



Meditation Based Lifestyle Modification (MBLM) in outpatients with mild to moderate depression: A mixed-methods feasibility study

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ABSTRACT

Background: Integrative mental health care can be applied to treat depression with a person-centered, lifestyle-modifying, and more salutogenic approach to mental health and human flourishing. In this article, we report on the feasibility and acceptability of a new mind-body program, Meditation Based Lifestyle Modification (MBLM), in outpatients with mild or moderate depression.

Methods: This is a single-arm mixed-methods feasibility study of $n = 25$ outpatients in psychiatric care. Depressive symptoms, scores for mindfulness, aspects of spirituality, and eudaemonic well-being based on yoga philosophy were assessed at baseline and at the end of the intervention. Adherence was monitored and face-to-face interviews were held after the program to explore the acceptability and feasibility of MBLM.

Results: Twenty patients (75 %) completed at least six sessions of the course. Adherence was 87.5 % of allocated sessions. In qualitative analysis, more than half of the participants experienced novelty and inspiration through practicing the ethical aspects of yoga (e.g., nonviolence, truthfulness, etc.). Almost all participants experienced a decrease in emotional distress. Virtually all participants reported more self-confidence and self-acceptance. In quantitative analysis, participants reported a clinically important decrease in depressive symptoms of 39.23 % ($p = .002$), eudaemonic well-being increased significantly in a range of related scales and scores for mindfulness increased ($p < .001$).

Conclusion: MBLM is a highly acceptable and feasible program for outpatients with mild to moderate depression. This comprehensive, lifestyle-modifying approach is highly relevant to preventing and treating mental illness, and treating psychic comorbidities in patients with chronic somatic illness.

1. Introduction

According to the World Health Organization, more than 300 million people suffer from depression worldwide, leading to more years lived with disability (YLD) than any other condition—mental or physical—around the globe.¹ Since the 1970s, pharmacological treatment for depression has expanded significantly. In the United States from 1999 to 2014, the percentage of people using antidepressants increased by 64 %. Between 2011 and 2014, about one in eight Americans aged 12 and over reported taking antidepressants in the previous month and one-fourth of all people who took antidepressants in the past month reported having

taken them for 10 years or more.² Still, global prevalence rates have not dropped³ and the age-standardized incidence rate of depression is increasing in regions with a high sociodemographic index.⁴ In recent discussions, antidepressant use has been subjected to increasing criticism, especially regarding treating mild to moderate depression. It has been argued that the benefits of antidepressant medication seem to be of questionable clinical relevance for the average patient with depressive disorder,⁵ while clinically relevant risks of both serious and non-serious adverse events are associated with use of and withdrawal from antidepressants.⁶ New approaches are needed to improve management and quality of treatment. Integrative mental health care offers potential

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solutions with a person-centered, lifestyle-modifying, and more salutogenic approach. It combines somatic, psychosocial, and spiritual perspectives from both evidence-based conventional medicine and complementary medicine.⁷ Within this, yoga and meditation are among the most widely used complementary health approaches. Meditation Based Lifestyle Modification (MBLM) is a new, complex mind-body intervention for integrative mental health care.⁸ Similarly to second-generation mindfulness-based interventions,⁹ it is overtly spiritual in nature, combines a range of meditative practices, and features ethics as a key component. Based on classical yoga, it covers three domains: 1. *Ethical Living* based on yoga virtue ethics, 2. *Healthy Lifestyle* based on body-oriented yoga, and 3. *Mantra Meditation* based on meditation with spiritual mantras.

