

Yoga for young women with depression: a randomized controlled trial

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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...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON43267

Source

ToetsingOnline

Brief title

Yoga for young women with depression

Condition

- Mood disorders and disturbances NEC

Synonym

Depression, depressive symptoms

Research involving

Human

Sponsors and support

Primary sponsor: Lentis (Groningen)

Source(s) of monetary or material Support: Lentis;Triodos;Mind and Life

Intervention

Keyword: Depression, Yoga, Young women

Outcome measures

Primary outcome

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 outcome

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 description

Background summary

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.

Study 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.

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.

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.

Study burden and risks

The burden for patients consists of completing questionnaires and computer tasks at four points in time (time costs per assessment is 100, 90, 60 and 60 minutes) and includes a structured clinical interview (15 minutes). The benefit for patients in the active treatment condition consists of receiving a yoga training in which techniques are used that have proven to be effective in treatment of mood disorders. Patients will receive nine 90-minute treatment sessions. The patients will also be asked to engage in homework exercises during the course of treatment (about 30 minutes per day, 6 days a week). To our knowledge, there are no negative effects of this treatment. We consider the risks of this study to be low, as patients are primarily asked to invest time and effort.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

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 .
- Being able to 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)

Primary purpose: Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	07-03-2017
Enrollment:	170
Type:	Actual

Ethics review

Approved WMO	
Date:	22-11-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	
Date:	02-02-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	
Date:	30-03-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	
Date:	04-10-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO
Date: 12-03-2018
Application type: Amendment
Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 22129

Source: Nationaal Trial Register

Title:

In other registers

Register	ID
CCMO	NL59324.042.16
OMON	NL-OMON22129