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# A mindful yoga intervention for young women with major depressive disorder: Design and baseline sample characteristics of a randomized controlled trial

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## Abstract

**Objectives:** Despite the gains made by current first-line interventions for major depressive disorder (MDD), modest rates of treatment response and high relapse indicate the need to augment existing interventions. Following theory and initial research indicating the promise of mindful yoga interventions (MYIs), this study examines mindful yoga as a treatment of MDD.

**Methods/Design:** This randomized controlled trial uses a sample of young females (18–34 years) to examine the efficacy and cost-effectiveness of a 9-week manualized MYI added to treatment as usual (TAU) versus TAU alone. Primary outcome measures consist of clinician-administered (Hamilton Depression Rating Scale) and self-report (Depression-Anxiety-Stress Scales) measures of depression. Underlying mechanisms will be examined, including rumination, negative self-evaluation, intolerance of uncertainty, interoceptive awareness, and dispositional mindfulness. Assessments were conducted at preintervention and will be conducted at postintervention, 6-, and 12-month follow up.

**Results:** The baseline sample consists of 171 females (88 were randomized into the MYI), reporting a baseline $M_{age}$ = 25.08 years ($SD_{age}$ = 4.64), $M_{Hamilton\text{-}depression}$ = 18.39 ($SD_{Hamilton}$ = 6.00), and a $M_{DASS\text{-}depression}$ = 21.02 ($SD_{DASS}$ = 9.36).

**Conclusion:** This trial will provide important information regarding the benefits of adding yoga-based interventions to TAU for young women with MDD and the mechanisms through which such benefits may occur.

KEYWORDS

depression, mediators, mindful yoga, randomized controlled trial, women

**Abbreviations:** CBT, cognitive behavioral therapy; DASS-sf, Depression Anxiety Stress Scales, short form; MDD, major depressive disorder; MYI, mindful yoga intervention; SCID-I, structured interview for DSM-IV; TAU, treatment as usual.

# 1 | INTRODUCTION

## 1.1 | The costs of depression in young women

Major depressive disorder (MDD) is highly prevalent and leads to large personal and societal costs (Demyttenaere et al., 2004). According to the World Health Organization, the lifetime prevalence of depression is 12%, and MDD is the third leading contributor to disease burden (Kessler et al., 2009; World Health Organization, 2011). The costs of MDD are unequally distributed, with females being twice as likely to experience MDD compared to males (Kessler, 2003). Furthermore, young adults (18–34 years) show the highest rates of initial onset (Kessler, Petukhova, Sampson, Zaslavsky, & Wittchen, 2012) and overall prevalence (Bromet et al., 2011). Treatment could prevent suffering and costs, but almost 50% of young adults with depression do not seek help (Eisenberg, Downs, Golberstein, & Zivin, 2009; Eisenberg, Golberstein, & Gollust, 2007; Wang et al., 2007).

Of those who do receive standard medication and psychological treatments (e.g., cognitive behavioral therapy), many fail to benefit. Specifically, nonresponse rates have been estimated to be as high as 45–50% (Preskorn, 2013; Spijker et al., 2002). Moreover, studies have found that between 27 and 31% of patients taking antidepressant medication discontinue treatment because of side effects (Anderson, 2000; MacGillivray et al., 2003). Among responders, the benefits are often modest as indicated by medium effect sizes (Cuijpers et al., 2013). The benefits are also likely to be temporary, with studies showing 29–54% relapse rates during the time span of 1–2 years posttreatment (Dobson et al., 2008; Gortner, Gollan, Dobson, & Jacobson, 1998; Ramana et al., 1995; Shea et al., 1992; Vittengl, Clark, Dunn, & Jarrett, 2007). These results suggest that, despite the gains made by current first-line interventions for MDD, more effort is needed to develop treatments that are appealing to young adults and can help to provide long-lasting benefits. This is especially necessary for young women, who disproportionately bear the burden of MDD (Bromet et al., 2011; Kessler, 2003).

## 1.2 | Treatment innovations may benefit from targeting processes involved in MDD

Innovative interventions for MDD may benefit from targeting processes that are involved in the persistence and recurrence of depression. One such process is rumination, which involves a response to negative events and moods with a perseverative focus on the causes and consequences of the event or mood (Treynor, Gonzalez, & Nolen-Hoeksema, 2003). Maladaptive rumination differs from adaptive reflection in that rumination involves an *abstract* thinking style regarding why one feels depressed and the meaning of problematic events, in contrast to adaptive reflection, which involves a concrete style regarding how one feels and specific steps needed for problem solving (Watkins, 2008). Rumination has been found to predict MDD onset in young adults (Nolen-Hoeksema, Parker, & Larson, 1994); increased levels of depression (Nolen-Hoeksema, 2000); and transition to chronic, relapsing depression (Wiersma et al., 2010). Furthermore, longitudinal studies have shown that more rumination in females partly explains gender differences in depressive symptoms (Hamilton, Stange, Abramson, & Alloy, 2015; Treynor et al., 2003).

Another process involved in MDD includes chronic negative self-evaluation, for example, a self-critical response style involving negative self-judgment after perceived failure. Self-criticism has been found to predict the development of depressive symptoms in young adults (Auerbach, Ho, & Kim, 2014), chronicity of first MDD episodes (Park, Goodyer, & Teasdale, 2005), and postintervention relapse (Zuroff, Santor, & Mongrain, 2005). Evidence that females demonstrate more self-criticism (Powers, Zuroff, & Topciu, 2004) suggests that this variable may play an important role in the observed gender differences in depression rates.

