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## Mindful Yoga Intervention as Add-on to Treatment as Usual for Young Women With Major Depressive Disorder: Results From a Randomized Controlled Trial

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Objective: To examine the added value of a 9-week mindful yoga intervention (MYI) as add-on to treatment as usual (TAU) in reducing depression for young women (18-34 years) with major depressive disorder (MDD). *Method:* Randomized controlled trial (RCT; n = 171) comparing TAU + MYI with TAU-only. Assessments were at baseline, postintervention, and at 6- and 12-month follow-up. Primary outcome measures were clinician-rated and self-reported symptoms of depression, together with a diagnostic interview to establish MDD diagnosis that was restricted to the baseline and 12-month follow-up assessments. Quality of life in various domains was assessed as secondary outcome measure. As potential mediators for treatment efficacy, we included self-report measures of rumination, self-criticism, self-compassion, intolerance of uncertainty, perceived body awareness and dispositional mindfulness, together with behavioral measures of attentional bias (AB) and depression-related self-associations. Results: Adding MYI to TAU did not lead to greater reduction of depression symptoms, lower rate of MDD diagnosis or increase in quality of life in various domains of functioning at post and follow-up assessments. There were no indirect effects through any of the potential mediators, with the exception of self-compassion. Conclusion: Adding MYI to TAU appeared not more efficacious than TAU-only in reducing depression symptoms in young women.

What is the public health significance of this article?

Overall, this study suggests that adding a mindful yoga intervention to treatment as usual for young women with depression does not lead to increased benefits in terms of stronger reduction in symptoms of depression, lower rate of major depressive disorder diagnosis, or better quality of life within various domains of functioning.

Keywords: depression, women, mindfulness, yoga, mediators

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Nina K. Vollbehr played lead role in conceptualization, data curation, formal analysis, investigation, project administration and writing of original draft and equal role in funding acquisition and methodology. H. J. Rogier Hoenders played lead role in funding acquisition and supervision and equal role in conceptualization, methodology and writing of review and

## Optimizing Standard Treatment for Young Women With Depression

Among women, depression is the third leading cause of burden of disease worldwide (James et al., 2018). It is estimated that women are two times more likely to develop major depressive disorder (MDD) than men during their lives (Bromet et al., 2011), and young women (aged 18–34) are especially at high risk of developing MDD (De Graaf et al., 2012). Although a small majority of patients eventually receives treatment during their lifetime (57%; Rubio et al., 2011), these patients often do not respond (fully) to treatment. For example, research has shown that only about 50% respond to psychotherapy and medication treatment (Casacalenda et al., 2002). Further, a substantial number (about 40%) continues to experience residual symptoms (Conradi et al., 2011) and relapse rates are high 1–2 years posttreatment (26%–43%; Steinert et al., 2014). From these data, it becomes clear that there is a need to further optimize treatment as usual for MDD.

One way to enhance the efficacy of treatment is to offer a combination of interventions. For instance, there is evidence that a combination of medication and psychotherapy was more effective than medication alone (Karyotaki et al., 2016). Similarly, adjunctive interventions such as relaxation, creative expression therapy, exercise, and mindfulness-based interventions show potential in optimizing standard treatment for acute depression or relapse prevention (Spijker et al., 2012). One intervention that offers a combination of mindfulness and exercise is mindful yoga, a mind-body practice consisting of physical postures, breathing and meditation practices, and the cultivation of a nonjudgmental (mindful) awareness of body sensations and thoughts (Anderson & Sovik, 2000). Research with a general population sample in the United States has shown that yoga is popular with young women, with some findings indicating greater popularity among non-Hispanic White, college educated women (Cramer et al., 2016a), and other findings indicating popularity among young women across ethnic, demographic, and socioeconomic status (Neumark-Sztainer et al., 2020). These findings suggest that yoga may be an attractive form of adjunctive treatment for young women suffering from depression.

## Evidence for Mindful Yoga as a Treatment for Depression

Both mindfulness and exercise are involved in yoga interventions and both have been found to be effective treatments for symptoms of depression in young adults (Bailey et al., 2018; Chi et al., 2018).

editing. Agna A. Bartels-Velthuis played lead role in supervision and equal role in conceptualization, methodology and writing of review and editing. Maaike H. Nauta played supporting role in conceptualization, funding acquisition, methodology and writing of review and editing. Stynke Castelein played supporting role in conceptualization, funding acquisition, methodology, supervision and writing of review and editing. Maya J. Schroevers played supporting role in conceptualization, funding acquisition, methodology and writing of review and editing. A. Dennis Stant played supporting role in conceptualization, funding acquisition, methodology and writing of review and editing. A. Dennis Stant played supporting role in conceptualization, funding acquisition, methodology and writing of review and editing. Casper J. Albers played supporting role in methodology, supervision and writing of review and editing and equal role in formal analysis. Peter J. de Jong played lead role in funding Yoga interventions (including postures, breathing practices, and meditation) have also been shown to reduce symptoms of depression in young people (Falsafi, 2016; Woolery et al., 2004). However, since these studies relied on participants with elevated levels of symptoms of depression instead of an actual diagnosis of MDD, it is difficult to know whether the beneficial findings will generalize to young adults with MDD.

Regarding the evidence for yoga interventions in adult populations with MDD, a recent review that included 18 randomized controlled trials (RCTs) with a total of 1,532 participants found mixed results regarding the intervention's efficacy (Vollbehr et al., 2018). This review pointed to several potential reasons for the mixed findings, including methodological limitations such as small sample sizes (only two studies included over a hundred participants, whereas seven studies had samples in the range of 50-100 participants and nine studies included less than 50 participants). Further limitations of previous research include short follow-up periods (only seven RCTs out of 18 used a follow-up, of which only three were 6 months or longer), and the absence of a manualized intervention (eight of the 18 studies did not use a treatment manual). Another potential reason for the diverse findings may be the variability of control groups that were used. Specifically, yoga interventions showed a significant effect on depression when compared to psychoeducation control groups, but not when yoga was compared to treatment as usual (TAU). This might be because TAU offers a better active control to the extent that it consists of interventions that have been found to be effective in reducing depression.

However, the exact nature of TAU in these yoga trials is often unclear, which is more generally a problem for behavioral intervention research (Freedland et al., 2011). Studies investigating yoga interventions in MDD patients who currently received some form of standard treatment are scarce—we found only six such trials (Broota & Dhir, 1990; Falsafi, 2016; Ravindran et al., 2021; Sarubin et al., 2014; Subbanna et al., 2021; Tolahunase et al., 2018). In five of these trials, TAU was limited to the use of medication (Broota & Dhir, 1990; Ravindran et al., 2021; Sarubin et al., 2014; Subbanna et al., 2021; Tolahunase et al., 2018). In one trial, only some of the participants received some form of TAU (medication or psychotherapy), and it was unclear whether these percentages differed between the yoga and control group (Falsafi, 2016). Clearly, then, the available trials offer limited potential in drawing conclusions about the benefits of adding a form of yoga to existing evidence-based treatment.

In addition to studies that examined the benefits of adding yoga to TAU, other research has examined a standalone yoga intervention versus TAU control. We found only one such study using this design

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The data that support the findings of this study are available on request from the corresponding author, Nina K. Vollbehr. The data are not publicly available due to their containing information that could compromise the privacy of the research participants.

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(Helgadóttir et al., 2016). In this trial, about one-third of the control group received antidepressant medication and about three-fourths received a form of psychological treatment as standard treatment. Another design to examine yoga's effect on depression was used in a trial for women with prenatal depression (Field et al., 2012). This study provided standard prenatal care to all participants and randomized half of these women into a yoga intervention. However, no specific form of treatment for depressive symptoms was offered to the control group in Field et al. (2012). The findings from Helgadóttir et al. (2016) and Field et al. (2012) are difficult to interpret because if only few (or no) participants received evidencebased TAU for MDD, these studies might be more likely to find positive results for a yoga intervention (Davidson & Kaszniak, 2015). To arrive at more solid conclusions with regard to the clinical relevance of yoga-based treatment as standalone or add-on intervention, it would be critical to include a standard evidence-based treatment as control condition in the design (Freedland et al., 2011). The present study was therefore designed as a RCT to test if the effectiveness of a standard evidence-based intervention (TAU) would benefit from adding a mindful yoga intervention (MYI) to TAU as an add-on intervention.

