Meditation-based lifestyle modification in mild to moderate depression—A randomized controlled trial

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**Abstract**

**Objective:** Depression is a global key challenge in mental health care. The implementation of effective, low-risk and cost-effective interventions to reduce its disease burden is a necessity. The aim of this study was to investigate the efficacy of the new Meditation-Based Lifestyle Modification (MBLM) program, a “second-generation” mindfulness-based intervention, in depressive outpatients.

**Methods:** Eighty-one patients with mild to moderate depression were randomized into three groups: intervention group (MBLM), control group (CONTROL), and treatment as usual group (TAU). The primary outcome was the change of depressive symptoms as administered by the Beck Depression Inventory-II (BDI-II) after 4 and 8 weeks. Secondary outcome variables included the Brief Symptom Checklist-18 and the Perceived Stress Scale-10. A 6-month follow-up was conducted.

**Results:** A greater reduction of depressive symptoms was found in MBLM participants compared to CONTROL ($p < .001$, $\eta^2_p = 0.11$, $d = 0.70$) and TAU ($p < .001$, $\eta^2_p = 0.10$, $d = 0.67$) with a 13.15 points reduction of BDI-II score versus 1.71 points (CONTROL) and 3.34 points (TAU) after 8 weeks. Between-group post hoc tests for all secondary outcomes and at follow-up also yielded significant between-group differences with medium to large effect sizes in favor of MBLM.

**Conclusions:** Study results showed beneficial effects of MBLM in depressed outpatients. Further high-quality controlled clinical studies including qualitative research are needed to investigate the specific and unspecific effects of the MBLM program in depression and other medical conditions.

**KEYWORDS**
depression, ethical living, mantra, meditation, yoga
INTRODUCTION

Depression is a complex disorder determined by biological factors, the environmental milieu, live events, and multilayered interactions between the aforementioned (Malhi & Mann, 2018). People with depression suffer from depressed mood, loss of interest or pleasure, thought disorders, diminished ability to concentrate, loss of energy, feelings of worthlessness or guilt, and suicidal ideations (American Psychiatric Association, 2013). The prevalence of depression has been growing in the last two decades, and with a 12-month prevalence of 6%, it has been recognized as the leading cause of disability in the world combined with a significant socioeconomic burden for the health systems (Malhi & Mann, 2018). Especially in regions with a high sociodemographic index, the age-standardized incidence rate has increased (Liu et al., 2019). This underscores the role of depression as a global key challenge in public health and the necessity of implementing cost-effective interventions to reduce its disease burden (Ferrari et al., 2013; Friedrich, 2017).

Conventional treatment includes pharmacological options, brain stimulation, and psychotherapeutic interventions. First-line pharmacotherapy commonly uses drugs that affect cerebral monoamine levels. The monoamine hypothesis in the context of depression has persisted for over 50 years and may be one of the reasons for a lack of innovation in the field of depression research and treatment. In this context, the efficacy of drugs that increase cerebral serotonin or norepinephrine levels is being debated increasingly and controversially (Bschor & Kilarski, 2016). In addition, adverse effects of antidepressive pharmacological interventions can be severe regarding both their utilization and discontinuation (Hensler et al., 2019). Brain stimulation treatments such as electroconvulsive therapy, repetitive transcranial magnetic stimulation, or deep brain stimulation for passive induction of neuronal plasticity can only be considered for the treatment of specific cases (Synofzik et al., 2010) and may not be used on a widespread basis due to ethical considerations, high technical requirements, and associated expenses.

In psychotherapy, several waves of behavioral therapy have been distinguished on the basis of historical, theoretical, and practical considerations (Kahl et al., 2012). The first wave focused methodologically on the principles of classical conditioning and operant learning, in which the behavior of the individual was supposed to be altered through exposure to specific stimuli. In the second “cognitive” wave, the central focus shifted to information processing, in which interrelations between thoughts, emotions, and behavior were analyzed and altered through cognitive reappraisal. The third wave of behavioral therapy is characterized by multifaceted methods in which mindfulness, acceptance, and cognitive defusion, among others, are implemented therapeutically (Kahl et al., 2012). These methods overlap with treatments that have found their way into integrative psychiatry (Sarris et al., 2015) through mind–body medicine (National Center for Complementary and Integrative Health, 2017). Unlike first- and second-wave cognitive behavioral therapy (and other classical psychotherapies), the primary focus of these techniques is not on verbally processing biographical events, developmental traumas, conflicts, or dysfunctional conditioning (Kahl et al., 2012). Embedded mindfulness-based applications focus on a disidentification of inner experience and states of consciousness, which lead to greater serenity, improved emotion regulation, and a decrease in symptoms. In depression treatment, for example, Mindfulness-Based Cognitive Therapy for Depression (MBCT-D) (Finucane & Mercer, 2006; Segal et al., 2002) and Acceptance and Commitment Therapy (ACT) (Hayes et al., 2006) have been developed in this context and have been shown to be effective. Whether these therapies are more effective than the second wave therapies has not yet been fully established, but mindfulness-based interventions are superior to cognitive theory in terms of consciousness psychology and epistemology, since they adopt a metapsychological perspective on cognitive and emotional processes (Brunnhuber & Michalsen, 2012). Recent developments in psychotherapy and mind–body medicine go even one step further. In these approaches, flourishing and eudaimonic well-being (Ryff & Singer, 2008) are the main focuses of therapy rather than a mere correction of mental health symptoms. In this “fourth-wave” psychotherapy, approaches include positive psychology interventions and spiritually informed therapies that have evolved from existential and humanistic backgrounds (Peteet, 2018). In mind–body medicine, “second-generation” mindfulness-based interventions overtly include psychospiritual (e.g., mindfulness) or spiritual (e.g., belief or faith) elements and feature ethical aspects as a key component of the intervention (Van Gordon & Shonin, 2020). A central feature of these approaches is that they intend to support the suffering individual in developing to his or her fullest potential. In a systematic review of research from 1872 till 2010, the large majority of studies found that religious involvement is related to greater well-being and happiness, and more than the half of studies found less depression or faster recovery from depression in spiritually active people (Koenig, 2012). Spiritual practices and experiences mediate positive psychological traits that in turn affect emotions, cognitions, behavior, and coping styles that may lead to better mental (and physical) health (Koenig, 2011). Across different studies, spiritual meditation had a greater impact than the secular forms of meditation on psychological variables (Wachholtz & Austin, 2012).