A third process involved in depression is intolerance of uncertainty, which involves negative reactions (e.g., anxiety, beliefs about danger, avoidance) to situations in which the outcome is uncertain. Originally thought to be a vulnerability factor specific to anxiety disorders, intolerance of uncertainty has recently been shown to play a role in mood disorders (Mahoney & McEvoy, 2012). Recent studies have found that intolerance of uncertainty may be more present in females (Bottesi et al., 2016; Cooke et al., 2017).

Interoceptive awareness/body awareness is a fourth depression-related process (the two terms are often used interchangeably; Mehling et al., 2012). Both terms refer to the ability to recognize and regulate internal bodily signals (Farb et al., 2015; Mehling et al., 2012). The idea that awareness of internal experience can be adaptive (vs. maladaptive, such as occurs with increased anxiety) has been suggested to hinge on the extent to which such awareness includes a nonjudgmental attitude (Farb et al., 2015; Mehling et al., 2012). A growing body of research shows that this sort of adaptive body awareness is positively associated with affect regulation (Pollatos & Schandry, 2008; Pollatos, Traut-Mattausch, Schroeder, & Schandry, 2007) and negatively associated with depression and rumination (Lackner & Fresco, 2016; Pollatos, Traut-Mattausch, & Schandry, 2009). Regarding gender differences, previous research has found that females tend to experience more emotional distress in response to uncomfortable bodily sensations and to experience their body as less safe (Grabauskaite, Baranauskas, & Griskova-Bulanova, 2017).

A fifth depression-related mechanism consists of dispositional mindfulness, which can be defined as including awareness of the present moment (applicable to the rumination and interoceptive awareness processes) and a nonjudgmental attitude toward any experience (applicable to the self-criticism and the intolerance of uncertainty processes) (Bishop et al., 2004). Mindfulness has been shown to be inversely related to depressive symptoms in both cross-sectional (Gilbert & Christopher, 2010; Gilbert & Gruber, 2014) and intervention (Barnhofer et al., 2009) studies.

## 1.3 | Mindful yoga for MDD

The current study examines whether a mindful yoga intervention (MYI) will lead to better outcomes when added to treatment as usual

(TAU). Mindful yoga involves physical postures, breathing exercises, and meditation practices that include cultivation of a nonjudgmental awareness of body sensations and thoughts (Anderson & Sovik, 2000; Desikachar, 1999). Initial studies with yoga interventions have shown that yoga can help to reduce depressive affect in young adult and female samples (Field et al., 2012; Woolery, Myers, Sternlieb, & Zeltzer, 2004). Research has also shown that depressive affect is reduced by components of yoga, such as meditation (Hofmann, Sawyer, Witt, & Oh, 2010) and nonaerobic exercise (Powers, Asmundson, & Smits, 2015). However, a recent meta-analysis of the effectiveness of yoga for depression concluded that most studies were of low methodological quality, thereby making it difficult to draw firm conclusions about yoga's effectiveness for depression (Vollbehr et al., 2018). Methodological limitations often consist of small sample sizes, use of nonmanualized intervention protocols, inadequate description of the TAU in control groups, and short follow-up periods. Therefore, more studies using high-quality methods are needed to investigate the initial and sustained effects of mindful yoga for depression. In conclusion, mindful yoga represents a promising treatment for MDD for a number of reasons, including the initial findings listed above showing beneficial effects on depression symptoms and the potential of mindful yoga to mitigate processes involved in the persistence of MDD.

## 1.4 | Mindful yoga as targeting processes involved in MDD

One depression-related process that mindful yoga may mitigate is rumination as training involves shifting from an abstract thinking style to a concrete focus on body sensations. This idea is supported by findings that mindful yoga increases awareness of present-moment experience, even more so than other meditative practices (Carmody & Baer, 2008). Further evidence is found in a study that compared a yoga intervention to health education sessions for depressed participants (Kinser, Elswick, & Kornstein, 2014). This study showed that participants in the yoga group reported less rumination at 1-year follow up compared to participants in the control group. Another study in a group of depressed women found that women who received a 12-week MYI reported significantly less rumination postintervention compared to a walking control condition (Schuver & Lewis, 2016).

Second, MYIs may reduce self-criticism given that training instructions involve a nonjudgmental attitude regarding difficult sensations and self-critical thoughts during physical postures (Anderson & Sovik, 2000; Desikachar, 1999). This idea is supported by findings in nondepressed samples showing that mindful yoga leads to increased self-compassion (i.e., self-kindness after failure; Sauer-Zavala, Walsh, Eisenlohr-Moul, & Lykins, 2013) and nonjudgmental attitudes toward one's negative emotions (Carmody & Baer, 2008). In both studies, reductions in self-criticism were greater for mindful yoga compared to other meditation practices. Third, mindful yoga may reduce intolerance of uncertainty as the intervention includes practices to develop nonjudgmental awareness of difficult emotions and cognitions. Initial research suggests that such nonjudgmental awareness is inversely related to intolerance of uncertainty (Kraemer, O'Bryan, & McLeish, 2016).