### Mechanisms of Mindful Yoga

Optimizing MDD interventions can be advanced through gaining knowledge about their mechanisms of action (Kazdin, 2007). It is also important to determine the conditions in which an intervention works better, for instance, in distinct subgroups (Kraemer et al., 2002). As there is a dearth of RCTs that study mediators and moderators of yoga interventions (Vollbehr et al., 2018), this study was designed to address these questions.

Theory suggests that mindful yoga could reduce depressive symptoms by targeting mechanisms that are involved in the maintenance of depression, including rumination (Nolen-Hoeksema, 2000), negative self-evaluation (Auerbach et al., 2014), intolerance of uncertainty (Mahoney & McEvoy, 2012), interoceptive awareness (Pollatos et al., 2009), and dispositional mindfulness (Gilbert & Gruber, 2014). Specifically, mindful yoga includes shifting from an abstract thinking style to a concrete focus on body sensations and might thereby reduce rumination (Watkins, 2008). Mindful yoga instructions also involve a nonjudgmental attitude toward difficult sensations and self-critical thoughts during the yoga postures, which could help to reduce negative self-evaluation. Further, mindful yoga may reduce intolerance of uncertainty, as the training involves practices to develop nonjudgmental awareness of challenging emotions and cognitions. Mindful yoga may also increase interoceptive awareness as the intervention includes practices to develop awareness of bodily sensations. Last, given that we developed the current mindful yoga intervention with a focus on developing a mindful awareness of present moment experience, the training may also increase dispositional mindfulness.

Indeed, initial research has found evidence that yoga interventions may alter these five mechanisms, as yoga participants report less rumination (Kinser et al., 2014; Schuver & Lewis, 2016), more selfcompassion (Carmody & Baer, 2008), more body awareness (Cramer et al., 2016b), and more mindfulness (Carmody & Baer, 2008). Although there are no studies on mindful yoga interventions specifically, recent research has shown evidence of intolerance of uncertainty mediating the relation between mindfulness and reduced anxiety (Papenfuss et al., 2021, 2022). Regarding potential moderators, we did not find any studies investigating moderation in the efficacy of yoga for MDD. However, in mindfulness research, level of symptoms of depression and number of previous episodes have been found to moderate treatment effects (Arch & Ayers, 2013).

As positive affect has been found to be important in the recovery from depression (Geschwind et al., 2011), it is also important to study the effects of MDD interventions on well-being. Additionally, previous studies have found that even when symptoms of depression decrease, patients oftentimes continue to experience impairments in various domains of functioning and quality of life (Slofstra et al., 2019). It is therefore important to also take these types of variables into consideration when evaluating the effectiveness of interventions. Although there are initial indications that yoga might lead to enhanced well-being in healthy adults (Hendriks et al., 2017), we found only four clinical studies that measured aspects of well-being, impairment in various domains of functioning, or quality of life in their outcome assessment. One RCT found no significant difference in improvement in social relations in women with prenatal depression after a 12-week yoga intervention, compared to a control group of social support (Field et al., 2013). Another study found no significant group difference between a 10-week yoga intervention in patients with persistent major depression compared to a control group receiving health education regarding general health perception and social and role functioning (Uebelacker et al., 2017). A third study found no significant difference in quality of life after an 8-week yoga intervention in patients with unipolar and bipolar depression compared to a control group of psychoeducation (Ravindran et al., 2021). Finally, one study found no group difference between participants with MDD receiving an 8-week yoga or psychoeducation intervention in mental health-related quality of life at 1-year follow-up (Kinser et al., 2014). From these previous studies, it remains rather unclear whether a yoga intervention can lead to an increase of various aspects of well-being or quality of life. Our study was therefore designed to also address these questions.

## The Present Study

## **Study Aim and Hypotheses**

The overall objective of this study was to examine the potential benefits of adding a MYI to TAU for young women with MDD. Our hypotheses were that compared to TAU-only, MYI + TAU would lead to: (H1) greater reductions in depression symptoms, assessed with clinician-administered and self-report measures, and (H2) greater increases in quality of life within various domains of functioning, defined as (H2.1) daily functioning, (H2.2a) quality of life, (H2.2b) quality of general health, and (H2.3) well-being. In addition, we tested if the anticipated beneficial effects of MYI on symptoms of depression are partially mediated by (H3.1) reduced negative perseverative cognition, (H3.2) reduced negative selfevaluation, (H3.3) decreased intolerance of uncertainty, (H3.4) increases in perceived body awareness/interoceptive awareness, and (H3.5) increased mindfulness. We also assessed the costeffectiveness of adding MYI to TAU; these results will be published elsewhere.

Exploratory analyses were 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).

#### Method

## **Study Design and Participants**

We conducted a RCT with two conditions (TAU-only and MYI + TAU). This study protocol received ethical approval from the Medical Ethical Committee of the University Medical Center Groningen (Registration Number NL.59324.042.16/2016/533) and was conducted in accordance with the principles of the Declaration of Helsinki (Version 2013) and the Medical Research involving Human Subjects Act (in Dutch: Wet medisch-wetenschappelijk onderzoek met mensen). A more detailed description of the design, procedure and assessments is published elsewhere (Vollbehr et al., 2020). This article has been prepared using the journal article reporting standards-guidelines (Appelbaum et al., 2018) and the Consolidated Standards of Reporting Trials guidelines (Schulz et al., 2010) for reporting a RCT. The study was preregistered at Clinical Trials (http://www.clinicaltrials.gov/) with number NCT03388177.

We recruited 171 young women in ongoing treatment at several psychiatry outpatient clinics in the northern Netherlands. Inclusion criteria were a primary diagnosis of MDD, age  $\geq$ 18 and  $\leq$ 34 years, and the ability to fluently read, write, and speak the Dutch language. Exclusion criteria were a current diagnosis of bipolar disorder or substance dependance, current psychotic symptoms, active suicidality, the unwillingness or inability to attend nine weekly sessions of yoga, and a current regular yoga practice (average of  $\geq$ 30 min per week over the past 6 months).

## Procedure

Recruitment was from January 2017 to October 2018. Patients' therapists prescreened potential participants on the inclusion and exclusion criteria and handed out an information package when a potential participant fit the study profile. After informed consent, the research assistant administered the structured interview for Diagnostic and Statistical Manual of Mental Disorders, fourth edition (SCID-I; First et al., 2002) to verify the MDD diagnosis, and the inclusion and exclusion criteria, before inviting her to participate in the trial. Serious adverse events were monitored by the yoga trainer during the training (i.e., assessing whether participants experienced injuries or illness after or between sessions) and by the research assistant during the study assessments (i.e., assessing whether any important life events had happened during the study period). Further, at all assessment points participants completed questionnaires that assessed whether they had experienced hospital admissions and, if so, for which conditions.

### **Randomization and Masking**

A methodologist from the Psychology Department of the University of Groningen (CJA) was responsible for the randomization of the participants, using a computerized random number generation process. The methodologist informed the contact person (i.e., a clinical psychology graduate student) of the assignment for each

patient. The contact person then informed the participant regarding treatment allocation.

The research assistant assessed symptoms of depression at all assessments and was blinded to treatment allocation. For 11 participants, the blinding was broken (most common reasons were that participants emailed about yoga training [n = 4], ran into the research assistant when doing the yoga training [n = 2], or spoke about yoga during an interview [n = 2]). In these cases, the remaining assessments were done by another rater who was not otherwise involved in the study. We assessed the fidelity of the blinding procedure and found that the research assistant guessed treatment allocation correctly in less than 50% of cases at all assessments (T1: 45.9%, T2: 49.4%, T3: 40.0%), providing evidence for the adequacy of the rater blinding.