The new Meditation Based Lifestyle Modification (MBLM) (Bringmann et al., 2021b) therapeutic program can be attributed beneficially to these recent developments. MBLM is an 8-week mind–body intervention designed for mental health care settings, which is based on classical yoga. According to classical yoga texts, yoga implements ethical living, yoga exercises, breathing practices, and meditation to still the mind in a way that allows for self-realization (Bryant, 2015). In MBLM, the thematic exploration of the ethical principles of yoga takes place in an educational and group-psychotherapeutic setting and forms the basis for a lifestyle change that incorporates both the physical and the meditative levels. In a feasibility study without a control group, depressed patients showed increased eudaimonic well-being in addition to significantly improved depressiveness after participating in MBLM (Bringmann et al., 2021b). Furthermore, participants reported an increased capacity for self-reflection, mindfulness, and self-regulation. These results could be...
confirmed in a subsequent qualitative analysis, in which the high relevance of the ethical aspects for the participants and the associated reappraisal of their lives became apparent (Bringmann et al., 2021). Various components of MBLM also increased well-being and reduced stress in psychologically healthy participants (Matko et al., 2021).

Evidence of efficacy of MBLM in depressed patients has not yet been established in a prospective randomized study with active control groups. Therefore, in this study, we investigated the efficacy of MBLM in comparison to two conventional therapy programs, as they are common in clinical practice. We considered a multimodal therapy, including pharmacotherapy, psychotherapy, movement therapy, occupational therapy, and relaxation techniques as a "state-of-the-art" treatment as usual (TAU). On the other hand, we considered the mere administration of antidepressant medication as minimal therapy (CONTROL).

2 | METHODS

2.1 | Design

This three-arm, single-site, randomized controlled trial (ClinicalTrials.gov identifier: NCT03652220) was registered before the inclusion of the first patient and conducted at the Clinic for Psychiatry, Psychosomatics, and Psychotherapy, Zschadraß, Germany from August 2018 through June 2020. All participants provided written informed consent after receiving a full explanation regarding the study protocol and before randomized assignment to treatment arms. Participants were informed of the assignment after randomization (open allocation). The study was approved by the Ethics Review Board of the University of Chemnitz University of Technology (V-276-15-PS-MBLM-D-14062018). In this study, two steps of randomization were implemented (Phases 1 and II, see also Figure 1). In Phase I (8 weeks), participants were randomized 1:1:1 into three groups: intervention group (MBLM), control group (CONTROL), and TAU. In Phase II (16 weeks), participants of CONTROL and TAU groups were randomized to TAU or TAU + MBLM (ratio 3:1 to target equal group sizes in phase II), whereas all participants previously randomized to MBLM were allocated to TAU + MBLM. In this phase, participants of all groups began or continued TAU as described above. Patients allocated to TAU + MBLM additionally participated in the 8-week MBLM program (if they had not done so during the first 8 weeks). The streamlining of the study design to two groups for Phase II was chosen primarily for clinical reasons: it was necessary to enable the patients from the CONTROL group to undergo intensified therapy after 8 weeks. In addition, due to the a priori unknown effectiveness of the program, patients from the MBLM group should also be given TAU after 8 weeks. With this design, we were able to (A) compare clinical outcomes at follow-up of patients who had received MBLM as part of their multimodal therapy and those who had not. Additionally, we could (B) compare a subgroup of patients from the prior CONTROL group who received either TAU or TAU + MBLM treatment (augmentation effect).

2.2 | Participants

Outpatients of the Department of Psychiatry, Psychosomatics, and Psychotherapy, Diakoniekliniken Zschadrass, Colditz, Germany were recruited via their attending psychiatrist and via flyers posted in the waiting room of the clinic's outpatient department. The study included outpatients who were at least 18 years old, who had been diagnosed with mild or moderate depression according to the International Classification of Diseases, Tenth Revision criteria assessed by their attending psychiatrist during a consultation, and who achieved a total score of at least 10 points in the Beck Depression Inventory (BDI-II) (Beck et al., 1996). The BDI functioned as a screening instrument before the clinical interview and did not necessarily determine the diagnosis of a mild or moderate depression. As a prerequisite, participants were asked if they were physically able to do gentle yoga exercises and to sit still for 20 min. Patients with obsessive-compulsive disorder, cerebral organic diseases, or addictive disorders, psychotic symptoms, or acute suicidality were excluded. After providing informed consent, participants completed the baseline survey including sociodemographic and psychosocial questionnaires.