Fourth, MYIs may enhance body awareness as they include practices to develop awareness of bodily sensations. Several studies have shown that yoga practice is associated with more body awareness in healthy adults (Daubenmier, 2005; Tihanyi, Boor, Emanuelsen, & Koteles, 2016) and that obese participants reported increased body awareness after a yoga intervention (Cramer, Thoms, Anheyer, Lauche, & Dobos, 2016). In addition, mindfulness interventions (that include yoga and meditation) have been shown to improve interoceptive awareness (De Jong et al., 2016), and interoceptive awareness has been found to mediate the relationship between level of mindfulness and symptoms of depression (Fissler et al., 2016). Finally, MYIs may also increase dispositional mindfulness. Yoga training that incorporates a meditative aspect (including the present protocol) was found to have a stronger influence on reducing depression than yoga training without meditation (Cramer, Lauche, Langhorst, & Dobos, 2013) and has also been shown to increase dispositional mindfulness, more so than other traditional meditative practices such as breath meditation (Carmody & Baer, 2008).

## 1.5 | Appeal of MYIs

An additional promising feature of mindful yoga for MDD is its attractive appeal as a practice for physical and mental well-being (Birdee et al., 2008). This may help to circumvent stigma that could impede treatment seeking in young adults (Eisenberg et al., 2009). Indeed, evidence shows that yoga is increasingly being used to self-manage mood symptoms (Birdee et al., 2008). The appeal of yoga may also increase motivation to practice, thereby helping to self-manage distress and prevent the transition to a chronic, relapsing MDD. As yoga is especially popular with young women (Birdee et al., 2008), this group may be particularly likely to profit from the benefits of yoga-based interventions.

Overall, yoga-based interventions have promise as a treatment for MDD in young women given that yoga has been found to reduce depressive affect and to mitigate cognitive and affective vulnerabilities of MDD (some of which are especially relevant in young women). Furthermore, yoga has been shown to be attractive to this population. The promising preliminary findings and high rates of public use, combined with a lack of high-quality research, underscore the need for further research with rigorous designs to test mindful yoga as a treatment for depression.

## 1.6 | Current study

The present study aims to examine the efficacy and cost-effectiveness of a 9-week MYI for young women in addition to TAU, compared to TAU alone, using the following methods: a randomized controlled trial design, an adequate sample size, use of clinician-rated and self-report

outcome measures, and follow-up assessments of 6 and 12 months. This study also explores whether the main effects are mediated by processes that play a central role in the persistence of depression. These include rumination, self-criticism, intolerance of uncertainty, interoceptive awareness, and dispositional mindfulness.

#### 1.6.1 | Study aim and hypotheses

The overall objective of this project is to examine the potential benefits of adding an MYI to TAU for young women with MDD. This objective will be examined with the following four specific aims: to examine whether adding the MYI to TAU leads to (a) greater and sustained reductions in symptoms; (b) better general functioning; (c) whether this is cost-effective; and (d) whether these effects are mediated by change in rumination, self-criticism, intolerance of uncertainty, interoceptive awareness, and dispositional mindfulness. Our hypotheses are that, compared to TAU, MYI + TAU will lead to: (H1) greater reductions in depressive symptoms, assessed by clinician-administered and self-report measures and (H2) better general functioning, defined as (H2.1) daily functioning, (H2.2a) quality of life, (H2.2b) quality of physical health, and (H2.3) positive psychological functioning. We further hypothesize that (H3), compared to TAU, MYI + TAU will be cost-effective. We also expect that MYI effects on symptoms of depression are partially mediated by (H4.1) reduced self-report and indirect measures of rumination, (H4.2) reduced negative self-evaluation, represented by (H4.2a) reduced self-reported self-criticism, and (H4.2b) reduced indirect measures of depression identity, (H4.3) decreased intolerance of uncertainty, (H4.4) increased body awareness/interoceptive awareness, and (H4.5) increased mindfulness.

Exploratory analyses will be conducted to examine whether the effects of MYI are moderated by demographic variables (e.g., socioeconomic status), clinical factors (e.g., comorbidity), and variables from the process evaluation (e.g., treatment adherence).

## 2 | DESIGN AND METHODS

### 2.1 | Study design

The present study is a randomized controlled trial with assessments at pre- and postintervention and at 6- and 12-month follow up. Participants meeting the inclusion criteria were randomly assigned to one of two conditions: (a) TAU or (b) TAU plus MYI. TAU consisted of interventions following the Dutch treatment guidelines for MDD (pharmacotherapy, psychotherapy, or both; Spijker et al., 2012). This design will allow us to test whether adding MYI is more efficacious and cost-effective than standard interventions. This study was approved by the Medical Ethical Committee of the University Medical Center Groningen (registration number NL.59324.042.16/2016/533). At the time of writing, the recruitment and baseline assessments have been completed. Trial registration: Clinical Trials, NTC60-63600-98-127, http://www.clinicaltrials.gov/.

### 2.2 | Study population

We recruited 171 women (18–34 years) who were currently in treatment at several adult psychiatry outpatient clinics in the northern Netherlands during the first 2 years of the project.

#### 2.2.1 | Inclusion criteria

Inclusion criteria were as follows: a primary diagnosis of MDD; age of ≥18 and ≤34 years; and ability to fluently read, write, and speak the Dutch language.