In this article, we report on the feasibility and acceptability of MBLM in outpatients with mild or moderate depression. The rationale behind the therapeutic components of MBLM in terms of their potential antidepressant effect is complex. Multiple, heterogeneous processes are contribute to the pathogenesis of depression: biological, psychological, social, and spiritual factors, including reciprocal relationships with others. Disturbed circadian rhythm, demanding life events, and stress reactivation modify the transmission of various neurotransmitters and the hypothalamic-pituitary-adrenal axis to contribute to depression.¹⁰ Today, there is strong evidence that meditation has a positive impact on a whole range of psychological and physiological variables, for both healthy people^{11,12} and patients^{13,14} who practice meditation. The majority of studies on the antidepressant effects of mantra meditation in healthy populations reported positive results¹⁵ and exceeded the effects of mere relaxation techniques.¹¹ Looking at different layers of mechanisms behind it, pilot studies suggest that meditation may down-regulate epigenetic pathways related with depression.¹⁶ On a neurophysiological level, meditation has been shown to improve both local and systemic biomarkers of neuroplasticity,¹⁷ to reduce stress-related autonomic and endocrine responses, and to increase neural activity in brain regions of affect regulation and attention control.¹⁸ On a psychological level, mantra meditation is usually seen as an attentional technique that fosters self-regulation and the ability to initiate and sustain meta-awareness.¹⁹ This may be supportive in releasing cognitive or emotional patterns of distress like rumination, negative cognition, and anxiety, which are common in depression. In more experienced practitioners, an emphasis on effortless and increasingly subtle repetition of the mantra, leading into silence of the mind, may have additional effects on outcomes related to well-being.²⁰ Finally, a spiritual background of meditation could be inherent to appreciating the full value of meditation practice²¹ and can lead to stronger effects.²² The *Healthy Lifestyle* domain of MBLM mainly physical yoga postures, breath control and selected lifestyle recommendations according to Ayurvedic medicine. Reviews and meta-analyses provide clinical evidence that body-oriented yoga can be considered as an effective treatment option for patients with depressive disorders.^{23,24} Proposed physiological mechanisms emphasize mood-enhancing properties related to the inhibitory effects of yoga on physiological stress and inflammation via modulation of the autonomous nervous system, the activity of stress-related hormones and neurotransmitters, and epigenetic mechanisms.^{25,26} On a psychological level, positive effects on reappraisal, self-regulating coping behaviors, less rumination, mindfulness, feelings of connectedness, and body awareness have been discussed.^{27,28} Some of these mechanisms have been confirmed empirically and are largely coherent with theory.²⁹ The *Ethical Living* domain of MBLM is a psychotherapeutic intervention that combines group sessions with individual home practices based on the virtue ethics of yoga philosophy. Psychotherapy in general is effective for adult patients diagnosed with depression³⁰ and there is a noticeable revival of interest in the application of virtue ethics to psychotherapeutic practice.³¹ Similarly to the emerging field of positive psychology, MBLM follows a eudaemonic approach to mental health and well-being. Virtue-based treatments and psychotherapies were found to be effective both in promoting eudaimonia and in addressing depression.^{32,33} As

with MBLM, they can be combined with problem-oriented approaches to reduce the symptoms of depression.³² From an integrated perspective, whole-model frameworks of the mechanisms underlying classical yoga and MBLM have been proposed by Gard et al.³⁴ and Sullivan et al.^{35,36} In these models, the practice of classical yoga engages multicomponent top-down and bottom-up processes on physiological, cognitive, and behavioral levels that facilitate self-regulation, embodiment, and resilience.

2. Methods

2.1. Study design

This single-arm mixed-methods feasibility study was conducted with a convenience sample of patients being treated for depression at the outpatient department of a psychiatric hospital in a rural area of Saxony, Germany. The study was a pilot prior to a larger randomized controlled trial registered at clinicaltrials.gov (NCT03652220). All participant visits and interventions occurred on the hospital premises. All participants completed informed consent forms prior to the study. All methods used in this study were approved by the Ethics Review Board of University of Chemnitz University of Technology (V-276-15-PS-MBLM-D-14062018).