#### **Mindful Yoga Intervention**

MYI was delivered as a manualized 9-week group training with 1.5-hr weekly sessions, designed to enhance awareness of bodily sensations, emotions and thoughts, and to change processes that contribute to depression. The intervention consisted of yoga postures, breathing practices, and meditation practices of traditional hatha yoga (Anderson & Sovik, 2000), combined with instructions designed to increase mindful awareness. As no information about the best length of a yoga intervention is yet available (Sherman, 2012), we based the length and frequency of the intervention on similar mindfulness-based stress reduction and mindfulness-based cognitive therapy training protocols, which are comparable interventions that have been found effective in reducing depression in adults (Chiesa & Serretti, 2010) and symptoms of depression in young people, especially when the length of the intervention is at least 8 weeks (Chi et al., 2018). Our intervention also matched the length and frequency of yoga interventions for (mental) health conditions used in previous studies (Sherman, 2012). In addition, a pilot study with the current intervention showed its feasibility for a patient population, as most participants practiced daily (six out of eight participants practiced daily for 15-45 min; Vollbehr et al., 2021). The feasibility study findings also indicated that the intervention may be related to the potential mediating mechanisms of repetitive negative thinking, perceived body awareness, fear of emotion, and acting with awareness (Vollbehr et al., 2021, 2022).

Between sessions, participants completed an online module that included psychoeducation about depression, self-monitoring assignments, and videos for home practice (recommended time: 30-45 min a day). We encouraged participants to do home practice, as a meta-analysis of mindfulness intervention studies indicated that the amount of home practice showed a small but significant association with intervention outcomes (Parsons et al., 2017). Parsons et al. (2017) found that most participants practiced 30 min per day for 6 days a week, which is in line with the findings from our feasibility study. We therefore created home practice exercises of 30-45 min. 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 of teaching experience). More detailed information about the intervention has been published elsewhere (Vollbehr et al., 2020, 2021). As the yoga teacher was also involved as a researcher, she was not involved in recruitment, screening, treatment allocation, or assessments.

## Treatment as Usual

TAU was delivered as individualized standard of care (Freedland et al., 2011) and was administered according to the Dutch Treatment Guideline (Spijker et al., 2012). A more detailed description of this guideline and the treatment involved in the study can be found in Supplemental Materials. At the end of the study, the treatments received by participants were assessed from their medical files, including additional diagnoses, interventions, medication, and number of sessions. Information about additional diagnoses and TAU can be found in Supplemental Materials. Briefly, about half (54.1%) of the participants had another diagnosis in addition to MDD. The other diagnosis was most often an anxiety disorder (n = 34) or a personality disorder (n = 31). Mean treatment duration was 1 year (SD = 1.17, range 0-10). The majority of participants (51.8%)received more than one form of TAU, most often cognitive behavioral therapy (n = 114), other psychological treatments (n = 53), medication consultation (n = 46), or psychiatric nursing treatment (n = 36). We did not restrict therapists from making changes during the study regarding (a) diagnosis, (b) medication, (c) interventions, or (d) finishing the treatment. However, we did ask therapists to not add an extra intervention to participants who were randomized in TAU-only to compensate for not receiving the yoga training.

#### Outcomes

Assessments took place (a) after informed consent and before randomization (T0), (b) after the last MYI session or the same number of weeks for the TAU condition (T1, about 10–15 weeks after T0), (c) 6 months after T1 (T2) and (d) 12 months after T1 (T3). All questionnaires were in Dutch and were validated in the Dutch language, except for the three items from the Multidimensional Assessment of Interoceptive Awareness, for which we used our own translation, as no Dutch translation of this scale was yet available. To assess interrater reliability of the clinicianadministered interviews, we had an independent rater (not otherwise involved in the study) assess 10% of these interviews at all assessment points.

## **Descriptive Measures**

The following demographic factors were assessed: age, level of education (12 categories according to the Dutch educational system), relationship status (yes/no), employment status (yes/no), children (yes/no), and living situation (eight categories). Additional factors that could influence outcomes were also assessed, including motivation to participate in the study (scale range 1–9, *not motivated* to *very motivated*), rating of current TAU (scale range 1–10, *very low quality* to *very high quality*), expectation of success of the MYI in reducing depression symptoms (scale range 1–9, *not successful* to *very successful*), and current yoga, meditation, and exercise practice (scale range 0–5, *not* to *every day*). Demographics were only assessed at baseline, whereas the other variables were assessed at all four assessment points.

## **MDD** History

Information regarding previous episodes, start of current episode, and age at first episode were assessed using the SCID-I interview (First et al., 2002).

## **Outcome Measures**

Severity of depression was assessed with a clinician-administered scale, the Hamilton Depression Rating Scale (HDRS; Hamilton, 1960). The internal consistency was low at baseline and acceptable to good at the subsequent three assessment points ( $\alpha = .63$  [T0]; .78 [T1]; .84 [T2]; .85 [T3]). The interrater reliability was excellent at all assessment points (interclass correlation coefficient = 0.94 [T0]; 0.95 [T1]; 0.94 [T2]; 0.97 [T3]). We also used a self-report questionnaire, the Depression scale of the Depression Anxiety Stress Scales–short form (DASS-sf; Henry & Crawford, 2005; Lovibond & Lovibond, 1995). The internal consistency was good at all four time points ( $\alpha = .88$  [T0]; .93 [T1]; .94 [T2]; .93 [T3]). Before randomization and at the last assessments point the presence/absence of a diagnosis of MDD was assessed, using the SCID-I interview (First et al., 2002). The interrater reliability was good and excellent (Fleiss  $\kappa = 0.64$  [before randomization]; 1.00 [T3]).

Impairment across several situations was assessed with the Work and Social Adjustment Scale (WSAS; Mundt et al., 2002). The internal consistency was low at baseline and good at the subsequent three assessment points ( $\alpha = .62$  [T0]; .85 [T1]; .89 [T2]; .91 [T3]). Psychological well-being was assessed with the Purpose and Personal Growth scales of the Ryff Scales of Psychological Well-Being–short form (Ryff & Keyes, 1995). The internal consistency for both scales was acceptable to good at all four assessments (Purpose:  $\alpha = .78$  [T0]; .81 [T1]; .83 [T2]; .85 [T3]; Personal growth:  $\alpha = .73$  [T0]; .81 [T1]; .80 [T2]; .82 [T3]). Quality of life was assessed with two items from the World Health Organization Quality of Life Questionnaire – BREF (Harper & Power, 1998): (a) overall quality of life and (b) satisfaction with general health.

## **Mediators**

We used self-report questionnaires for five potential mediators; rumination was assessed with the Perseverative Thinking Questionnaire (Ehring et al., 2011), which showed good internal consistency  $(\alpha = .92 [T0]; .95 [T1]; .96 [T2]; .97 [T3])$ . Self-criticism and self-compassion were assessed with the Self-Compassion Scale (SCS; Neff, 2003), which showed good internal consistency ( $\alpha =$ .88 [T0]; .93 [T1]; .94 [T2]; .94 [T3]). Recent evidence has shown that the SCS can best be used to measure two separate factors of self-criticism and self-compassion instead of one bipolar construct (López et al., 2015). We therefore analyzed these data using these two factors. Intolerance of uncertainty was assessed with the Intolerance of Uncertainty Scale-short form (Carleton et al., 2007), which showed good internal consistency ( $\alpha = .84$  [T0]; .89 [T1]; .89 [T2]; .91 [T3]). Perceived body awareness was assessed with the Awareness scale of the Scale of Body Connection (Price & Thompson, 2007), which showed good internal consistency ( $\alpha = .82$ [T0]; .86 [T1]; .87 [T2]; .87 [T3]). To assess the trust-aspect of body awareness, we used three additional items of the Multidimensional Assessment of Interoceptive Awareness Scale (Mehling et al., 2012), which demonstrated good internal consistency ( $\alpha = .86$  [T0]; .85 [T1]; .89 [T2]; .85 [T3]). Mindfulness was measured by the Five Facet Mindfulness Questionnaire (Baer et al., 2006; Bohlmeijer et al., 2011), which showed acceptable to good internal consistency  $(\alpha = .76 [T0]; .85 [T1]; .98 [T2]; .88 [T3]).$ 

