"[tiab] OR "mobile deliver* therap*"[tiab] OR "mobile deliver* psychotherap*"[tiab] OR "mobile based intervention*"[tiab] OR "mobile based treat*"[tiab] OR "mobile based therap*"[tiab] OR "mobile based psychotherap*"[tiab] OR "internet intervention*"[tiab] OR "internet treat*"[tiab] OR "internet therap*"[tiab] OR "internet psychotherap*"[tiab] OR "internet deliver* intervention*"[tiab] OR "internet deliver* treat*"[tiab] OR "internet deliver* therap*"[tiab] OR "internet deliver* psychotherap*"[tiab] OR "internet based intervention*"[tiab] OR "internet based treat*"[tiab] OR "internet based therap*"[tiab] OR "internet based psychotherap*"[tiab] OR "self management intervention"[tiab] OR "web intervention*"[tiab] OR "web treat*"[tiab] OR "web therap*"[tiab] OR "web psychotherap*"[tiab] OR "web deliver* intervention*"[tiab] OR "web deliver* treat*"[tiab] OR "web deliver* therap*"[tiab] OR "web deliver* psychotherap*"[tiab] OR "web based intervention*"[tiab] OR "web based treat*"[tiab] OR "web based therap*"[tiab] OR "web based psychotherap*"[tiab]) AND ("random*" OR "RCT") AND ("german" OR "germany").

Participant or population: All adults over the age of 18 with depressive symptoms are included in this review. Comorbid diseases are allowed. There will be no exclusion based on ethnicity or other sociodemographic factors.

Intervention: This review will include self-management interventions that (1) are available in German for free or are covered by German public health insurance, (2) focus on depressive symptoms using psychotherapeutic techniques, (3) are delivered digitally, either smartphone-based or web-/desktop-based, (4) have an intervention duration of more than 2 weeks, (5) use teletherapy (i.e. phone calls or video sessions with therapists) only supplementally to the self-management intervention and (6) have been studied with at least one randomized controlled trial.

Comparator: This review will include different types of control conditions: (1) Treatment-as-usual (TAU), (2) waitlist, (3) active control conditions, including attention, relaxation or education and (4) no intervention. Specifically excluded are control conditions using face-to-face psychotherapy.

Study designs to be included: This systematic review and meta-analysis will only include randomized controlled trials.

Eligibility criteria: Population: All adults over the age of 18 with depressive symptoms are included in this review. Comorbid diseases are allowed; there will be no exclusion based on ethnicity or other sociodemographic factors. Intervention: This review will include self-management interventions that: Are available in German for free or are covered by public health insurance; focus on depressive symptoms using psychotherapeutic techniques; are delivered digitally, either on smartphones or web-/desktop-based; have an intervention duration of more than 2 weeks; use teletherapy (i.e. phone calls or video sessions with therapists) only supplementally to the self-management intervention; have been studied with at least one randomized controlled trial. Comparison: Treatment-as-usual (TAU); waitlist; active control conditions, including attention, relaxation or education; no intervention; specifically excluded are control conditions using face-to-face psychotherapy. Outcome: Depression as measured with validated questionnaires or as number of symptoms according to diagnostic manuals.

Information sources: The electronic database PubMed will be used for systematic literature search. Additionally, the “DiGA-Verzeichnis” of the “Bundesinstitut für Arzneimittel und Medizinprodukte” as well as the manufacturers' websites of the identified interventions will be searched for relevant studies. The knowledge of an expert on digital interventions for mental disorders also serves as a source of information.

Main outcome(s): Reduction of depressive symptoms immediately after the end of the intervention and measured by validated self- or clinician-rated depression scales.

Data management: Rayyan will be used to organize the whole study selection process. At first, two independent researchers (NW, PV) will remove existing duplicates and then screen the identified studies by title and abstract. After that, the full text from the remaining studies will be checked regarding the eligibility criteria. Disagreement will be resolved by a discussion between NW and PV and if not resolved, an expert will be consulted. The whole process will be visualized in a flow chart. Data extraction from the selected studies will also be carried out by two independent researchers (NW, PV) with a structured data extraction form, including basic information about the study, information about the intervention and statistical characteristics.

Quality assessment / Risk of bias analysis: In order to evaluate the methodological quality of the selected studies, two independent researchers (NW, PV) will assess the risk of bias for each study using the Cochrane Risk of bias assessment tool (RoB 2). The bias domains included in RoB 2 are (1) bias arising from the randomization process, (2) bias due to deviations from intended interventions, (3) bias due to missing outcome data, (4) bias in measurement of the outcome and (5) bias in selection of the reported result. If disagreements among the two researchers cannot be resolved in a discussion, an expert will be consulted. After the risk of bias assessment for each study, the risk of bias will be summarized across the different studies for each of the five RoB 2-domains.

Strategy of data synthesis: All statistical analyses will be performed using ReviewManager 5.4. For each study, the effect size Cohen's d and their 95 % CI will be extracted or calculated from available data in the paper. For this purpose, data from intention-to-treat analyses will be preferred over data from per-protocol

analyses. A random effect model will be assumed to pool the effect sizes to an overall effect size, as well as for subsequent exploratory subgroup analyses. The heterogeneity of the studies will be analyzed visually with the forest plot as well as calculated by the Higgin's I-squared statistic. To check for possible publication bias, funnel plot asymmetry will be tested using the Egger's test.

Subgroup analysis: Subgroup analysis will be done for the factors psychological or psychotherapeutic guidance and type of intervention. Additional possible factors would be the severity of the depressive symptoms or the device used.

Sensitivity analysis: Sensitivity analyses will be performed to examine if the exclusion from studies with high risk of bias, assessed with the RoB 2, will change the overall outcome. An additional sensitivity analysis will be conducted to examine whether exclusion of trials that have been conducted with a non-german speaking population changes the overall outcome.

Language: Only randomized controlled trials published in English or German will be considered for inclusion.

Country(ies) involved: Germany.

Keywords: Depression; Internet-Based Intervention; Mobile Applications; Cognitive Behavioral Therapy; Germany; Meta-Analysis.

Dissemination plans: The systematic review and meta-analysis will be conducted as part of two master theses. The authors would like to remain open to the possibility of subsequently publishing the study in a peer-reviewed journal.

Contributions of each author:

Author 1 - Pia Vock - PV conceived and designed the plan for this systematic review and meta-analysis. She will be involved in every following stage (e.g. study selection and data extraction, analysis and interpretation of data, writing the paper).

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Author 2 - Nikolaj Wächtershäuser - NW conceived and designed the plan for this systematic review and meta-analysis. He will be involved in every following stage (e.g. study selection and data extraction, analysis and interpretation of data, writing the paper).

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