2.2. Participants

Patients with a current diagnosis of a mild or moderate depressive episode according to WHO ICD-10 criteria and interest in yoga or meditation were referred by their consultant psychiatrists for screening. ICD-10 uses an agreed list of ten depressive symptoms. At least one of the depressive key symptoms (persistent sadness or low mood; loss of interests or pleasure; fatigue or low energy) needs to be present most days, most of the time for at least 2 weeks. Additionally, associated symptoms are defined as disturbed sleep; poor concentration or indecisiveness; low self-confidence; poor or increased appetite; suicidal thoughts or acts; agitation or slowing of movements; guilt or self-blame. Key and associate symptoms then define the degree of depression (mild depression: four symptoms); moderate depression: five to six symptoms. Symptoms should be present for a month or more and every symptom should be present for most of every day. Further inclusion criteria were: over 18 years of age; physical ability to perform simple yoga postures and to sit for 20 min in a chair for meditation; motivation to attend weekly classes and perform daily exercises. Exclusion criteria were: current psychotic symptoms, compulsive disorders, suicidal tendencies, organic brain disorders, and severe somatic or psychiatric multi-morbidity.

2.3. The intervention: meditation based lifestyle modification as add-on therapy

Similar to the well-established MBSR program,³⁷ MBLM consists of eight consecutive, weekly group sessions of 180 min each, and 45 min of recommended, daily home exercises. The intervention is composed of three domains: *Ethical Living*, *Healthy Lifestyle*, and *Mantra Meditation* (see Fig. 1). The *Ethical Living* domain conveys major aspects of yoga practice concerning ethical restraints (nonviolence, truthfulness, non-stealing, non-excess, and non-greed) and observances (purity, contentment, and transcendence). Participants receive written material for each week's topic and the therapist introduces examples from everyday life (e.g., for truthfulness, different forms of untruth like "making something up" or "attributing something falsely to somebody" are presented and their motivational background is discussed). Participants also receive a worksheet with suggested mindful-living exercises related to the week's topic to deepen understanding (e.g., for truthfulness, these are exercises such as "today I will try to be truthful (and non-violent) in my communication rather than nice" or "today, I will do my work in a way that I do not have to go back to correct myself"). In the

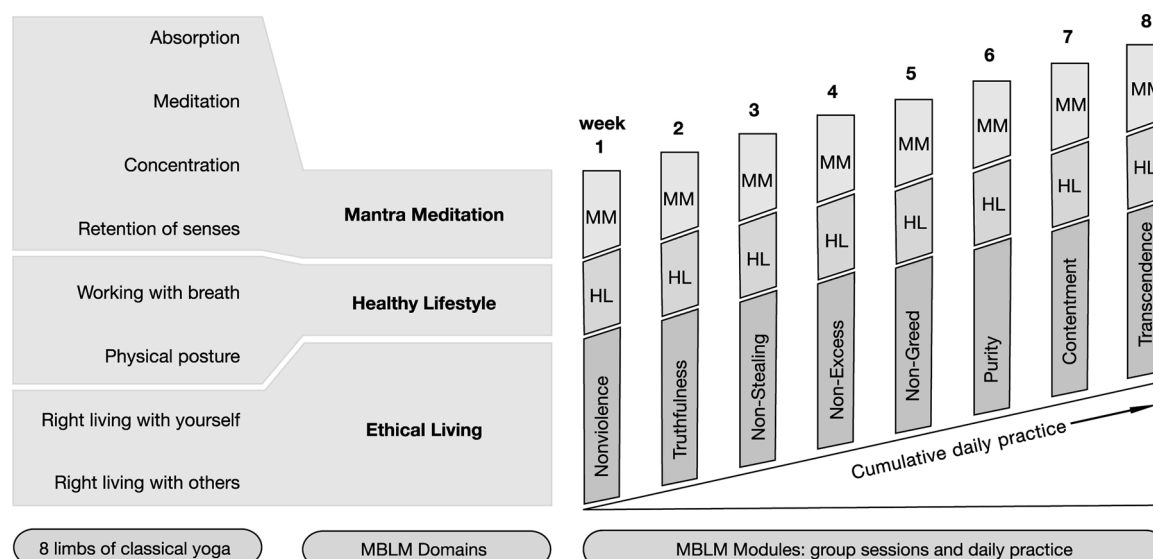


Fig. 1. Projection of the 8-limbed path of classical yoga (left side) onto the Meditation Based Lifestyle Modification program (right side). Weekly sessions are accompanied by a daily routine involving all domains of MBLM.