2.3 | Primary and secondary outcome measures

Participants were asked to complete standardized questionnaires at four time points: at baseline before the intervention (T0); after 4 weeks (T1); after 8 weeks, immediately following the intervention (T2); during follow-up, 6 months after the intervention had started (T3).

The primary outcome measure was the change in the score of the BDI-II at T1 and T2 (Beck et al., 1996). The BDI-II is a 21-question multiple-choice self-report inventory, one of the most widely used psychometric tests for measuring the severity of depression. It is composed of items relating to symptoms of depression such as hopelessness and irritability and cognitions such as guilt or feelings of being punished, as well as physical symptoms such as fatigue, weight loss, and lack of interest in sex. Cut-off scores: values of 13 and less can be considered as subclinical depression; 14–19 as mild depression; 20–28 as moderate depression; and 29–63 as severe depression. The minimum clinically important difference of the BDI is reported in the literature to be a 17.5% reduction from baseline (Button et al., 2015).

Secondary outcome variables included (1) the Brief Symptom Checklist-18 (BSI-18) (Franke et al., 2017) to assess complementary information about the change in somatization, depression, and anxiety and (2) the Perceived Stress Scale-10 (PSS-10) (Cohen et al., 1983) for measuring the perception of stress. Further, secondary outcome variables assessed in this study project, including 24-h heart rate variability, qualitative data (in-depth interviews with a subset of participants), and a range of measures of spirituality (for details see the study’s registry at ClinicalTrials.gov), will be discussed in separate publications. Due to the novelty of the MBLM program, we chose to extend our research questions beyond the evaluation of...
FIGURE 1  Participant flow. BDI-II, Beck Depression Inventory-II; CONTROL, drug continuation therapy; MBLM, meditation-based lifestyle modification; TAU, treatment as usual
primarily clinical parameters, which are, however, beyond the scope of this article. Adverse effects were assessed by prespecified questionnaires with a list of common problems related to yoga and meditation practice (Kessler et al., 2017; Matsushita & Oka, 2015) to be filled in at T2 by the participants of MBLM and TAU group (see Supporting Information Material for a complete list of items). In the questionnaire, participants could retrospectively state how many days the adverse event was present (days per week, number of weeks). Adherence to home practices related to MBLM (mantra meditation, yoga, ethical living) were assessed by prestructured patient diaries that were collected on a weekly basis. Participants were asked to fill in minutes of daily practice (yoga and meditation, respectively) and to keep a diary of exercises associated with ethical living. Blinded research assistants collected patient-reported data, and research personnel blinded to group allocation entered and monitored the data.

2.4 | Study interventions

Patients were asked to participate over a period of 8 weeks (Phase I) and consecutively for another 16 weeks (Phase II) according to their allocated treatment. All involved physicians and therapists were specialists in their respective fields and had multiple years of professional experience.

2.5 | Meditation Based Lifestyle Modification (MBLM)

Participants in the MBLM group were allowed to continue their antidepressant medication (if any) and participated in the 8-week MBLM program. The MBLM program is a mind–body intervention, which includes three domains of practice, based on the eightfold path of classical yoga (Bringmann et al., 2021b): ethical living, healthy lifestyle, and mantra meditation. It consists of eight consecutive, weekly group sessions of 180 min each, and 45 min of recommended, daily home practice. Each group session (as well as training at home) includes the three domains of practice. In the first part, ethical living, the therapists introduce major aspects of yoga practice concerning virtue-based ethics, including constraints (nonviolence, truthfulness, nonstealing, nonexcess, and nongreed) and spiritual observances (purity, contentment, and transcendence). During the second part, healthy lifestyle, the participants learn breathing exercises and gentle yoga postures suitable for people with depression and anxiety. Participants also receive individualized healthy lifestyle advice based on basic Ayurvedic recommendations before the course (see Appendix A in Supporting Information Material) (Kessler et al., 2017). The third part of each group session is a mantra meditation period where participants silently recite a mantra, which they have chosen themselves from a list and learned to apply in an introductory session before the course. A detailed description of MBLM and its feasibility for depressive disorders have been published elsewhere (Bringmann et al., 2021a, 2021b).

2.6 | Multidisciplinary psychiatric outpatient care (TAU)

During the whole study period, participants in the TAU group received an individually tailored multimodal therapy based on the national guidelines for the treatment of unipolar depression (DGPPN et al., 2015), including pharmacotherapy, psychotherapy, and accessory therapies (e.g., relaxation techniques, movement therapies, psychotherapy, and occupational therapy; for details, see Supporting Information Data). Although international standards may vary in what is considered as “TAU,” we labeled the multidisciplinary psychiatric outpatient care as TAU, as it was the standard care for outpatients in the study center.

