

Yoga for young women with depression

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22129

Source

Nationaal Trial Register

Health condition

Major depressive disorder
Depression
Young adult women
Yoga

Sponsors and support

Primary sponsor: Lentis Geestelijke Gezondheidszorg

Centrum Integrale Psychiatrie

Hereweg 80

9725 AG Groningen

Source(s) of monetary or material Support: Lentis Geestelijke Gezondheidszorg

Hereweg 80

9725 AG Groningen

ZonMw

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2593 CE Den Haag

Triodos Foundation

Nieuweroordweg 1

3700 AB Zeist

Mind & Life Institute
4 Bay Road
Hadley, MA 01035
United States of America

Intervention

Outcome measures

Primary outcome

Primary outcome measures will consist of clinician-administered and self-report measures of depression symptoms. Quality-Adjusted Life Years will be used as primary outcome measure in the economic analysis.

Secondary outcome

Secondary hypotheses will also be examined. Potential mediators of YBT will be assessed, including (a) ability to disengage attention from information regarding the causes and consequences of negative events and moods, measured by self-report and a computerized measure of attentional bias and (b) reduced self-criticism (and increased self-compassion) after perceived failure, measured by self-report and a computerized measure of self-concept. Also, the influence of YBT on symptom interference in daily functioning, quality of life and physical health and positive psychological functioning (i.e., positive emotion and quality of relationships) will be assessed.

Study description

Background summary

Rationale: Major Depressive Disorder (MDD) is widespread, as nearly one in five Dutch will experience the disorder within their lifetime. In addition to individual suffering, MDD creates great economic costs in the Netherlands and is a leading contributor to the national disease burden. Although first-step interventions can be helpful, many individuals with MDD do not seek treatment and current interventions often fail to prevent the development of chronic, relapsing MDD. There is thus a pressing need to develop and test new interventions for depression. This need is particularly urgent in young adult women, as this population is especially vulnerable to developing MDD. Yoga-based interventions represent an innovative approach with great potential for treating depression. The rationale of using yoga as a MDD intervention in young women includes initial findings that yoga reduces depressive affect and yoga's appeal in this population. Although the initial findings are promising, previous

research has a number of methodological limitations such as insufficient statistical power, inadequate control groups, and short follow-up periods. The proposed project is designed to use rigorous methods to examine yoga as a treatment for acute depression and as means of preventing the transition to a chronic, relapsing disorder in a sample of young women. Objective: To examine whether adding yoga-based therapy (YBT) to treatment as usual (TAU) for young women with MDD leads to (1) greater reductions in symptoms and (2) greater cost-effectiveness in that the economic benefits of adding YBT to TAU outweigh the costs.

Hypothesis: Primary hypotheses are that compared both to TAU, YBT (+TAU) will show greater long-term (H1.1) reductions in clinician-administered (Hamilton Depression and Anxiety Rating Scales) and self-report (Depression Anxiety Stress Scales) measures of depression and (H1.2) cost-effectiveness. Secondary hypotheses are that YBT effects are partially mediated by cognitive mechanisms, including (H2.1) brooding and (H2.2) self-criticism. Exploratory analyses will examine potential moderators of YBT.

Study design: The study will consist of a randomized controlled trial comparing YBT+TAU with TAU. Assessments are completed at pre- and post-intervention (or equivalent time period in TAU), and at 6- and 12-month follow-up.

Study population: Young adult women (age 18-34 years) with a primary diagnosis of MDD. Intervention (if applicable): The intervention will consist of manualized YBT administered in 9 weekly 90-minute group sessions with home practice +TAU. TAU will consist of interventions recommended by the Dutch guidelines for depression, including psychotherapy, pharmacotherapy, psychosocial support by psychiatric nurses, or some combination of these.

Main study parameters/endpoints: Primary outcome measures will consist of clinician-administered and self-report measures of depression symptoms. Quality-Adjusted Life Years will be used as primary outcome measure in the economic analysis.

Study objective

We hypothesize that compared to treatment as usual (TAU), Yoga-based Therapy (YBT)+TAU will lead to:

Hypothesis 1: Greater reductions in depressive symptoms, assessed with (a) clinician-administered measures (Hamilton Depression Rating Scale) and (b) self-report measures (Depression Anxiety Stress Scales). Group differences will be examined at post-treatment and 6- and 12-month follow up.

Hypothesis 2: A reduction of societal costs and improved health outcomes (assessed with QALYs).

Secondary hypotheses: (1) The benefits of YBT on depression will be partially mediated by (a) reduced brooding about the causes and consequences of negative events and moods and (b) reduced self-criticism/increased self-compassion after perceived failures; and (2) The YBT group will show greater increases in physical health and psychological well-being (e.g., positive emotion, life satisfaction, and perceived ability to manage one's life).

Exploratory analyses: We will examine whether the effects of YBT are moderated by demographic variables (e.g., socioeconomic status) clinical factors (e.g., co-morbidity) and variables from the process evaluation (e.g., treatment adherence).

Study design

Assessments are completed at pre- and post-intervention (or equivalent time period in TAU), and at 6- and 12-month follow-up.

Intervention

The intervention will consist of manualized YBT administered in 9 weekly 90-minute group sessions with home practice +TAU. TAU will consist of interventions recommended by the Dutch guidelines for depression, including psychotherapy, pharmacotherapy, psychosocial support by psychiatric nurses, or some combination of these.

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- Primary diagnosis of a major depressive disorder.
- Age ≥ 18 and ≤ 34 .
- Ability to fluently read, write, and speak Dutch.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- Current diagnoses of bipolar disorder and substance dependence.
- Current psychotic symptoms.
- Active suicidality.
- Unwilling or inability to attend to 9 weekly sessions of yoga.
- Regular yoga practice (on average over the past 6 months, 30 or more minutes per week).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL
Recruitment status: Pending
Start date (anticipated): 15-12-2016
Enrollment: 170
Type: Anticipated

Ethics review

Positive opinion
Date: 01-12-2016
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 43267
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6170
NTR-old	NTR6317
CCMO	NL59324.042.16
OMON	NL-OMON43267

Study results