Healthy Lifestyle domain, participants receive individualized dietary and lifestyle advice based on basic Ayurvedic recommendations prior to the course. During the group sessions, the therapist models *Ujjayi* breathing³⁴ and a fixed sequence of gentle yoga exercises suitable for depression and anxiety³⁸ that can be practiced safely at home without further guidance; the week's topic (e.g., truthfulness) is emphasized and enlivened while doing the exercises. The sequence ends with a deep relaxation exercise in a lying position. The third part of each group session is the *Mantra Meditation* domain, where participants are encouraged to sit in an upright posture on a chair or a meditation cushion and silently recite their mantra, which they have chosen and learned in an introductory session prior to the course. For a detailed description of MBLM in general, see Bringmann et al. (2020). For a detailed description of MBLM-D, the adaptation of MBLM for patients with depression which has been used in this study, see Supplement 1. In this study, MBLM was administered as an add-on therapy while current therapies were continued (Table 1).

2.4. Qualitative data

Patients who had completed the 8-week program were contacted to

Table 1
Sociodemographic and clinical characteristics of n = 25 participants.

	n	%
Female	22	88.0
Married	19	76.0
Employed	12	48.0
Religious affiliation	4	16.0
Age		
35 - 45	8	32.0
46 - 55	7	28.0
56 - 65	10	40.0
Type of depression		
Currently mild episode	4	16.0
Currently moderate episode	21	84.0
Recurrent episodes	12	48.0
Continued therapy		
Antidepressants	14	56.0
Psychotherapy	16	64.0
Previous therapy		
Psychotherapy	19	76.0
Mantra meditation	4	16.0
Body-oriented yoga	12	48.0

arrange a face-to-face interview within two months of finishing the MBLM course. The interviews started with open questions about the MBLM course to elicit contextual insights about the individual's overall experience of participation. They then followed a semi-structured interview guide with open questions on acceptance, feasibility and subjective effects regarding the three domains of MBLM, and on the differences participants experienced between the group setting and their practice at home. During the qualitative interviews, core messages were immediately paraphrased and important verbatim statements were transcribed simultaneously (by NB). The transcription was reviewed by a member of the research team (HCB) to remove any information that could be used to identify participants, who were given the opportunity to review their transcripts.

2.5. Quantitative data

Each participant was asked to complete a number of validated questionnaires at baseline and after 8 weeks. The client satisfaction questionnaire and the questionnaire to record adverse events were administered after 8 weeks only.

2.5.1. Feasibility and acceptability

Feasibility and acceptability were evaluated via accrual, retention, and adherence rates quantified in the enrollment and session logs. Our target accrual rate was set at 1.5 participants per week over 4 months, to achieve a total sample size of 25 participants. Retention rate was defined as the percentage of allocated participants completing at least 6 weeks of lessons and completing the 8-week study measures. Adherence rate was defined as the percentage of allocated sessions attended by all participants. Participants were asked to keep a diary of their daily practice: each week, they received a worksheet with thematic mindful-living exercises. They could use the worksheet to make diary entries to record their personal experiences, and to record the duration of their yoga and meditation practice each day. Satisfaction with the course was assessed with the German adaptation of the 8-item *Client Satisfaction Questionnaire CSQ-8*,³⁹ which is a brief global measure of client satisfaction. General satisfaction with different aspects of the received treatment is assessed with scores ranging from 8 (low satisfaction) to 32 (highest satisfaction).

2.5.2. Adverse events

To track adverse events, a list of common problems related to yoga

and meditation practice^{40,41} was presented following the personal interview after course completion. The participants were asked to indicate whether the issues occurred during home practice or in the group, the severity of symptoms, and the time period during which they had these problems. In addition, respondents were asked to assess whether or not the adverse events were related to a particular component of the MBLM course.

2.5.3. Depression

To measure depression severity, we used the well-established *Beck Depression Inventory BDI-II*.⁴² Scores are clustered as 0–13: minimal depression; 14–19: mild depression; 20–28: moderate depression; and 29–63: severe depression.