In addition to psychiatric and psychotherapeutic treatment, the multidisciplinary approach included therapies conveyed by specially trained nurses, occupational therapists, movement therapists, art therapists, and social workers. Body-oriented yoga, therapies related to mindfulness-based stress reduction (Rusch et al., 2018), and mantra meditation were excluded from the portfolio of therapies available for study participants. For analysis of therapy hours and to reduce complexity, we did not distinguish whether psychotherapy was carried out in a group setting or in single sessions. Psychotherapy was delivered nonmanualized according to the professional training of the therapists. Similarly, we did not distinguish between different types of movement therapies, occupational therapies, and relaxation techniques. Patients were allowed to switch between therapy modules during the treatment phases if indicated by their consulting psychiatrist. Exercises at home were not part of the protocol.

2.7 | Drug continuation therapy (CONTROL)

In the control group, the participants received medical advice from their psychiatrist as needed, but at least one time during the period of 8 weeks. Participants of this group were excluded from all nonpharmacological therapies. Any pre-existing antidepressant medication was continued. Adjusting the dose or changing the medication was possible to prevent or respond to severe adverse events.

2.8 | Sample size and data analysis

The primary objective was to compare the efficacy of MBLM, TAU, and CONTROL in total scores of BDI-II after 4 weeks (T1) and after 8 weeks (T2). As we did not have any data at the time to estimate what difference to expect between the treatment conditions, we elected to power the study to be able to detect a moderate effect size difference of \( d = 0.5 \) between the groups, based on reported effect sizes for yoga in depression (Cramer et al., 2013; Klatte et al.,
Sample size calculation with G*Power 3.1 (Faul et al., 2007) has been performed for a repeated-measures (e.g., T₀, T₁, and T₂) analysis of variance (ANOVA) with an α-level of α = .05, a power of (1 – β) = 0.90, resulting in a total sample size of N = 72. We expected a rather low level of 10% dropouts, considering missing side effects of intervention and extensive efforts to support patient’s adherence (weekly classes, working sheets). We, therefore, planned to recruit a total of N = 81 patients into the study, or 27 patients for each group, respectively. For both steps of randomization and concealment of allocation, MinimPy (Saghaei & Saghaei, 2011), which implements a software-based minimization algorithm (O’Callaghan, 2014; Scott et al., 2002) was used to create homogeneous subpopulations with respect to age, gender, BDI-II score before the intervention, recurrence of depression, and adverse childhood events.

To check for balance between the study groups, we compared demographic data and other important baseline characteristics with ANOVA or χ² tests where applicable.

To improve the effectiveness of interventions, a repeated-measures analysis of covariance (ANCOVA) was conducted to analyze time-by-group interactions, with group allocation as the independent variable and (in subsequent models) BDI, BSI, and PSS-10 as the dependent variables. For the primary outcome (BDI), three time points were available for analysis (T₀, T₁, and T₂). For the secondary outcomes (BSI-18, PSS-10), two time points were available (T₀ and T₂). As recommended for longitudinal analysis of RCTs, all analyses were adjusted by including baseline outcome values as covariates in the model (Committee for Medicinal Products for Human Use, 2015). Before the analysis, we made sure that the specific assumptions for normality and homogeneity of variance for the ANCOVA were met.

For follow-up analyses after 6 months (T₃), we performed an exploratory analysis with the same statistical methods on subgroups of interest. We report p values and the respective partial η²/Cohen’s d as effect size. Exploratory post hoc t tests were conducted for treatment contrasts of interest, reporting corresponding p values and Cohen’s d as effect size. Bonferroni–Holm correction was used where applicable. We used R 3.6 for all our quantitative analyses and p values <.05 were considered significant. Outcomes were analysed on an intention-to-treat basis. Missing data were imputed using Multivariate Imputations by Chained Equations algorithm (van Buuren & Groothuis-Oudshoorn, 2011). No restrictions were imposed on the value range of the imputed results. The data that support the findings of this study are available from the corresponding author upon reasonable request.

3 | RESULTS

3.1 | Descriptive analysis

Recruitment took place from August 2018 till January 2020. The last follow-up measurements took place in June 2020. Demographic and clinical characteristics at baseline are stated in Table 1. One participant was lost during the study during Phase I, and three participants during Phase II (Figure 1). Dropped-out participants did not differ in baseline characteristics as shown in Table 1, except for a higher rate of adverse childhood events (p = .02). Overall, 20.0% of all questionnaire items were missing completely at random (Little’s missing completely at random test, p = .55) and were imputed before analysis.

3.2 | Phase I results

The baseline-adjusted analysis of the primary outcome revealed a significant interaction between time and group, F(2,2) = 7.45, p < .001, η² = 0.11, d = 0.70. Significant interactions were also found for MBLM vs. CONTROL, F1(1,2) = 9.91, p < .001, η² = 0.11, d = 0.70, and MBLM versus TAU, F1(1,2) = 9.42, p < .001, η² = 0.10, d = 0.67. This interaction was qualified by a mean decline in BDI score from baseline to 8 weeks (baseline unadjusted) of 13.1 points in participants allocated to MBLM treatment, as compared to 3.3 points in the TAU group and 1.7 points in the CONTROL group (Table 2 and Figure 2). Differences between groups for each time point are shown in Table 3.

On average, patients in the TAU group received more program hours of therapy per week than the MBLM group (MBLM: 3.0 h, SD = 0.0 vs. TAU: 4.0 h, SD = 1.2; p < .001). Weekly treatment in the TAU group was delivered on average as 1.4 (SD = 0.7) h of psychotherapy, 1.0 (SD = 0.9) h of movement therapy, 0.9 (SD = 0.9) h of occupational therapy, and 0.7 (SD = 0.6) h of relaxation therapy.