Two additional mediators consisted of reaction time tasks. The exogenous cueing task (ECT), based on Koster et al. (2005) was used

to assess attentional bias (AB) toward depression-related words. The ECT was programed with the E-prime 2.0 software package. We used a Dutch version of the ECT that has been used in depression research (Elgersma et al., 2018, 2019), with words that score high on subjective familiarity in the Dutch language (Hermans & Dehouwer, 1994). Cues consisted of 10 depression-related, 10 positive, and 10 neutral words that were selected based on representing depressionrelated, positive, and neutral categories (see Supplemental Materials, for a complete description of the procedure of the ECT). We calculated the internal consistency of the ECT by calculating the split half reliability for the first and second half of the ECT for each type of trial as well as for the AB scores (calculation of the AB scores can be found in "Data preparation, ECT analyses"), as recommended by Elgersma et al. (2019). The Spearman-Brown correlations were high for all types of trials, ranging from 0.75 (neutral valid) to 0.80 (positive invalid) at T0, and from .74 (depressive valid/invalid and positive valid) to 0.82 (neutral valid) at T1, indicating a good internal consistency. The Spearman-Brown correlations were low for the AB scores, ranging from 0.004 to 0.067 at T0 (n = 167), and from 0.053 to 0.089 at T1 (n = 155).

Depressive self-identity was assessed with the Implicit Association Test (IAT; Greenwald et al., 1998). A self-depressed IAT was used to assess the strength of implicit self-depressed associations, based on Glashouwer et al. (2012). Target categories consisted of words indicating self or other and attribute categories consisted of depression- or elated-related words. Each category consisted of five stimuli (see Supplemental Materials, for a complete description of the IAT procedure). The IAT score was calculated using the D1 algorithm from Greenwald et al. (2003). Larger IAT scores indicated a relatively stronger self-depression (vs. self-elation) association. Internal consistency was assessed by creating two IAT scores (blocks c and f and blocks d and g). Split-half reliabilities of the IATs were good, with Spearman–Brown corrected correlations between test halves of 0.77 at T0 (n = 169) and 0.77 at T1 (n = 155), which is comparable to previous research (Glashouwer & de Jong, 2010).

## Evaluation of the Yoga Intervention and Treatment Adherence/Fidelity

After the intervention, participants were asked to rate (a) to what extent the MYI was successful in reducing their depression (range 1–9, *not successful* to *very successful*), (b) the overall quality of the training, (d) the online module, and (e) the instructor (for these four items: range 1–10, *very low quality* to *very high quality*). Participants also rated the extent to which MYI had positive effects for them with a 4-point scale of *not*, *a little*, *somewhat*, and *a lot*.

Treatment accuracy, consistency of the intervention, and quality of the teacher were assessed by having two independent raters observe a random 10% of the group sessions. Raters were senior yoga teachers with at least 5 years of yoga practice and 2 years of teaching experience. They rated whether (a) the practices and postures were taught as described in the manual and (b) a mindful cue was given at each posture (e.g., a moment of silence, "notice," "observe"). The rates also assessed the therapist's intervention skills (e.g., ability to model and embody the spirit of mindful yoga; being focused on the present moment, showing a nonjudgmental/accepting attitude toward participants), and use of mindful cues (e.g., extent to which the therapist used mindful cues to elicit awareness of the present moment, acceptance of current experience and self-compassion) on a 5-point scale ranging from 1 (*low*) to 5 (*high*). The teacher's competence (e.g., overall quality of the intervention in this session delivered by the teacher), and quality of the yoga exercises during the session were rated on a 5-point scale ranging from 1 (*not*) to 5 (*excellent*). These questions were adapted from a questionnaire designed to rate mind-fulness interventions (Chawla et al., 2010).

The mean of the two raters for treatment adherence was 97.7% for postures and 95.6% for mindful cues given with the postures. Mean teacher's attitude was 4.50 and mean quality of the mindful cues was 4.14. Competence of the teacher was rated with a mean of 4.04 indicating *good* overall quality and the yoga exercises were rated with a mean of 3.84, also indicating *good* overall quality.

## **Statistical Analyses**

We aimed for a sample of n = 64 per condition to provide power of 80% ( $\alpha = .05$ ) to detect medium effect size differences for the primary outcome measures of symptoms of depression (Cohen's d = 0.5; Cohen, 1988). We therefore recruited 171 participants (MYI + TAU: n = 88, TAU: n = 83), using a conservative attrition rate of 25% (comparable studies show rates of 15%–20%; Butler et al., 2008; Sarubin et al., 2014). At 12-month follow-up, we had n = 77 (MYI + TAU) and n = 70 (TAU) per group for our primary outcome measures. Power analysis using G \* Power (Version 3.1.9.4; Faul et al., 2007) indicated that the current sample size provided a statistical power of 33% to detect small effect size differences, 97% to detect medium effect size differences, and 100% to detect large effect size differences between conditions.

All analyses were performed based on intention-to-treat. Missing data on the outcome measures were handled using Multiple Imputation through Chained Equations (MICE; van Buuren, 2018a). MICE uses linear regression to estimate missing values on variables, using the other variables as predictors, and logistic regression to estimate missing values on these variables. We had a maximum of 11% (MYI + TAU) and 17% (TAU) missing for our primary outcome measures. The missing completely at random test was not significant, indicating that our data were missing completely at random. We therefore decided to generate m = 5 imputed data sets using the Multiple Imputation Macro in SPSS 26.0 (Van Buuren, 2018b). In order to reduce the number of variables in the data set, we created different data sets for the analyses of the primary outcome measures (12 variables), secondary outcome measures (23 variables), mediators (34 variables), and moderators (111 variables). Due to missing data handling limitations in SPSS 26.0, the results of the analyses on the imputed data sets were manually converted into one set of results, using an Excel datasheet. To ensure the accuracy of this conversion and the subsequent calculations, these were checked by our methodologist (CJA).

We also conducted per protocol analyses. For these analyses, we used three factors to determine which participants were selected for the per protocol analyses. First, participants of both conditions were included if they were still receiving TAU at T1. Second, participants in the TAU-only condition were selected if they did not practice yoga at T1. Third, participants in the MYI + TAU condition were selected if they attended  $\geq$ 5 of 9 MYI sessions (Kuyken et al., 2010; Teasdale et al., 2000).

We used IBM SPSS Statistics 26 for all analyses. Repeated measures ANOVAs were used for the primary and secondary hypotheses, with the values of the primary and secondary outcome measures as dependent variables, condition as the between-subjects factor, and time (all four assessment points) as the within-subjects factor. Between-group effect sizes were calculated using  $\eta^2$  (Kelley, 1935). For the HDRS, we also assessed the minimal clinically important difference (MCID). Based on previous research (Hengartner & Ploederl, 2022), we set the MCID as a difference of three points.

Next, the mediation hypotheses were tested with 10,000 samples bootstrapping regression model using the PROCESS macro for SPSS (Hayes, 2012). We tested the indirect effects of condition (MYI + TAU vs. TAU) on all three primary outcome measures (baseline to follow-up) through the potential mediating variables (baseline to postintervention, nine variables in total) according to the methods suggested by Preacher and Hayes (2008). We conducted a total of 27 mediation analyses. Potential moderators were tested with regression analyses. We used regression analyses with a total of 132 analyses, with change in the primary outcome measures from baseline to 12-month follow-up as dependent variable (except for the SCID outcome measure where we used diagnostic status at 12-months), and the interaction term of condition and the (standardized) potential moderating variable as moderator. We tested all potential moderators, including baseline depression information from the SCID (three variables; e.g., number of previous episodes), demographic variables (six variables; e.g., age), rating of treatment, motivation, and expectations (three variables), clinical variables (six variables; e.g., additional diagnosis), primary and secondary outcome measures at baseline (six variables), potential mediators at baseline (nine variables), and TAU variables at baseline (11 variables; e.g., type of treatment). Mediation and moderation analyses were per protocol.