2.5.4. Mindfulness

The one-dimensional *Freiburg Mindfulness Inventory FMI*⁴³ assesses nonjudgmental awareness of present moment experiences. The questionnaire uses a 4-point Likert scale. Scores range from 14 to 56, a higher score indicating a higher degree of mindfulness.

2.5.5. Spirituality

The *Aspects of Spirituality ASP* questionnaire⁴⁴ was developed to measure different aspects of spirituality beyond conventional conceptual boundaries in secular societies. The items of the ASP are scored on a 5-point Likert scale and differentiate 4 factors: religious orientation; search for insight/wisdom; conscious interactions; and transcendence conviction. Scores range from 0 to 100 % on each scale, and individuals not regarding themselves as religious or spiritual should have lower scores for all scales.

2.5.6. Eudaimonic well-being

The *Tri-Guna Scales TGS*⁴⁵ measure three components of an ancient Indian model of well-being — the three *gunas*, or qualities/tendencies⁴⁶: *sattva* (goodness, constructiveness, harmony), *rajas* (passion, activity, confusion) and *tamas* (darkness, destruction, chaos). The items of the TGS are scored on a 5-point Likert scale and differentiate 8 factors: thoughts, emotions, motives, will power, level of activity, working style, social behavior, health behavior, and spiritual orientation. High scores on the *sattva* scales and lower scores on the *tamas/rajas* scales correlate with better mental and physical well-being and a lower level of stress.

2.6. Data analysis

The qualitative data analysis software *f4analyse* was used to store and analyze the transcripts. A thematic analysis was then conducted.⁴⁷ Patterns and topics within the qualitative data were identified in the following process (HCB and NB): familiarization with the data, generating codes in a recursive process, searching for themes, inter-personally reviewing and refining themes, and defining final themes. Consistency of thematic analysis was checked independently by a third member of the research team (MJ). For reporting, statements have been literally translated into English. We used R⁴⁸ for all our quantitative analyses. Missing data was imputed using Multivariate Imputations by Chained Equations (MICE) algorithms.⁴⁹ Data from the BDI, FFA, ASP, and TGS variables were analyzed using paired sample *t*-tests comparing differences between baseline and week 8. Daily practice was analyzed and visualized using descriptive statistics. The duration of yoga and meditation practice was reported as protocolled in participant diaries. The daily focus on ethical living was marked as “done” if participants wrote a meaningful comment on the exercise in their diary. Because of the pilot nature of the study and exploratory analysis, the sample size was not calculated. The aim was to enroll *n* = 25 patients, approaching a common sample size in this field⁵⁰ and guidelines on qualitative research implementing thematic analysis recommend a sample size between *n* = 20 and *n* = 30.⁵¹

3. Results

3.1. Recruitment

During a recruitment period of 21 weeks, 33 patients diagnosed with mild or moderate depression were referred for further screening by their consultant psychiatrist if they indicated a general interest in yoga and meditation. Of these, 25 (75.76 %) participants were included in the study. Six patients (18.18 %) declined to participate after hearing details of the course. Two patients (6.06 %) had to be excluded as their health conditions did not match the inclusion criteria. The mean accrual rate was 1.3 included participants per week, close to the target of 1.5. Participants who attended to less than six of the eight course modules (*n* = 5) were marked as drop-outs and excluded from further analysis (see Fig. 2).

3.2. Sample characteristics

Sociodemographic and clinical details of the *n* = 25 participants are listed in Table 1.