#### 2.2.2 | Exclusion criteria

Exclusion criteria were as follows: a current diagnosis of bipolar disorder or substance dependence, current psychotic symptoms, active suicidality, unwilling or inability to attend nine weekly sessions of yoga, and current regular yoga practice (average of ≥30 minutes per week over the past 6 months).

#### 2.2.3 | Loss to follow up

Strategies that were implemented to reduce loss to follow up included minimizing participants' response burden by using short questionnaires, employing staff experienced in communicating with research participants, and using newsletters to keep contact between assessments. We will register when patients are lost to follow up and assess the reasons for discontinuing the study.

### 2.3 | Recruitment and screening procedure

Figure 1 illustrates participant recruitment and flow through the study. Consecutive sampling was used to recruit patients from two sources: (a) new patients who had just been admitted and had completed their intake interviews and (b) current patients with ongoing treatment (and who were still symptomatic). If the patient met the inclusion criteria, her therapist handed out a package containing detailed information about the study in the form of an information letter and a flyer, along with an informed consent form. The therapist prescreened the patient regarding the exclusion criteria of the study and handed out the package if she fitted the profile of the study. After giving informed consent, the research assistant administered the structured interview for DSM-IV (SCID-I; First, Spitzer, Gibbon, & Williams, 2002) in order to verify the target diagnosis of MDD and to assess exclusion criteria.

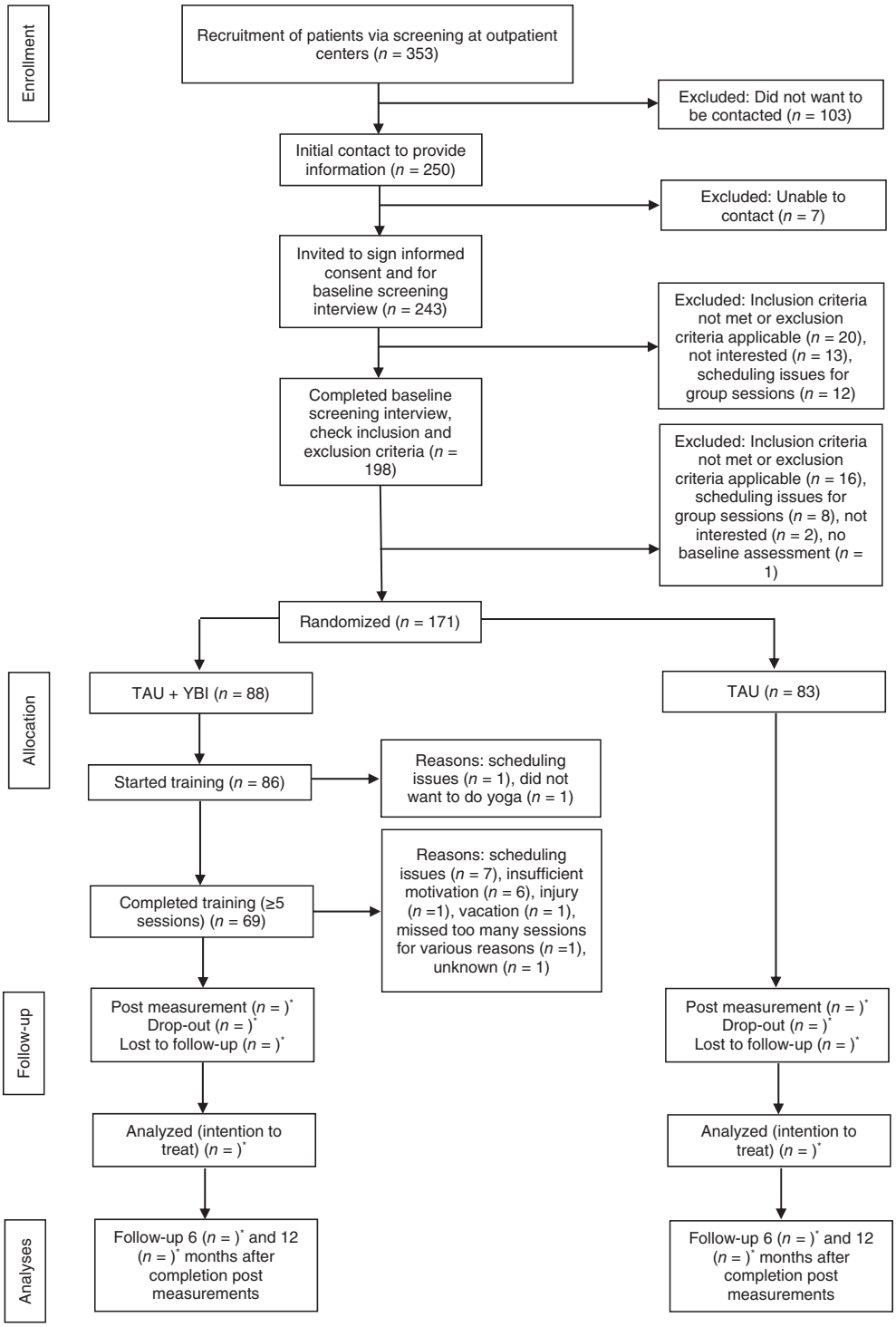


**FIGURE 1** Participant recruitment and flow through the study. Asterisk indicates assessments at postintervention, and 6- and 12-month follow ups have not been completed yet

## 2.4 | Treatment allocation

To ensure random allocation, a computerized random number generation process was used. A methodologist from the Psychology Department of the University of Groningen (not otherwise involved in the study) was responsible for the randomization of the participants. The methodologist informed the contact person (i.e., a clinical psychology doctoral student) of the assignment for each patient. The contact person then informed the participant regarding treatment allocation.