Participants in the MBLM group practiced daily on average 20 min (SD = 8.95 of mantra meditation and 22 min (SD = 14.43) of yoga at home. Exploratory post hoc analysis indicated a large effect of MBLM after eight weeks compared to CONTROL, whereas TAU and CONTROL did not differ significantly (Table 3). Similarly, secondary outcomes revealed significant time-by-group interactions in favor of the MBLM group for both BSI-18, F(2,1) = 7.29, p < .001, η² = 0.9, d = 0.63, and PSS-10 scores, F(2,1) = 18.30, p < .001, η² = 0.19, d = 0.97. Again, significant interactions were also found for MBLM versus CONTROL (BSI-18: F(1,1) = 9.91, p < .002, η² = 0.09, d = 0.63; PSS-10: F(1,1) = 33.68, p < .001, η² = 0.25, d = 1.15) and MBLM versus TAU (BSI-18: F(1,1) = 11.45, p < .001, η² = 0.10, d = 0.67; PSS-10: F(1,1) = 19.17, p < .001, η² = 0.17, d = 0.91). Further details and post hoc analyses are depicted in Tables 2 and 3.

3.3 | Phase II results

In analysis A, we contrasted patients who had received MBLM as a part of their treatment regime within 6 months with patients who had received any therapy but not MBLM (N = 81). Due to the different time courses of the therapies, we only compared T₀ with T₄. In the 6 months till follow-up, patients in the non-MBLM group
received more hours of therapy per week than the patients who received MBLM (MBLM: 2.1 h, SD = 1.2 vs. non-MBLM: 3.2 h, SD = 1.1; p < .001). Significant differences regarding BDI, BSI-18, and PSS-10 were found with medium to large effect sizes for time-by-group interaction (BDI: F(1,1) = 14.86, p < .001, η² = 0.09, d = 0.63; BSI-18: F(1,1) = 8.74, p < .001, η² = 0.05, d = 0.46; PSS-10: F(1,1) = 14.37, p < .001, η² = 0.08, d = 0.59) and large effect sizes for post hoc differences after 6 months (Table 4 and Figure 3).

In analysis (B), we measured the differences between a small subgroup of patients from the prior CONTROL group who were either randomized to TAU or TAU + MBLM (n = 27). In the 4 months between T2 and T3, patients in the TAU group received more hours of therapy per week than the patients in the TAU + MBLM group (TAU: 3.5 h, SD = 1.1 vs. TAU + MBLM: 2.0 h, SD = 0.6; p < .001). A significant difference was found only for PSS-10 with a large effect size for time (T2 vs. T3) by group interaction, F(1,1) = 9.09, p < .001, η² = .16, d = 0.87, as well as for post hoc difference after 6 months (Table 4 and Figure 3). Mean levels of depression at baseline of Phase II (T2) were lower in these groups compared to baseline of Phase I (mean BDI score of 21.53 vs. 25.36).

### TABLE 1 Demographic and clinical characteristics of study participants by group

| Label                  | N   | Missing | Levels                  | Groups       |
|------------------------|-----|---------|-------------------------|--------------|
|                        | Total |         |                        | MBLM | CONTROL | TAU |
| Age                    | 81   | 0       | Mean (SD)               | 49.1 (11.1) | 51.0 (12.7) | 45.0 (11.1) |
| Gender                 | 81   | 0       | Female                  | 21 (77.8)  | 21 (77.8)  | 23 (85.2)  |
|                        |      |         | Male                    | 6 (22.2)   | 6 (22.2)   | 4 (14.8)   |
| Marital status         | 81   | 0       | Unmarried               | 2 (7.4)    | 5 (18.5)   | 7 (25.9)   |
|                        |      |         | Divorced                | 4 (14.8)   | 5 (18.5)   | 3 (11.1)   |
|                        |      |         | Married                 | 20 (74.1)  | 14 (51.9)  | 17 (63.0)  |
|                        |      |         | Widowed                 | 1 (3.7)    | 3 (11.1)   | 0 (0.0)    |
| Current occupation     | 78   | 3       | Employed                | 13 (48.1)  | 15 (55.6)  | 12 (44.4)  |
|                        |      |         | Unemployed              | 6 (22.2)   | 3 (11.1)   | 8 (29.6)   |
|                        |      |         | Pension (disability)    | 5 (18.5)   | 6 (22.2)   | 6 (22.2)   |
|                        |      |         | Pension (old age)       | 1 (3.7)    | 3 (11.1)   | 0 (0.0)    |
| Denomination           | 78   | 3       | Catholic                | 1 (3.7)    | 0 (0.0)    | 0 (0.0)    |
|                        |      |         | Protestant              | 7 (25.9)   | 11 (40.7)  | 5 (18.5)   |
|                        |      |         | None                    | 17 (63.0)  | 14 (51.9)  | 21 (77.8)  |
|                        |      |         | Other                   | 1 (3.7)    | 0 (0.0)    | 1 (3.7)    |
|                        |      |         | (Missing)               | 1 (3.7)    | 2 (7.4)    | 0 (0.0)    |
| Cigarettes per day     | 81   | 0       | Mean (SD)               | 2.7 (6.0)  | 6.0 (7.7)  | 4.2 (6.8)  |
| Alcoholic bev. per week| 79   | 2       | Mean (SD)               | 1.1 (1.6)  | 1.8 (3.3)  | 1.2 (1.8)  |
| Depression type        | 81   | 0       | First episode           | 10 (37.0)  | 11 (40.7)  | 10 (37.0)  |
|                        |      |         | Recurrent episodes      | 17 (63.0)  | 16 (59.3)  | 17 (63.0)  |
| Years since the first episode | 81 | 0 | Mean (SD)               | 6.4 (7.9)  | 8.2 (8.1)  | 10.1 (8.5) |
| ACE >4                 | 74   | 7       | No                      | 19 (73.1)  | 19 (76.0)  | 17 (73.9)  |
|                        |      |         | Yes                     | 7 (26.9)   | 6 (24.0)   | 6 (26.1)   |
| Months of psychotherapy| 81   | 0       | Mean (SD)               | 25.1 (27.0) | 24.1 (29.1) | 30.4 (29.7) |