3.3. Retention, adherence and client satisfaction

Mean retention of allocated group sessions was 87.5 % (7 of 8, range = 1–8), suggesting that most participants were inspired to continue participating. Reasons for missing group sessions were severe medical conditions not associated with the course (*n* = 4), family holiday (*n* = 2), illness (*n* = 2), and work commitment (*n* = 1). Patients engaged in most of the proposed mindful-living exercises related to the *Ethical Living* domain (on average 85.1 %). Exercises associated with the ethical observances (*yamas*: nonviolence, truthfulness, non-stealing, non-excess, and non-greed) were followed more often than those associated to ethical constraints (*niyamas*: purity, contentment, and transcendence); as depicted in Fig. 3A (91.3 % vs. 74.8 %, *p* < .001). The duration of daily yoga and meditation practice was calculated by adding the recorded practice times in group sessions and at home. Practice remained steady over the course and was 41.12 min/day (21.3 min/day of yoga and 19.9 min/day of mantra meditation). See Fig. 3B–C for illustration of these results. Client satisfaction at the end of the course as reported in the CSQ-8 was very high (*M* = 29.57, *SD* = 1.91).

3.4. Adverse events

The most common adverse events experienced by the participants during the 8-week course are detailed in Table 2. Adverse events were reported by 30.80 % of the patients, with an average duration of 6.08 days of medium symptom severity. More than half of participants reported transient inner tension, recollection of bad experiences, and feeling exhausted; these symptoms were associated with or aggravated by participating in the *Ethical Living* modules. During meditation, participants experienced similar patterns of adverse events, but to a much lesser degree (around 25 %). The *Healthy Lifestyle* modules resulted in the least adverse events, most of which were transient joint pain and feeling exhausted.

3.5. Qualitative results

Of the 20 patients who completed the MBLM course, 19 could be interviewed. Despite repeated efforts, one patient could not be reached by phone. The interviews lasted between 30 and 60 min. Thematic analysis resulted in four main themes addressed by the participants: supportive experiences during practice, challenges, relief of symptoms, and empowerment.

3.5.1. Supportive experiences during practice

More than half of the participants emphasized the novelty and

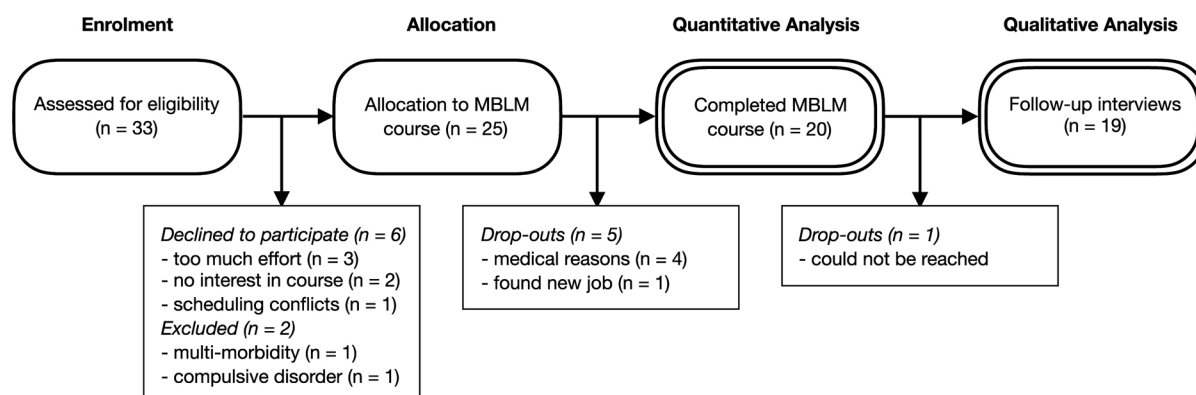


Fig. 2. Participant flow.