## **Data Preparation**

The data of one participant (in MYI + TAU) were excluded from all analyses because of having already completed treatment at the start of the study (she had entered the study due to an error). For several outcome measures, the assumption of normality was violated. Yet, since the variance was equally distributed in both groups, we retained the planned analyses (Ernst & Albers, 2017). As the Levene's test of variance was significant for the SCID and DASS depression outcomes at T3, we calculated the ratio of the variances. These values were between one and two (1.34 and 1.42) and therefore not problematic for the analyses. In several cases, the sphericity assumption was violated (main analyses: HDRS, WSAS, quality of life and health, purpose and growth; per protocol analyses: HDRS, DASS). In these cases, we reported the Huyn-Feldt corrected results (Howell, 2002).

## Analyses of the Exogenous Cueing Task (ECT)

For MYI + TAU, there were n = 84 remaining at T0 and n = 82 at T1. For TAU, there were n = 82 at T0 and n = 72 at T1. Incorrect responses were removed. After visual inspection of the data, as recommended by Koster et al. (2005) and in line with previous studies (Elgersma et al., 2018, 2019), reaction times (RTs) < 200 ms

and RTs > 1,000 ms were excluded as outliers, indicating anticipatory responding and distractions. A total of 97.68% (T0) and 97.44% (T1) of data were used in the analyses. Median RTs were generated per individual, per type of trial (positive invalid, positive valid, depression invalid, depression valid, neutral invalid, neutral valid). We followed previous studies in using the median RT (rather than the mean) as it is a simple and robust way of dealing with potential outliers (e.g., Elgersma et al., 2018, 2019).

We calculated a general AB score for depression, as recommended by Mogg et al. (2008) and used in previous studies (Elgersma et al., 2019), using the following formula:

#### (See below)

The general AB was scored such that larger values indicate relatively greater AB for the depression stimuli.

As recommended in similar studies (Elgersma et al., 2019), scores deviating more than 3 *SD*s from the group mean were considered outliers. At T0, we found two outliers (one in each condition). At T1 there were no outliers. We conducted analyses with and without these outliers.

## Analyses of the Implicit Association Task

Mean error rate was 6.10% for T 0 (SD = 4.39 range 0%–33.8%), and 6.43 for T1 (SD = 4.70, range 0%–32.5%). There were no participants with more than 10% of trials below 300 ms, and no participants were found to have an unusual *D*-score (>5 *SD* from mean), therefore no additional participants were excluded from the analyses (e.g., Glashouwer & de Jong, 2010). At T0, there were n =86 remaining in MYI + TAU, and n = 82 at T1. For TAU, these were n = 82 at T0 and n = 72 at T1.

## Results

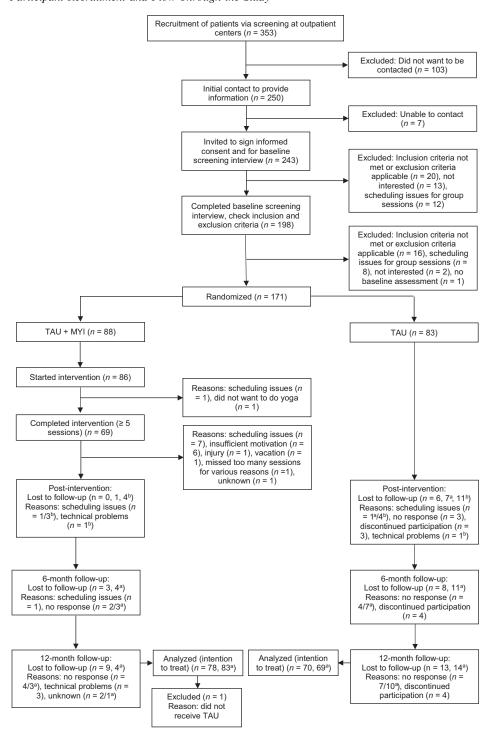
## **Recruitment, Attrition and Baseline Characteristics**

Figure 1 shows the participant flow. A total of 171 participants were randomized, of whom 88 received the MYI + TAU. All participants completed baseline assessments of symptoms of depression and 169 completed the demographic characteristics questionnaires. At 12-month follow-up, in MYI + TAU n = 77 (89%) completed the assessments and in TAU n = 70 (84%). Table 1 shows an overview of the baseline demographic and clinical characteristics of the participants for each condition (see Supplemental Materials, for additional baseline characteristics). Mean level of clinician-rated depression using the HDRS was 18.57 (SD = 5.94, range 7-33), indicating moderate depression (Zimmerman et al., 2013). Mean level of self-reported depression using the DASS was 21.11 (SD = 9.29, range 2-42), indicating severe depression (Lovibond & Lovibond, 1995). No serious adverse events related to the yoga training were reported during the course of the study. Several participants experienced serious adverse events unrelated to the study: hospitalization for already existing or acute physical injury or condition (e.g., appendicitis or concussion from an accident; n = 3[T1], n = 5 [T2], n = 6 [T3]); hospitalization for already existing or acute psychiatric condition (n = 1 [T2]).

AB score = (mean RT invalid depressive cue - mean RT valid depressive cue)

- (mean RT invalid neutral cue - mean RT valid neutral cue).

Figure 1 Participant Recruitment and Flow Through the Study



*Note.* TAU = treatment as usual group; MYI = mindful yoga intervention group. <sup>a</sup> For the self-report measures. <sup>b</sup> For the reaction time tasks.

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Table 1

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	<u>_</u>	T0	TI		L	T2		T3
Variable	MYI $(n = 87)$	TAU $(n = 83)$	MYI $(n = 87)$	TAU $(n = 77)$	MYI $(n = 84)$	TAU $(n = 75)$	MYI $(n = 81)$	TAU $(n = 70)$
Age, years, M (SD) Summone of damasecion M (SD)	25.20 (4.90)	$24.90 (4.36)^n = {}^{81}$						
Clinician rated (HDRS)	19.05 (5.81)	18.07 (6.06)	12.77 (7.18)	12.58 (6.40)	10.77 (7.69)	9.29 (7.08)	7.25 (7.03)	8.06 (7.49)
Self-reported (DASS-sf) MDD diagnosis <sup>a</sup> , (n, %)	21.61 (9.32)	$20.57 \ (9.29)^n = 81$	$15.40 (11.65)^n = 80$	$15.47 \ (9.97)^n = 70^n$	$12.29 \ (11.87)^n = 83$	$12.61 \ (10.33)^n = n^2$	$9.29 (9.58)^n = 84$	$11.91 (11.43)^n = 0.9$
Yes	87 (100)	83 (100)					18 (22.5)	26 (37.1)
No Number of previous episodes <sup>b</sup> , $n$ (%)							(C.17) 29	44 (62.9)
0	24 (29.3)	29 (36.3)						
1–2 episodes	42 (51.2)	34 (42.5)						
3 or more	16 (19.5)	17 (21.3)						
Duration current episode <sup>c</sup> , $n$ (%)								
2 weeks-3 months	1(1.3)	I						
3–6 months	10 (12.5)	13 (16.7)						
6 months-1 year	16 (20.0)	9 (11.5)						
1–2 years	28 (35)	26 (33.3)						
2 years or more	25 (31.3)	30 (38.5)						
Treatment duration (months), $M$ (SD)	11.45 (15.47)	11.93 (12.14)						
Age of onset first episode, $M(SD)$	$18.05 (5.61)^n = 81$	$18.18 (4.88)^n = \frac{82}{2}$						
Quality of treatment, $M$ (SD) <sup>d</sup>	7.18 (1.39)	$7.23 (1.06)^n = \frac{81}{21}$						
Motivation for study, $M(SD)^{e}$	7.93 (0.96)	$7.88 (0.95)^n = 81$						
Experience with yoga <sup>1</sup> , $n$ (%)								
Yes	24 (27.6)	25 (30.9)						
No	63 (72.4)	56 (69.1)						
Positive expectations $MYI^e$ , $M$ (SD)	6.02 (1.41)	$5.99 (1.35)^n = 81$						
Potential mediators, $M(SD)$		18 = 200 00 11	98 = 400 000 00000	$g_L = a \cos \cos \cos \cos 20$				
Rumination $(PIQ)$	(28.1) 42.14	$41.44 (8.60)^{-3}$	36.35 (10.70) = 36.35	$35.63 (10.32)^{-76}$				
Self-criticism (SCS)	5.36 (.81)	$5.47 (0.82)^n = \frac{61}{21}$	$4.80(1.51)^n = 0.000$	$5.05 (1.01)^n = 70^{-10}$				
Self-compassion (SCS)	2.85 (.89)	$2.92 (0.96)^n = 81$	$3.33 (1.15)^n = 80$	$3.15 (.94)^n = 70^n$				
Intolerance of uncertainty (IUS)	42.28 (6.70)	$41.33 (7.52)^n = 81$	$38.99 (8.45)^n = 86$	$38.50 (8.74)^n = 76$				
Perceived body awareness (SBC-A)	27.47 (6.58)	$27.83 \ (7.15)^n = 81$	$30.45 (7.17)^n = 86$	$28.24 \ (7.10)^n = 76$				
Body trust (MAIA)	2.67 (1.18)	$2.83 (1.33)^n = 81$	$3.03 (1.53)^n = 86$	$3.19 (1.38)^n = 76$				
Mindfulness (FFMQ)	63.36 (8.94)	$(63.25 \ (9.32)^n = 81)^n$	$70.03 (12.18)^n = \frac{86}{2}$	$68.66 \ (10.50)^n = 76$				
Attentional bias (ECT)	$2.43 (38.81)^n = 84$	$-4.46(38.29)^n = 82$	$2.90(38.16)^n = 82$	$-4.95 (40.16)^n = 72$				
Self-depressed associations (IAT)	$-0.12(.42)^n = 86$	$-0.15 (.42)^n = 82$	$-0.32 \ (0.35)^n = 82$	$-0.21 \ (0.43)^n = 72$				