Abbreviations: ACE, adverse childhood events; CONTROL, drug continuation therapy; MBLM, Meditation-Based Lifestyle Modification; TAU, treatment as usual.
3.4 | Adverse events

The most common adverse events experienced by the participants during Phase I of the study are detailed in Table 5 (for a complete list, see Supporting Information Data and Table 2). No serious adverse events occurred. The pattern of adverse events differed between the MBLM and TAU groups. More participants of the TAU group expressed symptoms compared to the MBLM group (on average, 4.8 vs. 3.3 participants per symptom; p < .001). Also, the mean duration of adverse symptoms in the TAU group lasted longer than in the MBLM group (0.9 vs. 0.5 days, p < .001).

4 | DISCUSSION

Patients who participated in the MBLM program during the 6-month study period showed higher improvements in self-rated depressiveness, psychosomatic symptoms, and stress at 4 weeks, 8 weeks and 6 months, compared with the other group(s). The improvement in the primary outcome (self-rated depression levels) was of clinical relevance at both time points, both within-group and between-group comparisons. After 8 weeks, we saw a clinically important reduction of depression levels in the MBLM group of 49% versus 13% in the TAU group. This difference was still clearly visible after 6 months (47% vs. 19% reduction).

MBLM showed greater effects than body-oriented yoga (Brinsley et al., 2020; Cramer et al., 2017; Gong et al., 2015; Klatte et al., 2016) and meditative movement (Zou et al., 2018) compared to the existing literature. This is in line with previous findings that combined interventions incorporating multiple components usually outperform simpler yoga or meditation interventions (Matko et al., 2021). On the other hand, this study also showed larger effect sizes than found in a meta-analysis of MBCT-D (Lenz et al., 2016). We hypothesize that these can be attributed to additive and synergistic effects caused by the ethical components of yoga as implemented by MBLM. The ethical component of yoga, on which MBLM is based, is still strongly underrepresented in current research. But the benefit of ethics in mind–body interventions is currently discussed in the mindfulness literature and in theoretical models (Matko et al., 2021). Preliminary clinical studies also suggest additional benefits on well-being and prosocial behaviour (Andy Smith et al., 2011; Chen & Jordan, 2020).

With respect to MBLM, the additive effects of the ethics modules on postural yoga and meditation has already been shown in healthy participants (Matko et al., 2021). In a feasibility study with depressive patients and in the qualitative evaluation for a subgroup of patients in the present study, the ethical component of MBLM was identified as a key factor in individual empowerment and appreciation of one's

### Table 2

| Outcome | Group   | Baseline (T₀) | 4 weeks (T₁) | 8 weeks (T₂) | ΔM  | p     | η²  |
|---------|---------|---------------|--------------|--------------|-----|-------|-----|
| BDI-II  | CONTROL | 23.30 (8.40)  | 20.89 (8.14) | 21.59 (9.67) | -1.71 | <.001 | 0.113 |
|         | TAU     | 26.04 (8.12)  | 24.33 (7.78) | 22.70 (9.26) | -3.34 |       |     |
|         | MBLM    | 26.74 (9.46)  | 16.81 (10.65)| 13.59 (10.63)| -13.15|       |     |
| BSI-18  | CONTROL | 24.44 (11.99)| 23.04 (12.72)| -1.4  | <.001 | 0.086 |
|         | TAU     | 22.70 (11.52)| 21.74 (11.39)| -0.96 |       |       |
|         | MBLM    | 21.70 (11.71)| 12.48 (11.11)| -9.22 |       |       |
| PSS-10  | CONTROL | 27.52 (4.59) | 27.15 (4.58) | -0.37 | <.001 | 0.191 |
|         | TAU     | 28.26 (4.93) | 27.07 (6.41) | -1.19 |       |       |
|         | MBLM    | 28.04 (4.60) | 20.11 (5.34) | -7.93 |       |       |

Abbreviations: BDI-II, Beck Depression Inventory; BSI-18, Brief Symptom Index-18; ΔM, change of mean score between 8 weeks and baseline; η², partial squared eta for baseline-adjusted model; p, p value; PSS-10, Perceived Stress Scale-10.
Another difference between MBLM and TAU, which could explain the contrast in efficacy, was the dosage of therapy. Although patients in the TAU group received about 1 h more therapy per week, participants in the MBLM group practiced yoga, meditation, and the implementation of ethical principles at home for about 4 h per week. Repetition and steady practice are traditionally important in the yoga tradition (Carpenter, 2003) and it is known from meditation studies that the effect on mental health increases with ongoing practice (Sedlmeier et al., 2018).