## 2.5 | Blinding

Given the nature of the study, participants could not be blinded. The participant's therapist was notified of treatment allocation for that participant. However, a research assistant, who assessed symptoms of depression at baseline, postintervention and at 6- and 12-month follow ups, was blinded to treatment allocation. The participants were asked to not disclose the nature of their treatment to the research assistant. In case the participant or therapist accidently revealed the

treatment allocation to the research assistant, a researcher from a different department assessed symptoms of depression at the remaining time points for that participant. Rater blinding is verified by the rater registering in which group the participant is thought to be after each assessment.

## 2.6 | Intervention

The MYI group received MYI in addition to TAU. We developed MYI as a manualized 9-week group training based on mindful yoga to enhance awareness of bodily sensations, emotions, and thoughts and to change processes involved in depression. MYI uses yoga postures, breathing practices, and meditation practices of traditional hatha yoga (Anderson & Sovik, 2000), combined with instructions designed to increase mindful awareness. Regarding the mindful awareness treatment element, the instructor repeatedly cues the participants to (a) notice their breath and inner sensations in their body, (b) be aware of their attention wandering away and bring it back to inner sensations, and (c) be compassionate toward themselves in that there is no ideal state of the body or mind that they have to attain but, instead, that they should only do what works for their body during the postures. When necessary, the postures could be adapted for participants with limited mobility (e.g., doing postures seated on a chair) or pregnant participants (e.g., using cushions to make sure that a posture that uses a twist is not too deep) as it is found that yoga can be performed safely during pregnancy (Jiang, Wu, Zhou, Dunlop, & Chen, 2015). The intervention was secularized, in that it omitted references to the Hindu background of yoga (e.g., use of mantras, traditional Sanskrit names of postures, etc.). The participants were given information about the Hindu background of yoga but were instructed that the intervention would consist of the practices—breathing practices, yoga postures, and meditation—without reference to the religious background or other ethical or philosophical ideas that are part of traditional yoga.

In addition to the yoga practices, elements from cognitive behavioral therapy (CBT) are used to provide participants insight about patterns of rumination, self-criticism, and coping with negative emotions. For example, participants are instructed about the relation between thoughts and emotions and are cued to notice the (negative) thoughts they are having while in a yoga posture (and to shift attention from the thought back to a sensation they are currently experiencing). The CBT elements were added to provide psychoeducation to facilitate the potential benefits of the yoga postures by providing a model of the processes involved in depression that could be used by participants to better understand the usefulness of the yoga practices.

MYI was administered with a manualized protocol that has been tested in a pilot study (Vollbehr, Hoenders, Bartels-Velthuis, & Ostafin, 2019) and was delivered in a group format consisting of nine weekly sessions, each lasting 1.5 hours. The majority of each session consists of practice, including yoga exercises (80% of practice time) with meditation and breathing exercises (20% of practice time). Each of the nine sessions has a different theme: (a) introduction and self-care, (b) body awareness, (c) regulation of attention from outer to inner experiences, (d) awareness of sensations and emotions, (e) acceptance, (f) awareness of thoughts and thought patterns, (g) self-compassion, (h) making meaningful choices, and (i) continuing at home with the practice. Each session started with a short introduction of the theme, and during the practices, there was reference to the theme by the cueing of the yoga instructor.

Between the sessions, participants completed an online module with (a) additional psychoeducation about depression, information about the practices taught, and the processes involved in depression; (b) CBT-inspired self-monitoring assignments; and (c) practice videos to encourage home practice of the yoga exercises for approximately 30–45 min a day. MYI was delivered by a psychologist (NKV) who is also a trained yoga teacher (a Yoga Alliance Registered Yoga Teacher® 500 with over 15 years of yoga experience and over 4 years teaching experience). As the yoga teacher is also involved as a researcher, she was not involved in recruitment, screening, condition assignment, or data collection at any of the assessment points.

## 2.7 | Treatment as usual

The TAU-only condition consisted of interventions recommended by the Dutch guidelines for depression (Spijker et al., 2012) and included pharmacotherapy (antidepressant medications) and psychotherapy (e.g., CBT, interpersonal psychotherapy). Mental health clinicians administered TAU. In order to improve the interpretation of the study results, we recorded frequency, content (e.g., cognitive restructuring), format (group vs. individual), and intensity of contact within TAU. Such quantification of TAU will allow us to examine potential alternative explanations (e.g., contact time) in the case of positive (or null) effects for MYI.

## 2.8 | Outcome assessment

Table 1 provides an overview of the measures and assessment points. Assessments took place (a) after consent to participate and before randomization (T0) and will take place (b) after the last MYI session or after the same number of weeks in the TAU condition (T1, approximately 10–15 weeks after T0), (c) 6 months after T1 (T2), and (d) 12 months after T1 (T3).

### 2.8.1 | Primary outcome measures

The primary outcome consists of (a) depression symptoms assessed by clinician-administered (Hamilton Depression Rating Scale; Hamilton, 1960) and self-reported (Depression Anxiety Stress Scales, short form [DASS-sf]; Lovibond & Lovibond, 1995) measures of depression and (b) the presence/absence of a diagnosis of MDD, assessed by the structured interview for DSM-IV (SCID-I; First et al., 2002).

