

INPLASY PROTOCOL

Yoga for depressive disorder– registry of a systematic review and meta-analysis

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None declared.

Review question / Objective: What is the effect of yoga interventions on depression severity and remission rate in patients with depressive disorders compared to passive and active controls?

Condition being studied: The study will focus on clinically diagnosed depression (DSM-IV/-V or ICD-10/-11).

Information sources: Following Databases will be searched with the described search term: Medline, Cochrane, Scopus, PsycInfo. As a source of grey literature, BASE (Bielefeld academic search engine) will be searched.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 09 March 2023 and was last updated on 09 March 2023 (registration number INPLASY202330033).

INTRODUCTION

Review question / Objective: What is the effect of yoga interventions on depression severity and remission rate in patients with depressive disorders compared to passive and active controls?

Rationale: The prevalence of depression in the population is increasing rapidly (1, 2). There is a growing gap of people affected and people receiving adequate therapy (2). This problem already existed in 2019 (1), and after an estimated number of 53.2 million additional cases of major depressive disorder globally caused by the

pandemic (2), the urgent of a low-threshold and widespread therapy approach is evident. Complementary therapy approaches show one possible field to help patients suffering from depression. Yoga intervention is one approach of high interest. Many potential molecular mechanism are described (3) and earlier research already showed beneficial effects of yoga (4, 5). Due to rising amount of research in this field, an update of existing reviews is appropriate. Conducting an up-to-date Meta Analysis provides an overview of current state of evidence, which provides important information for practitioners, decision makers and stakeholders.

Condition being studied: The study will focus on clinically diagnosed depression (DSM-IV/-V or ICD-10/-11).

METHODS

Search strategy: For literature search, search terms were created and modified upon requirements of other databases. As an example, the search term for PubMed is presented: (“Depression”[Mesh] OR “Depressive Disorder”[Mesh] OR depress* [Title/Abstract] OR dysthymi*[Title/Abstract]) AND (“Yoga”[Mesh] OR *yoga[Title/Abstract] OR yoga* [Title/Abstract] OR yogi* [Title/Abstract] OR asana* [Title/Abstract] OR pranayama [Title/Abstract] OR dhyana [Title/Abstract] OR Surya Namaskara [Title/Abstract]).

Participant or population: Participants with clinically diagnosed depressive disorders with a minimum age of 18 are eligible. No restriction regarding gender and ethnicity are made. If there are mixed populations in a study, eligible patents will be included in the review if data for this subgroup is available.

Intervention: Any type of yoga intervention will be included in the review, without restriction to type, duration, frequency or length of intervention.

Comparator: Different groups of comparators will be included and analyzed

separately: passive control (e.g. waitlist, treatment as usual), active psychological control (e.g. meditation, mindfulness approaches), active physiological control (e.g. sports, stretching, walking groups).

Study designs to be included: Only randomized controlled trials will be included.

Eligibility criteria: Inclusion: - Age > 18 years, - clinically diagnosed depressive disorder (DSM-IV/-V or ICD-10/-11), - yoga intervention; Exclusion: - studies investigating other comorbidities (e.g. cancer, back pain, anxiety).

Information sources: Following Databases will be searched with the described search term: Medline, Cochrane, Scopus, PsycInfo. As a source of grey literature, BASE (Bielefeld academic search engine) will be searched.

Main outcome(s): The primary outcomes are severity of depression and remission rate. Severity has to be reported at baseline and after intervention. Common scales of severity measurement will be included, e.g. BDI-score and HD-score. Remission has to be reported after intervention.

Additional outcome(s): As secondary outcomes, safety of yoga as an intervention and health related quality of life will be examined. For safety measurement, the number of patients with serious adverse events (SAE) and the number of patients with adverse events (AE) will be assessed. Health related quality of life will be assessed with a focus on psychological component scores and/or mental health subscales.

Data management: Citavi will be used as software tool to manage literature and to record decision making. First titles, then abstracts, and further full texts will be screened for eligibility independently by two authors. If disagreements appear, a third author will be consulted. Further disagreements will be discussed until consent is reached. Data extraction will be

done in Excel, statistical analyses will be done in R and R Studio.

Quality assessment / Risk of bias analysis:

Risk of bias analysis will be measured by the Cochrane risk of bias tool 2.0. Two authors will independently assess all included studies for their risk of bias. If disagreements appear, a third author will be consulted. Further disagreements will be discussed until consent is reached.

Strategy of data synthesis:

Analyses will be made separately for short-term and long-term follow-ups. If at least two studies are available on a specific outcome, pooled analyses will be conducted. For continuous outcomes, standardized mean differences (SMD) with 95% confidence intervals (CI) will be calculated and Hedges's correction for small study samples will be used (6,7). Where no standard deviations are available, they will be calculated from standard errors, confidence intervals or t values. For dichotomous outcomes, odds ratios (OR) with 95% CI will be calculated (6,7). In the case of missing data attempts will be made to obtain the missing data from the trial authors. Random effects model will be calculated by using inverse variance method for continuous outcomes and the Mantel-Haenszel method for dichotomous outcomes (8). For a better comparability in case of non-significant heterogeneity, fixed effects model estimates will be added to the forest plots. Additionally, the Hartung-Knapp small-sample correction will be used (9). Statistical heterogeneity between studies will be explored by using the I² and τ^2 statistics. If statistical heterogeneity will be present in the respective meta-analysis, subgroup analyses and meta-regression (if at least a minimum of 10 studies could be included in the respective analyses) will also be conducted to explore possible reasons for heterogeneity (6,7,8).

Subgroup analysis:

Subgroup analyses will be performed for different grades of depression. Participants will be separated in two groups: diagnosis of major depressive disorder (diagnosed by DSM-IV or ICD-10) and non-major depressive disorder. The classification of different

types of control groups (as described earlier) also will yield a subgroup analysis.

Sensitivity analysis: Sensitivity analyses will be conducted for studies with high versus low risk of bias to test the robustness of significant results.

Country(ies) involved: Germany.

Keywords: Yoga; Depression; Depressive disorder; Complementary medicine; Psychology.

Dissemination plans: The review will be published in a peer reviewed scientific journal. Results of this review will be presented at scientific congresses.

Contributions of each author:

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