Unexpectedly, there was no significant difference between TAU and CONTROL and the improvement of the TAU group after 8 weeks was relatively small. This may have led to an overestimation of the therapeutic effect of MBLM. We found some evidence for the cause in a qualitative comparison of TAU and MBLM patients, in which TAU patients reported feeling partly uncomfortable in the therapy because the therapy did not seem appropriate to them. MBLM patients, on the other hand, felt inspired and appropriately cared for in the MBLM program (Gross et al., 2021). Another reason might be the patients’ prior therapy experience. As shown in Table 1, almost two-thirds of the patients suffered from recurrent depression. This means that these patients had a history of previous experience with therapies from TAU. Thus, a lower expectation of efficacy of TAU may have played a role. Finally, patients in the TAU group reported

| TABLE 3 Post hoc analyses |
|---------------------------|
| **Outcome** | **Contrast** | **4 weeks (T1)** | **8 weeks (T2)** |
| |  | **DM** | **d** | **p** | **DM** | **d** | **p** |
| BDI-II | CONTROL versus TAU | -1.29 | -0.2098 | .886 | 1.04 | 0.1686 | .886 |
| | CONTROL versus MBLM | 6.78 | 1.0990 | <.001 | 10.70 | 1.7356 | <.001 |
| | TAU versus MBLM | 8.07 | 1.3088 | <.001 | 9.66 | 1.5670 | <.001 |
| BSI-18 | CONTROL versus TAU | -0.174 | -0.0276 | .919 |
| | CONTROL versus MBLM | 8.240 | 1.3036 | <.001 |
| | TAU versus MBLM | 8.414 | 1.3312 | <.001 |
| PSS-10 | CONTROL versus MBLM | 7.443 | 2.0897 | <.001 |
| | TAU versus MBLM | 6.789 | 1.9062 | <.001 |

**TABLE 4 Follow-up results for exploratory analyses**

(A) Phases I and II: MBLM versus non-MBLM; mean (SD), intention-to-treat population (N = 81)

| **Outcome** | **Group** | **Baseline (T0)** | **8 weeks (T2)** | **6 months (T3)** | **ΔM** | **p** | **η²** | **DM** | **d** | **p** |
|-------------|-----------|-------------------|------------------|------------------|-------|------|-------|-------|------|------|
| BDI | Without MBLM | 24.80 (8.71) | 20.80 (10.95) | -4.00 | <.001 | 0.09 | 8.00 | 1.18 | <.001 |
| | With MBLM | 25.90 (8.76) | 13.68 (10.36) | -12.22 |
| BSI-18 | Without MBLM | 23.88 (12.27) | 22.10 (14.27) | -1.78 | .004 | 0.05 | 7.56 | 0.98 | <.001 |
| | With MBLM | 22.05 (11.09) | 13.10 (10.14) | -8.95 |
| PSS-10 | Without MBLM | 28.25 (4.93) | 25.85 (6.59) | -2.40 | <.001 | 0.08 | 4.82 | 1.22 | <.001 |
| | With MBLM | 27.63 (4.43) | 20.54 (5.64) | -7.09 |

(B) Phase II: TAU versus MBLM + TAU; mean (SD), intention-to-treat population (N = 27)

| **Outcome** | **Group** | **Baseline (T0)** | **8 weeks (T2)** | **6 months (T3)** | **ΔM** | **p** | **η²** | **DM** | **d** | **p** |
|-------------|-----------|-------------------|------------------|------------------|-------|------|-------|-------|------|------|
| BDI | TAU | 21.76 (10.42) | 19.88 (11.00) | -1.88 | .257 | 0.03 | 3.89 | 0.66 | .105 |
| | TAU + MBLM | 21.30 (8.77) | 15.60 (9.98) | -5.70 |
| BSI-18 | TAU | 23.59 (14.86) | 24.18 (15.53) | 0.59 | .084 | 0.06 | 5.28 | 1.01 | .015 |
| | TAU + MBLM | 22.10 (8.58) | 17.50 (8.59) | -4.60 |
| PSS-10 | TAU | 26.88 (5.16) | 26.47 (4.50) | -0.41 | .004 | 0.16 | 4.27 | 1.65 | <.001 |
| | TAU + MBLM | 27.60 (3.60) | 22.80 (4.83) | -4.80 |

Abbreviations: BDI-II, Beck Depression Inventory-II; BSI-18, Brief Symptom Index-18; d, Cohen's d; ΔM, change of mean score between 8 weeks and baseline; DM, estimated difference of means at T3; η², partial squared eta for baseline adjusted model; p, p value; PSS-10, Perceived Stress Scale.

own strengths (Bringmann et al., 2021a; Bringmann et al., 2021). Another difference between MBLM and TAU, which could explain the contrast in efficacy, was the dosage of therapy. Although patients in the TAU group received about 1 h more therapy per week, participants in the MBLM group practiced yoga, meditation, and the implementation of ethical principles at home for about 4 h per week. Repetition and steady practice are traditionally important in the yoga tradition (Carpenter, 2003) and it is known from meditation studies that the effect on mental health increases with ongoing practice (Sedlmeier et al., 2018).