**TABLE 1** Assessments of primary outcomes, secondary outcomes, mediators, moderators, and nonspecific factors

| Factor | Assessment tool (items) | Assessment point[a] | | | |
|---|---|---|---|---|---|
| | | T0 | T1 | T2 | T3 |
| Primary outcome measures | | | | | |
| Diagnosis | SCID-I | X | | | X |
| Symptoms of depression | HDRS (17) | X | X | X | X |
| | DASS-sf (21) | X | X | X | X |
| Cost-effectiveness | | | | | |
| Health | EQ-5D-5 L (6) | X | X | X | X |
| Health care consumption and productivity loss | —(15) | X | X | X | X |
| Secondary outcome measures | | | | | |
| Well-being | SPWB (18) | X | X | X | X |
| Quality of life | WHOQOL-bref (26) | X | X | X | X |
| Work and social functioning | WSAS (5) | X | X | X | X |
| Mediators | | | | | |
| Rumination | PTQ (15) | X | X | X | X |
| | ECT | X | X | | |
| Negative self-evaluation | SCS (24) | X | X | X | X |
| | IAT | X | X | | |
| Intolerance of uncertainty | IUS (12) | X | X | X | X |
| Interoceptive awareness | SBC-A (12) | X | X | X | X |
| | MAIA (3) | X | X | X | X |
| Mindfulness | FFMQ (24) | X | X | X | X |
| Moderators | | | | | |
| Demographic characteristics | —(15) | X | | | |
| History of depression | —(3) | X | | | |
| Process evaluation | | | | | |
| Patient expectations | —(1) | X | | | |
| Patient motivation | —(1) | X | X | X | X |
| Patient treatment adherence | —(1) | | X | X | X |
| Instructor's competence | —(2) | | X | | |
| Evaluation of the training | —(4) | | X | | |

Abbreviations: DASS-sf, Depression Anxiety Stress Scales, short form; ECT, Exogenous Cuing Task; FFMQ, Five Facet Mindfulness Questionnaire; HDRS, Hamilton Depression Rating Scale; IAT, Implicit Association Test; IUS, Intolerance of Uncertainty Scale; MAIA, Multidimensional Assessment of Interoceptive Awareness Scale; PTQ, Perseverative Thinking Questionnaire; SBC-A, Awareness Scale of the Scale of Body Connection; SCID-I, Structured Interview for DSM-IV; SCS, Self Compassion Scale; SPWB, Scale of Psychological Well-being; WHOQOL-bref, World Health Organization Quality of Life Questionnaire-brief; WSAS, Work and Social Adjustment Scale.

[a]T0 = baseline; T1 = post-training (±10–15 weeks after T0); T2 = 6 months after T1; T3 = 12 months after T1.

### 2.8.2 | Secondary outcome measures

Secondary outcome measures include symptom interference in daily functioning (Work and Social Adjustment Scale; Mundt, Marks, Shear, & Greist, 2002), quality of life and physical health (World Health Organization quality of life questionnaire-brief; WHOQOL Group, 1997), and positive psychological functioning (two subscales of the Scale of Psychological Well-being: the Purpose in Life and Personal Growth subscale; Ryff & Keyes, 1995).

Primary outcome parameters for the cost-effectiveness analyses consist of health condition (quality-adjusted life years [QALYs] derived from the EQ-5D-5 L; Herdman et al., 2011). Health care use and related cost aspects will be registered with a detailed Case Record Form previously used in mental health care (Van der Gaag, Stant, Wolters, Buskens, & Wiersma, 2011).

### 2.8.3 | Mediating variables

Potential mediators of MYI were assessed, including (a) rumination, measured both by self-report (perseverative thinking questionnaire; Ehring et al., 2011) and by a computerized, indirect measure of attentional bias (exogenous cuing task; Koster, De Raedt, Goeleven, Franck, & Crombez, 2005), which uses cues consisting of 10 depression-related,

10 positive, and 10 neutral words; (b) reduced negative self-evaluation, measured by a self-reported measure of self-criticism (and increased self-compassion) after perceived failure (Self Compassion Scale; Neff, 2003) and an indirect measure of depression identity (implicit association test; Glashouwer & de Jong, 2010) with depression-relevant self-descriptors (e.g., pessimistic, meaningless) and their contrasts (e.g., optimistic, valuable) as the attribute categories and self versus others as the target categories; (c) decreased intolerance of uncertainty, measured by self-report (Intolerance of Uncertainty Scale; Carleton, Norton, & Asmundson, 2007); (d) increased body awareness/interoceptive awareness, measured by self-report (the Awareness scale of the Scale of Body Connection; Price & Thompson, 2011) and three additional items of the Multidimensional Assessment of Interoceptive Awareness Scale (Mehling et al., 2012); and (e) increased mindfulness, measured by self-report (five facet mindfulness questionnaire; Baer, Smith, Hopkins, Krietemeyer, & Toney, 2006).

#### 2.8.4 | Moderating variables

Demographics were assessed (e.g., living situation, socioeconomic status), as well as clinical factors that could moderate treatment effect (e.g., initial depression severity, comorbidity, treatment adherence).