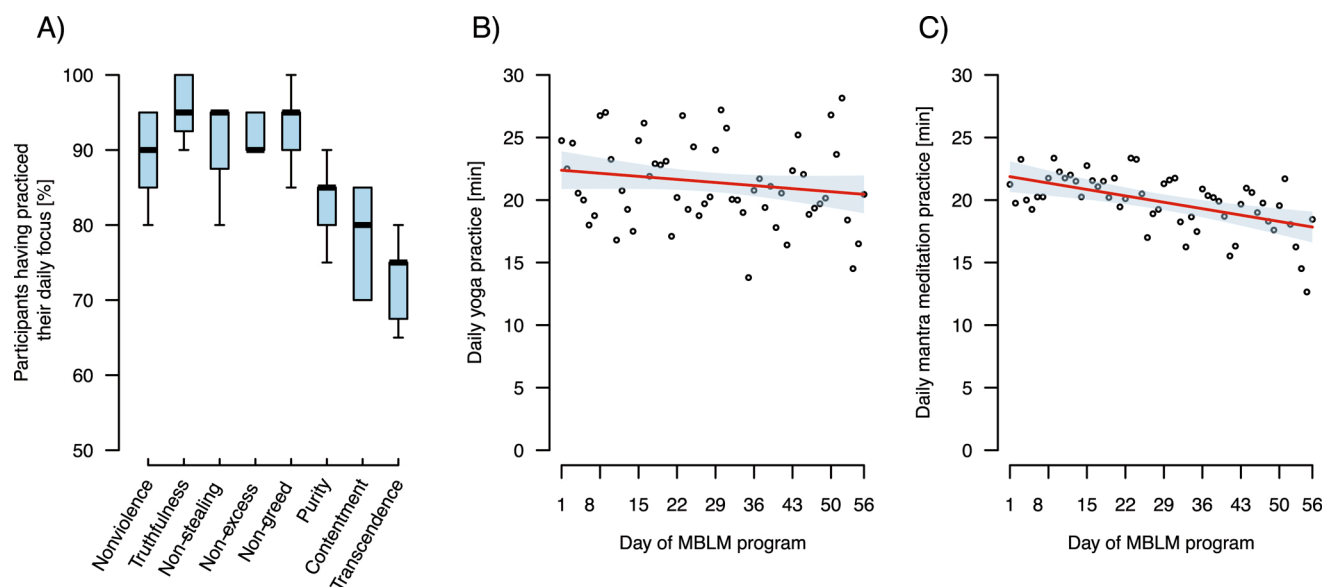


Fig. 3. A) Box-plot of participant's engagement for the main topic of each module (%). Lower and upper box boundaries 25th and 75th percentiles, respectively; line inside box median; lower and upper error lines minimum and maximum, respectively. B) Scatterplots of mean daily yoga practice and C) mean daily meditation practice (min). Overlay line linear regression model, shaded area 95 %-confidence band.

resulting inspiration that they experienced by studying and practicing the ethical aspects of yoga. The topics were described as interesting, motivating, and thought-provoking.

"The meaning of words became clearer, e.g., on the topics of truthfulness, nonviolence, non-stealing—what belongs to it, e.g., subtle violence, subtle lies, and how to steal something from yourself. Often there was an 'aha' effect." (woman, aged 59 years)

"... they started something in me, they made me think—sometimes something did 'click' and there was something where I said, 'I want to adopt and change that.' The course gave me drive. I woke up through the course ..." (woman, aged 57 years)

All interviewees expressed their felt support in their learning process through the group sessions. Sharing experiences related to the daily mindful-living exercises was reported to be interesting, important, and helpful.

"I could always get something for myself. It was important to hear from the others and to experience the others (how they dealt with the topics). I found that very authentic. Everyone spoke very honestly about themselves. That made me feel good." (woman, aged 55)

The group experience also reinforced the body-oriented yoga exercises. Participants communicated that the exercises seemed easier in the group and they were more motivated to test their own limits. This resulted in a higher experiential intensity, which was also mentioned to be associated with specific instructions given by the yoga instructor.

"Yoga was something else in the group, it spurred me on even more." (woman, aged 57)

"With guidance, I could do better with yoga." (woman, aged 50 years)

Similarly, patients also benefited from group setting during meditation. Most, but not all participants preferred meditation in a group, saying that the silent, energetic atmosphere in the room and the common ritual made meditation easier and deeper. These experiences were also a motivating factor for practice at home.