Unexpectedly, there was no significant difference between TAU and CONTROL and the improvement of the TAU group after 8 weeks
more and longer-lasting side effects, which may also have had a negative impact on treatment outcomes.

Our study was the first trial to evaluate the efficacy of the novel MBLM program in depression. The randomized-controlled design and low drop-out rates allowed a meaningful and reliable evaluation. However, some limitations need to be addressed. The study was designed specifically for depressed patients with an interest in yoga or meditation. Therefore, the results cannot be generally extended to depressed outpatients. Mind–body programs of a different type of cultural adaptations might be important for other populations. From a methodological point of view, the sole use of client-rated questionnaires is problematic due to introspective bias (which, however, can lead to both aggravation and amelioration of symptoms). Also, the trial was conducted in one center by the developers of the MBLM program, possibly inflating effect sizes due to allegiance effects. The aggregation of the three initial groups to two groups after 8 weeks was problematic for the long-term 6-month follow-up assessment. Since more patients from the previous CONTROL group were randomized to the group receiving TAU, the effects of TAU may have been underestimated at 6 months follow-up. Also, expectations of the MBLM program as a novel therapy may have positively biased the effects. Furthermore, it was not monitored whether patients in the TAU group regularly performed exercises at home (e.g., sports or relaxation techniques they had learned in therapy). This would, however, weaken the aforementioned argument of a higher therapeutic dose of MBLM and support greater efficacy of MBLM. Finally, given limited resources, only self-assessment questionnaires were used for the quantitative evaluation. This may have led to an underestimation of treatment effects in the TAU group, based on the lower satisfaction of TAU participants discussed earlier.

The positive study results of MBLM support the need for further research and clinical application of traditional whole system medicine in general, as its potential is not yet being fully realized among most

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**TABLE 5** Top 10 adverse events after 8 weeks (T2)

| Symptom                                      | d  | n  |
|----------------------------------------------|----|----|
| **MBLM**                                    |    |    |
| Recollection of bad experience               | 1.3| 8  |
| Feeling of exhaustion                        | 1.5| 5  |
| Need for continuous meditation               | 0.2| 4  |
| Palpitation                                  | 0.2| 4  |
| Greater self-criticism                       | 1.4| 3  |
| Inner tension                                | 1.3| 3  |
| Feeling of illness                           | 0.9| 3  |
| Difficulty in feeling comfortable in the world| 0.9| 3  |
| Tinnitus                                     | 0.7| 3  |
| Hypersensitivity/rejection of urban life     | 0.7| 3  |
| **TAU**                                      |    |    |
| Feeling of exhaustion                        | 2.8| 10 |
| Inner tension                                | 3.6| 6  |
| More fear/anxiety/depression                 | 2.3| 6  |
| Headache                                     | 1.9| 6  |
| Recollection of bad experience               | 0.9| 5  |
| Palpitation                                  | 1.1| 5  |
| Dizziness                                    | 1.9| 5  |
| Diarrhea                                     | 0.8| 5  |
| Muscular pain                                | 1.5| 4  |
| Tinnitus                                     | 1.7| 3  |

Abbreviations: d, average number of days the symptom was perceived during the 8 weeks of treatment; n, number of participants stating the adverse event. Items are sorted by n in descending order.
integrative practices (Mills et al., 2017). MBLM is an example of a more holistic approach based on classical yoga and ayurvedic medicine, which blends into recent developments of second-generation mind–body intervention and fourth-wave psychotherapy that are resource-oriented, strengthen self-efficacy, and are directed toward flourishing (Garcia-Toro & Aguirre, 2007; Hatala, 2013). Whole system approaches may have the potential to address the multifactorial conditions of depression in a more comprehensive way than conventional therapies. Specifically, the ethical and philosophical aspects of underlying traditions like yoga or other meditative practices are underrepresented in research of mind–body interventions and should be further investigated to test their therapeutic use. Follow-up studies should replicate the results of the present study or implement MBLM in other populations and conditions.

Overall, the results support the use of MBLM in depressed patients. Further high-quality controlled clinical studies including qualitative research are needed to investigate the specific and unspecific effects of the MBLM program in depression and other medical conditions. Furthermore, the effects of MBLM support the idea that research in mind–body medicine should also address the traditional background of interventions and examine their contextual factors for their potential therapeutic effects. In addition to efficacy studies, more theory-driven fundamental research is also required to advance the field of research adequately.

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CONFLICTS OF INTEREST
The authors declare no conflicts of interest.

ETHICS STATEMENT
Ethics approval was granted by the Ethics Review Board of the University of Chemnitz University of Technology (V-276-15-PS-MBLM-D-14062018).

AUTHOR CONTRIBUTIONS
Holger C. Bringmann conceptualized and designed the study under the supervision of Andreas Michalsen and Peter Sedlmeier. Stefan Brunnhuber supervised ethical and regulatory guidelines on the trial site. Holger C. Bringmann, Peter Sedlmeier, Andreas Michalsen, Michael Jeitler, Christian S. Kessler, and Benno Brinkhaus contributed to statistical analysis and reporting. Holger C. Bringmann wrote the first draft of the manuscript. All authors worked on the final version of the manuscript.

DATA AVAILABILITY STATEMENT
The data that support the findings of this study are available from the corresponding author upon reasonable request.

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