*Note:* T = time; DASS-sf = Depression Anxiety Stress Scales-short form; MDD = major depressive disorder; ECT = exogenous cueing task; FFMQ = Five Facet Mindfulness Questionnaire; HDRS = Hamilton Depression Rating Scale; IAT = Implicit Association Task; IUS = Intolerance of Uncertainty Scale; MAIA = Multidimensional Assessment of Interceptive Awareness; MYI = mindful yoga intervention group; PTQ = Perseverative Thinking Scale; SBC-A = Scale of Body Connection–Awareness Scale; SCS = Self-Compassion Scale; TAU = treatment as usual group. <sup>a</sup> MYI + TAU at T3: n = 80. <sup>b</sup> MYI + TAU: n = 80. <sup>c</sup> MYI + TAU: n = 80, <sup>c</sup> MYI + TAU: n = 80, <sup>c</sup> MYI + TAU: n = 81.

### **Clinical Information and Treatment as Usual**

Most participants reported one or two previous episodes of depression (n = 76), followed by participants for whom the current episode was their first (n = 53). A minority reported three or more previous episodes (n = 33). For the majority of participants, the current episode started more than 2 years ago (n = 55), or between one and 2 years ago (n = 54). The mean age at the start of the first episode was 18 years (SD = 5.24, range 6–33).

At T1, five participants (3%) had completed treatment. Mean number of received sessions of the participants still in treatment was 9.67 (SD = 6.15, range 0–38). Sixty-one additional participants (37%) had completed treatment at T2. Of the participants still in treatment, the mean number of sessions was 17.97 (SD = 12.69, range 0–74). At T3, another 23 participants (22.3%) had completed their treatment. Of the participants still in treatment, mean number of contacts was 16.10 (SD = 9.85, range 0–48). There were no group differences on any of these variables (ps > .315), except for the rating of the current treatment, with participants in MYI + TAU being more satisfied about their treatment (M = 7.69, SD = 0.86, range 6–9) compared to participants in TAU (M = 7.09, SD = 1.21, range 4–9), F(1, 68) = 5.81, p = 0.019, with an effect size of Cohen's d = 0.32.

## **Intervention and Yoga Practice**

Of the 88 participants who were randomized into MYI + TAU, 86 started the intervention and 69 (79%) completed at least five sessions. Most common reasons for noncompletion were scheduling issues (n = 8) and insufficient motivation (n = 6). Mean number of attended sessions was six (SD = 2.38, range 0-9). After the intervention, the quality of the MYI was rated with a mean score of 7.7 (SD = 1.42, range 4-10), the online module with 6.5 (SD = 1.98, range 1-10), and the teacher with 8.8 (SD = 1.17, range 5-10). Most participants indicated that they experienced some (n = 27, 34%), followed by quite some (n = 25, 31%) and a lot (n = 15, 19%) of positive effects of the training. Thirteen participants (16%) indicated they did not experience positive effects.

Postintervention, MYI participants indicated that they practiced yoga once a week (n = 28), 2–3 times a week (n = 19), 1–2 times a month (n = 15), and less than once a month (n = 8). Fifteen participants (17%) did not practice at all. Data regarding the use of the online module during the MYI were taken from track records of the online system. Mean number of completed online sessions was 3.6 (SD = 3.1, range 0–9). Eighteen participants did not complete any session. Four completed all nine sessions.

Six months after the intervention, 58% of the MYI participants reported that they continued to practice yoga, at the frequency of less than once a month (n = 22), once a week (n = 12), once or twice a month (n = 10), or 2–3 times per week (n = 5). At the 12-month assessment, 56% of participants reported they were still practicing yoga, at the frequency of less than once a month (n = 18), once or twice a month (n = 13), once a week (n = 13) or 2–3 times per week (n = 3). In the control group, several participants started to practice yoga over the course of the study (n = 9 at T1; n = 7 at T2; n = 9 at T3).

## Correlations

We correlated all variables assessing yoga practice, completed number of sessions of the MYI and online module, expectations, positive effects, evaluation of the training, online module and the teacher with change on the primary outcome measures from T0 to T3. These correlations were all small and nonsignificant (all ps > .12) and can be found in Supplemental Materials.

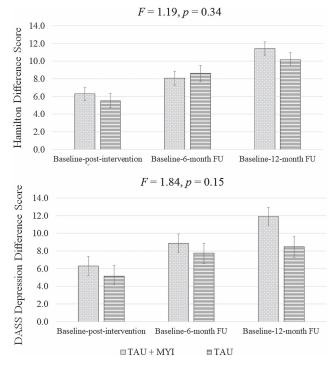
#### **Outcome Measures**

A repeated measures analysis of variance (ANOVA) with time (T0, T1, T2, and T3) as within factor and group (MYI + TAU vs. TAU-only) as between factor, and the Hamilton depression score as outcome measure, showed a significant effect for time, F (2.91, 488.52) = 156.13, p < 0.001 ( $\eta^2$  = 0.48), but no interaction between time and group, F(2.91, 488.52) = 1.19, p = 0.34 ( $\eta^2 = 0.01$ ). A repeated measures ANOVA using DASS depression as outcome also showed a significant effect for time, F(3, 504) = 67.62, p < 1000.001 ( $\eta^2 = 0.29$ ), but no interaction between time and group, *F*(3, 504) = 1.84, p = 0.15 ( $\eta^2$  = 0.01). Figure 2 shows the change in the depression measures. Means and standard deviations of the primary outcome measures can be found in Table 1. An ANOVA using the SCID diagnostic status at T3 as outcome measure showed no significant group difference, F(1, 168) = 3.16, p = 0.08 ( $\eta^2 =$ 0.02). Figure 3 and Table 1 show the percentage of participants meeting MDD diagnosis.

Per protocol analyses reflected similar findings as the general analyses. For the Hamilton depression score, a significant effect for

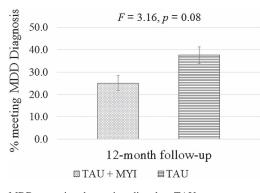
### Figure 2

Bar Graphs of the Difference Scores on the Hamilton (Top) and DASS-Depression (Bottom) Primary Outcome Measures From Baseline to Postintervention, 6-Month, and 12-Month Follow-Up



*Note.* DASS = Depression Anxiety Stress Scales; FU = Follow-up; TAU = treatment as usual group; MYI = mindful yoga intervention group Error bars represent one standard error.