#### 2.8.5 | Process evaluation

In order to maximize future effectiveness of MYI, we assessed several variables that may influence the implementation of the intervention. First, we examined participants' expectations of the yoga intervention at baseline by asking them to what extent they expect the yoga training to be successful in reducing their symptoms of depression. Second, we examined participants' motivation to participate in the study using self-report. Third, we examined treatment adherence through weekly self-report of home practice and online tracking of use of homework practice videos (administered via the online module). In addition, at the end of the intervention, as well as at both follow-up assessments, participants will be asked to report their average amount of practice time per week over the time of the intervention (post-treatment) and over the last 6 months (at the follow-up assessments). Fourth, we examined participants' perceptions of the MYI instructor's competence. Fifth, we assessed participants' evaluation of MYI features such as content of weekly group meetings, home practices, and the administration of the intervention. In addition, we will assess adherence to the MYI protocol of the instructor via an evaluation of videotape by two independent raters.

### 2.9 | Sample size

A sample of $n = 64$ per group will provide a power of 80% ($\alpha = .05$) to detect medium effect size differences between groups. Allowing a conservative attrition rate of 25% (comparable studies show rates of 15–20%; Butler et al., 2008; Sarubin et al., 2014), we wanted to recruit 170 patients. With an inclusion rate of 50% (comparable studies show rates of 55–75%; Butler et al., 2008; Kinser et al., 2014), we planned to screen 340 patients in the project's first 20 months, allowing us to achieve the targeted sample size.

### 2.10 | Analysis plan

The primary hypotheses will be examined with intention-to-treat analyses. Per-protocol analyses (≥5 sessions) will also be conducted. MYI + TAU will be compared with TAU-only to assess the benefits of adding MYI to TAU. The effect of MYI on both clinician-administered and self-report measures of symptoms will be examined with repeated-measures ANOVAs (within-subject time points of preintervention (T0), postintervention (T1), and 6-month (T2) and 12-month (T3) follow up). The secondary hypotheses regarding positive functioning will also be examined with repeated-measures ANOVAs.

In the economic evaluation, societal costs and health outcomes (QALYs, DASS-sf) will be compared between MYI + TAU and TAU. The uncertainty surrounding the incremental cost-effectiveness ratios will be assessed by bootstrap analyses (Efron & Tibshirani, 1993). In addition, cost-effectiveness acceptability curves (Fenwick, O'Brien, & Briggs, 2004) will be used to inform decision-makers on the probability that MYI + TAU is cost-effective.

Mediation hypotheses will be tested with a bootstrapping regression model. In line with previous mindfulness trials, these analyses will only include patients who have attended an adequate number of sessions of MYI, which is defined as participation in ≥five of nine MYI sessions (Kuyken et al., 2010; Teasdale et al., 2000). In this subsample of patients, we will test the mediating effect of rumination, self-criticism, intolerance of uncertainty, interoceptive awareness, and mindfulness on symptoms of depression as outcomes, using a multiple mediation model according to the method suggested by Preacher and Hayes (2008). Potential moderators will be tested with regression analyses.

## 3 | RESULTS

Figure 1 shows the participant flow. Over three mental health care institutions, 353 potential participants were screened, of whom 250 indicated interest in participating in the study (i.e., 71%). Of those interested, 198 were interviewed to confirm inclusion and exclusion criteria. Twenty-seven (14%) were excluded for various reasons. A total of 171 participants were randomized, of which 88 received the yoga-based intervention. All 171 participants completed baseline assessments of symptoms of depression, and 169 completed the demographic characteristics questionnaires. Next, we present the baseline characteristics of the sample.

Table 2 shows the baseline characteristics of the participants. The mean age was 25.08 years ($SD = 4.64$, range: 18–34). The mean level

of clinician-rated symptoms of depression was 18.39 (*SD* = 6.00, range: 6–33), indicating moderate depression (Zimmerman, Martinez, Young, Chelminski, & Dalrymple, 2013). The mean level of self-reported symptoms of depression was 21.02 (*SD* = 9.36, range: 2–42), indicating severe depression (Lovibond & Lovibond, 1995). Of participants, 53% were in a relationship, and 17% had children; 56% had a paid job for a mean of 22 hr/week (*SD* = 12.59, range: 1–60), and 46% were currently in school or university. Participants' highest level of completed education was mostly intermediate secondary education (32%), high school (31%), and university (18%). The majority of participants was living alone (25%), in student housing (18%), or with their partner (17%). Participants rated the quality of their current treatment as a 7.2 on a scale from 1 (very low quality) to 10 (very high quality) (*SD* = 1.24, range: 2–10), and their motivation for participating in the study as a 7.9 on a scale from 1 (not motivated) to 9 (very motivated) (*SD* = 0.96, range: 5–9). Of participants, 29% had some experience with yoga in the past.