*Note.* MDD = major depressive disorder; TAU = treatment as usual group; MYI = mindful yoga intervention group Error bars represent one standard error.

time was found, F(2.93, 395.03) = 112.21, p < 0.001 ( $\eta^2 = 0.45$ ), but no interaction between time and group, F(2.93, 395.03) = 1.69, p = 0.20 ( $\eta^2 = 0.01$ ). For the DASS depression score, a significant effect for time was found, F(2.93, 396.02) = 52.08, p < 0.001 ( $\eta^2 = 0.28$ ), but no interaction between time and group, F(2.93, 396.02) = 1.36, p = 0.27 ( $\eta^2 = 0.01$ ). Also, for the SCID there was no significant group difference, F(1, 135) = 0.68, p = 0.44 ( $\eta^2 = 0.005$ ). From T0 to T3 the MYI + TAU group showed a mean reduction of 11.42 points, and the TAU group of 10.17 points. This is a mean difference of 1.25 points, which does not meet the preset level of MCID.

Figure 4 shows the change in scores on the secondary outcome measures. Repeated measures ANOVAs were run for each measure with time (T0, T1, T2, and T3) as a within factor and group (MYI + TAU vs. TAU-only) as a between factor. The results showed (a) no effects for the MYI + TAU over TAU, in that there were no significant interaction effects between group and time for impairment across several situations, quality of life, satisfaction with health, purpose and growth (ps > .12) but (b) main effects of time for all variables (ps < .001). Together, these results indicated that both groups showed increases in general functioning, but that MYI + TAU did not demonstrate greater increases than TAU alone.

## Mediators

As indirect effects can occur even in the absence of main effects (Hayes, 2013), we performed per protocol regression analyses for each of the potential mediators on all three primary outcome measures. We did not find indirect effects for any of the mediation analyses (all confidence intervals included zero, see Supplemental Materials), except for self-compassion on the self-reported symptoms of depression outcome measure (DASS). A bias-corrected bootstrap 95% confidence interval for the indirect effect (1.56) based on 10,000 bootstrap samples did not include zero (.58–5.02), indicating mediation of self-compassion at 12-months follow-up. Of interest in regards to whether the MYI had expected yoga-related effects, the analyses showed a group difference in change from baseline to postintervention in self-compassion, F(1, 135) = 6.27, p = 0.002 ( $\eta^2 = 0.04$ ) and perceived body awareness, F(1, 135) = 9.89, p = 0.0022 ( $\eta^2 = 0.07$ ), with for both variables participants in the MYI + TAU group

reporting a larger increase compared to participants in the TAUonly group, but not in the other mediators ( $ps \ge .20$ ).

## Moderators

We conducted exploratory analyses to examine potential moderators of the intervention using per protocol analyses. We did not find substantial evidence for any of the potential moderators (i.e., showing a significant interaction effect on at least two out of three primary outcome measures).

## Discussion

#### Summary of the Main Findings

To our knowledge, this is the first RCT to investigate the efficacy of adding a MYI to TAU in young women with depression and to study potential mediators and moderators of the MYI effects. Regarding our primary hypothesis, compared to TAU-only, adding MYI to TAU did not result in a larger decrease of symptoms of depression at postintervention or follow-up or in fewer MDD diagnosis at 12-month follow-up. The findings showed that there was a 1.25-point difference between the conditions in decline on the Hamilton depression measure at 12-months follow-up, which is roughly half the 3-point criterion for a minimal clinically relevant difference (Hengartner & Ploederl, 2022).

The results also did not support our secondary hypothesis, as we did not find that adding MYI to TAU led to larger increases of wellbeing and general functioning. The third hypothesis was mostly unsupported as we did not find any of the candidate mediating variables to mediate the relation between condition and outcomes, except for self-compassion on self-reported symptoms of depression. Further, the moderation analyses did not support a role for any of the potential moderators.

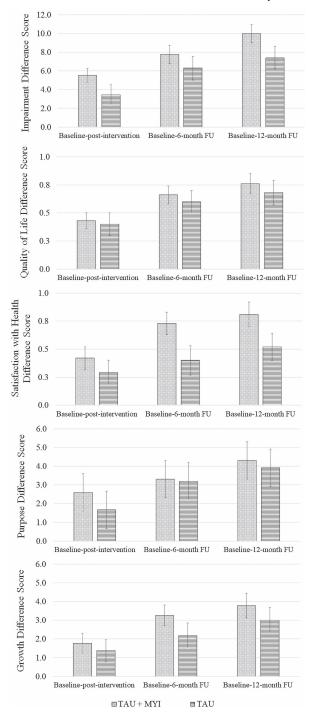
## Comparing the Current Findings With Previous Research

Our findings are in line with previous studies that have compared yoga with TAU on depression outcomes in clinical samples. Consistent with the majority of these studies (Vollbehr et al., 2018), we did not find a significant difference between MYI + TAU and TAU-only in reducing depression. As most of the previous research had methodological shortcomings such as small sample sizes, short follow-up periods, and the absence of a manualized intervention, the validity of the previous results may have been suboptimal. One way that the present study contributes to the literature is by addressing these methodological issues with design elements such as using a clinical sample, a large sample size, having a blinded rater, administering the intervention with a manual, and using a control condition of evidence-based interventions. The improved design elements make the current results more reliable and increase confidence in their interpretation with regard to the clinical value of adding MYI to TAU. Further, our study is one of the few trials that has examined the effectiveness of a yoga intervention for MDD in a clinical setting, as most studies have used community samples (Vollbehr et al., 2018).

This study examined the efficacy of MYI by adding it to TAU for young women with MDD. Regarding the addition of a yoga intervention to TAU, we found six other studies that compared

#### Figure 4

Bar Graphs of the Difference Scores on the General Functioning (Top), Quality of Life and Health (Middle) and Purpose and Growth (Bottom) Secondary Outcome Measures From Baseline to Postintervention, 6-Month, and 12-Month Follow-Up



*Note.* TAU = treatment as usual group; MYI = mindful yoga intervention group. Error bars represent one standard error; FU = Follow-up.

TAU-only with yoga plus TAU (Broota & Dhir, 1990; Falsafi, 2016; Ravindran et al., 2021; Sarubin et al., 2014; Subbanna et al., 2021; Tolahunase et al., 2018). Two of these studies had similar findings to ours with no group differences between the yoga group and the control group (Ravindran et al., 2021; Sarubin et al., 2014). The other four studies found a significant difference in decrease of symptoms of depression in favor of the yoga group (Broota & Dhir, 1990; Falsafi, 2016; Subbanna et al., 2021; Tolahunase et al., 2018). A potential explanation for the discrepancy with our findings might relate to differences in the TAU that was offered to the participants. In our study, all participants received an individualized standard form of TAU that could include medication as well as other forms of treatment, while in three out of four of the other studies the only treatment allowed was psychiatric medication (Broota & Dhir, 1990; Subbanna et al., 2021; Tolahunase et al., 2018), and in one study, only part of the participants received actual treatment (56.6% medication and 22.4% psychotherapy; Falsafi, 2016). Intensity of intervention is another potential reason for the positive findings in the other studies. Compared to the 1.5 hr/session a week for 9 weeks in the present study, the studies with positive findings all had more intensive interventions-three 20-30-min sessions in 3 days in Broota and Dhir (1990), 2 hr/session, five sessions per week for 12 weeks in Tolahunase et al. (2018), or four-to-six 1-hr sessions per week for 3 months in Subbanna et al. (2021). Another indication of the less intensive nature of our intervention is that the participants showed relatively low amounts of home practice.