**TABLE 2** Participants' characteristics (*n* = 169)

| Variable | |
|---|---|
| Age, years, *M* (*SD*) | 25.08 (4.64) |
| Symptoms of depression, *M* (*SD*) | |
| Clinician rated (HDRS[a]) | 18.39 (6.00) |
| Self-reported (DASS-sf) | 21.02 (9.36) |
| Relationship, *n* (%) | |
| Yes | 90 (53.3) |
| No | 79 (46.7) |
| Children, *n* (%) | |
| Yes | 28 (16.6) |
| No | 141 (83.4) |
| Paid job, *n* (%) | |
| Yes | 95 (56.2) |
| No | 74 (53.8) |
| Currently in school, *n* (%) | |
| Yes | 77 (45.6) |
| No | 92 (54.4) |
| Highest level of completed education, *n* (%) | |
| Primary school | 1 (0.6) |
| High school | 53 (31.4) |
| Intermediate secondary education | 54 (31.9) |
| Higher secondary education | 25 (14.8) |
| University | 30 (17.7) |
| Other | 6 (3.6) |
| Living situation, *n* (%) | |
| Alone | 42 (24.9) |
| With partner | 28 (16.6) |
| With partner and children | 20 (11.8) |
| Alone with children | 8 (4.7) |
| Student housing | 31 (18.3) |
| With friends | 10 (5.9) |
| With parents | 22 (13.0) |
| Other | 8 (4.7) |
| Quality of current treatment, *M* (*SD*)[b] | 7.2 (1.24) |
| Motivation for study, *M* (*SD*)[c] | 7.9 (0.96) |
| Experience with yoga, *n* (%) | |
| Yes | 49 (29) |
| No | 120 (71) |

Abbreviations: DASS-sf, Depression Anxiety Stress Scales, short form; HDRS, Hamilton Depression Rating Scale.
[a]*N* = 171.
[b]Scale 1–10.
[c]Scale 1–9.

## 4 | DISCUSSION

Despite the efficacy of current first-line MDD interventions (Cuijpers et al., 2013), modest rates of treatment response (Preskorn, 2013; Spijker et al., 2012) and high relapse rates (Steinert, Hofmann, Kruse, & Leichsenring, 2014) indicate the need to develop more effective treatment options. Mindful yoga represents an option that may have utility as an add-on to current interventions given its effects on depression symptoms because it may be well-suited to target depression-related processes such as rumination, self-criticism, intolerance of uncertainty, body awareness, and dispositional mindfulness and because its attractiveness may help to circumvent stigma that is associated with low treatment seeking. Although initial clinical studies have shown promise for yoga as a treatment for depression (Cramer et al., 2013), the low methodological quality of most of this work suggests caution in interpreting the results and a need for additional high-quality research (Vollbehr et al., 2018). The current study examines whether adding mindful yoga to TAU leads to better outcomes and the potential mechanisms of action underlying the beneficial outcomes.

The current study is specifically designed as a methodologically rigorous trial for adding a MYI to TAU for MDD. Positive findings will represent a potential benefit to current evidence-based treatment packages, which, while modestly effective, are suboptimal in terms of (a) attracting those who are in need of treatment (Eisenberg et al., 2007; Eisenberg et al., 2009; Wang et al., 2007), (b) rates of response to the intervention (Cuijpers et al., 2013; Preskorn, 2013; Spijker et al., 2002), and (c) relapse (Dobson et al., 2008; Gortner et al., 1998; Ramana et al., 1995; Shea et al., 1992; Vittengl et al., 2007).

We have carefully considered the potential limitations of the study and have taken steps to minimize them. For example, the results in psychotherapy research are often influenced by a number of potential biases such as investigator allegiance. We will address this limitation in a number of ways, including preregistering to a trial register, using a computerized random number generator for condition randomization sequence by a methodologist independent from the research team, adding the intervention to TAU, the blinding of assessors to treatment condition, verifying assessors' blindness, and reporting intention-to-treat analyses in manuscripts. The expectations of the patients about

and their satisfaction with the yoga intervention and the instructor will also be assessed. Furthermore, quality of the MYI sessions can be evaluated by assessing treatment adherence through video recordings. The yoga teacher is also involved as a researcher, which might lead to potential bias in the case of interaction with participants at various points in the study. In order to protect against bias, we blinded the yoga teacher to recruitment, screening, and data collection at all of the assessment points by having all of these tasks conducted by another researcher.

Attrition and differential attrition between conditions pose potential limitations to the study, in that both might reduce the validity of the findings. We will make efforts to reduce the (differential) attrition through frequent phone and email contact with all participants and by including a financial reimbursement for participation in the study. In addition, we have not included an active control group but will compare adding MYI plus TAU to a group that received TAU only. Potential changes in treatment during the course of the study would obscure inferences regarding the MYI effects. Therefore, we will assess the treatment received, including the type of treatment (e.g., antidepressant medication, psychological treatment), number of sessions scheduled, and specific changes (e.g., change in medication, finishing of the treatment, or starting a new form of treatment). Group differences in these variables would indicate the need for including them in the analyses (e.g., as potential covariates).

Although using TAU as a control group will lead to limitations of causal inference of the mechanisms through which MYI may be effective, the current study will represent an important first step in exploring the possible beneficial effects of MYI. Positive results may lead to subsequent studies with an active control group in order to (potentially) provide knowledge about the specific contributions of MYI and greater confidence in any positive causal/mechanistic inferences of the current study.

To our knowledge, our study will be the first adequately powered randomized controlled trial to examine the efficacy and cost-effectiveness of adding an MYI to TAU in a mental healthcare setting for young women with MDD. Positive findings will indicate the importance of considering MYI a valuable addition to TAU for young women with depression. In case of positive findings, we see an important next step to include examining the effects of this intervention in other patient groups, such as males and individuals of different age groups.

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## CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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