Several other studies that compared a yoga intervention to various control conditions have found positive results as well (Butler et al., 2008; Field et al., 2012, 2013; Mitchell et al., 2012; Prathikanti et al., 2017; Schuver & Lewis, 2016; Uebelacker et al., 2015). However, most of these studies used a psychoeducation control group (Butler et al., 2008; Field et al., 2012, 2013; Mitchell et al., 2012; Prathikanti et al., 2008; Field et al., 2012, 2013; Mitchell et al., 2012; Prathikanti et al., 2008; Field et al., 2012, 2013; Mitchell et al., 2012; Prathikanti et al., 2017; Uebelacker et al., 2015), controlling only for nonspecific factors. In contrast, yoga interventions have generally not been found to be more effective in reducing depression when compared to active control groups such as mindfulness training (Falsafi, 2016), massage therapy (Field et al., 2012), or walking (Schuver & Lewis, 2016). To summarize, our nonsignificant findings are in line with most other yoga intervention studies that used a strong (active) comparison condition.

It may be informative to also compare our findings with studies that investigated mindfulness-based interventions for patients with acute MDD using the addition of mindfulness interventions to TAU, compared to TAU alone. These studies have generally found a significant decrease of symptoms of depression in the intervention group plus TAU compared to the TAU-only group (Barnhofer et al., 2009; Kingston et al., 2007; Omidi et al., 2013; van Aalderen et al., 2012). However, as in most yoga intervention studies, the exact nature of TAU was either unclear (Kingston et al., 2007; van Aalderen et al., 2012) or was restricted to the use of antidepressant medication without psychological treatments (Barnhofer et al., 2009; Omidi et al., 2013). Therefore, it is possible that in these mindfulness studies the TAU control was weaker than the TAU received by all participants in the present study, which consisted of a variety of interventions recommended by the Dutch guidelines. As most participants in the present study received more than one type of recommended intervention, including psychological treatment such as cognitive behavioral therapy (n = 114) or other psychological interventions (n = 53), it might have been the case that TAU in the present study was already rather complete and that the MYI has not been able to add much—for example due to not having enough time or energy to dedicate to the MYI practices.

Considering our findings for the general functioning and quality of life outcomes, we found three studies investigating a yoga intervention that also assessed these positive outcomes in patients with depression. None of these studies found differences between yoga and psychoeducation control on mental health quality of life (Kinser et al., 2014), social and role functioning, and general health perception (Uebelacker et al., 2017), or quality of life (Ravindran et al., 2021). Our null-findings for the secondary outcome measures are thus in line with these previous findings.

Finally, regarding potential mechanisms of the yoga intervention, the results did not indicate mediating effects of any of the potential variables, except for self-compassion on self-reported symptoms of depression. Although we could not find any other yoga for depression studies that assessed mediation, we did find three studies that assessed yoga effects on potential mediating mechanisms. First, Falsafi (2016) found that a yoga intervention led to more mindfulness compared to wait-list control, but not when compared to a mindfulness intervention. Also, the yoga intervention did not lead to more self-compassion, compared to wait-list or mindfulness control. Second, Prathikanti et al. (2017) used self-efficacy and self-worth scales and found that there was no significant difference between the voga and control group of psychoeducation on these scales. Last, Schuver and Lewis (2016) used a rumination scale and found a significant group difference in favor of the yoga group postintervention, compared to walking control, but not at the 1-month followup. A potential reason for the discrepancy between our null-findings for rumination and the findings of Schuver and Lewis (2016) is that they used a walking intervention control whereas our study used TAU, which likely contained elements that targeted rumination (such as cognitive behavioral therapy). The type of control group might also explain the difference between our study and the findings of Falsafi (2016) for a change in mindfulness-we used actual evidence-based interventions as control where in the Falsafi (2016) study a wait-list control was used and only part of the participants received evidence-based treatment.

Although there was only one statistically significant mediation effect, the results did indicate main effects in favor of the MYI leading to increased self-compassion and perceived body awareness. These results may indicate evidence for MYI as an active intervention. These findings show that while it appears that there is some evidence that the MYI did what it was intended to do (increase of selfcompassion and perceived body awareness), these effects did not act as mediators of MYI on depression, with the above noted exception of self-compassion on self-reported depression symptoms.

### Strengths and Limitations

The present study has a number of methodological elements that add confidence to the results. First, we preregistered our study and designed a rigorous trial, adhering to the Consolidated Standards of Reporting Trials guidelines. Second, we were able to include a relatively large sample within mental health institutions that showed low attrition even at 12-month follow-up (15%, whereas comparable studies showed 29% attrition at 6 months; Uebelacker et al., 2017 or 67% at 1 year; Kinser et al., 2014). Our ability to include and retain this sample helped to provide adequate power for detecting medium to large effect size differences. Third, we used clinicianadministered measures to assess symptoms of depression (which showed excellent interrater reliability), thereby augmenting the selfreport measures. Fourth, our rater blinding was found to be valid, helping to prevent rater bias and increase confidence in the validity of the clinician-administered measures of depression. This is notable as we found no other RCTs studying yoga interventions for depression that adequately assessed rater blinding (Vollbehr et al., 2018). Fifth, we used a relatively long follow-up period of 1 year, making it possible to also draw longer term conclusions, and not only conclusions right after finishing treatment. Given that a critique of previous research is that due to a lack of longer term follow-up assessments, even when benefits of a yoga intervention are found, it is unclear whether they are lasting (Vollbehr et al., 2018). With this longer follow-up, we are able to give better information about whether initial benefits are lasting. Sixth, we conducted a thorough assessment of TAU through review of participants' medical files. This provided knowledge regarding what evidence-based interventions were used in TAU and helped to ensure that our control group was a strong comparison. This point is important because a weak TAU may lead to overestimations of the added value of the target treatment (Baskin et al., 2003). Seventh, we assessed treatment adherence of the yoga teacher, who was found to closely follow the manual by independent raters and received good ratings on quality and attitude by the participants. Finally, we assessed whether the yoga intervention was doing what it was designed to do by analyzing group differences on the potential mediators for the MYI completers and TAU group from baseline to postintervention. The results showed that the MYI indeed led to more self-compassion and perceived body awareness. This is a strength of the study as most other yoga intervention studies have not examined whether the intervention is active in the sense of influencing targeted mechanisms.

In addition to the strengths listed above, several limitations are relevant for interpreting the findings. First, participants in both conditions received evidence- and guideline-based specialized care, which might have hampered the additional effect of MYI for reasons such as having less time and energy for devoting to the yoga home practices. Perhaps related, participants generally did not complete the home practice. The MYI was designed to include an online module to facilitate the practice of exercises for at least 30-45 min per day, but none of the participants practiced this often; the majority practiced once a week or less. Although this suboptimal completion of the intervention might have prevented stronger benefits, this interpretation may not be the best one as correlation between amount of practice and change in the primary outcomes measures was not significant. Finally, this study was designed to enhance MDD treatment for young women, as they are especially at risk for developing MDD. However, the sample also means that the generalizability of our findings is limited to young women suffering from clinical depression, as we did not include men or older adults in the sample. This limitation may be important as research has shown that meditation interventions have different effects for men and women (Rojiani et al., 2017), and that psychotherapeutic interventions have shown larger effects sizes in adults compared to adolescents (Cuijpers et al., 2020). Also, as the participants consisted of young women in the northern part of the Netherlands, the sample had relatively little ethnic diversity, which may limit the generalizability of the results.

## Recommendations for Clinical Practice and Future Research

Findings that yoga is a popular practice among young women (Cramer et al., 2016a; Neumark-Sztainer et al., 2020) were supported in our study, as participants positively evaluated MYI as a form of treatment. This suggests that MYI may be beneficial for optimizing the attractiveness of treatment. Additional research may provide information regarding whether other groups such as the elderly or populations with chronic mood and anxiety disorders benefit more strongly from MYI. Further, given that the mean group difference of 1.25 is nearly half of the MCID and in the expected direction, there may be subgroups of young women with MDD that derive greater benefit from MYI. Clinical practice would benefit from research that determines such subgroups. Finally, it is possible that MYI may be more helpful when patients are recovered and have the energy and psychological resources that allow for more committed practice. From this perspective, future research may benefit from examining the potential of MYI as a relapse prevention treatment.

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