"I felt well, protected in the community—the flow of energy, the atmosphere in the room was beautiful. Meditation is always easier for me in the group." (woman, aged 59)

"... more intense than meditating alone. I came in faster and sometimes deeper into the relaxation." (woman, aged 55)

Table 2

Top 10 adverse events sorted by the average duration of symptoms.

	d	L	M	S	n	LE	HL	MM	NO
Inner Tension	13.1	0.7	12.4	0.0	11	10	0	2	5
Recollection of bad experience	11.7	0.8	8.4	2.4	14	13	0	2	6
Feeling of exhaustion	11.2	0.8	10.2	0.3	12	10	5	3	4
Difficulty in feeling comfortable in the world	8.0	0.0	8.0	0.0	5	4	1	3	3
Greater self-criticism	7.2	2.0	5.2	0.0	5	5	1	1	2
Joint pain	6.8	2.9	1.1	2.8	5	0	5	1	2
Greater emotional pain	6.3	0.8	3.4	2.2	9	7	0	2	4
Gastric and abdominal pain	6.2	0.1	3.6	2.4	6	6	0	1	4
Twitching in a certain body part	6.0	0.0	3.2	2.8	4	2	0	1	2
Scary thoughts	5.7	0.4	5.2	0.0	6	4	0	0	3

Note. Table shows the average duration of each event based on all participants in days (d), grouped by mild (L), moderate (M) and severe (S) symptoms. Participants reporting a symptom (n) also declared if they associated the symptom to the Life Ethics (LE), the Healthy Lifestyle (HL), the Mantra Meditation (MM) domain, or not (NO). Multiple choices were permitted.

3.5.2. Challenges

A challenging aspect of the course was the virtue ethics. Group discussions were sometimes experienced as emotionally disturbing and stress-provoking. Reasons for this were actualization of personal biographic content, difficulties in setting and protecting one's own boundaries, and difficulties in opening up to the group. Occasionally, the discussions led to inner turmoil which impaired the ability to meditate.

"I have been very busy with the topics. It worked a lot in me and 'stressed' me accordingly." (woman, aged 45)

"I have often been in an interplay of emotions—hearing the experiences of others, the excitement of expressing myself." (woman, aged 59)

"I experienced the group sessions as intense and exhausting with regard to the topics discussed." (woman, aged 55)

"By dealing with the topics it was sometimes more difficult for me to find my way into meditation, I felt emotionally upset." (woman, aged 45)

About half of the participants mentioned that it was difficult to integrate the contents and exercises of the course into daily life and establish a regular practice. Finding time and space in a busy life was sometimes a challenge. Individual participants also felt pressured to do the exercises or experienced them as a duty. Some also named problems of acceptance within their families. As a rule, these problems occurred especially in the first weeks and drifted into the background over time.

"... but with family, children, work, and everyday life it was almost too much to reconcile. I was actually overwhelmed." (woman, aged 45)

"At the beginning of the course, I sometimes put myself under pressure by setting an alarm, or because I did not have the right place to practice." (woman, aged 56)

3.5.3. Relief of symptoms

Almost all participants experienced reduction in emotional distress by participating in the course. In particular, the physical yoga exercises and meditation were experienced as enjoyable, pleasant, and soothing. Repeatedly, participants mentioned feeling more serenity, peace, and contentment as a result.

"Meditation makes me calmer, more balanced and less irritable." (man, aged 59 years)

"I have become calmer and more relaxed in the process of change." (woman, aged 57 years)

The majority of participants reported improved body awareness and physical well-being, especially in the context of physical yoga exercises. Some experienced that the movements in conjunction with the ethical aspects of yoga increased body awareness.

"After the lesson, I've been soothed, more in the body, more relaxed, and freer." (woman, aged 62 years)

"One was completely in one's body." (female, aged 56 years)

Several participants said that mantra meditation reduced disturbing thoughts and rumination during the practice. Individual participants also addressed states of deeper silence.

"The thoughts were much less." (woman, aged 62)

"When I succeeded in meditation, I really managed to let go of thoughts and I became calmer inside." (woman, aged 50)

"I was fascinated to have that silence in my head. At some point, the mantra went away. When the silence started, I felt like weightless. After the meditation, I felt always clearer in the head." (woman, aged 37)

3.5.4. Empowerment

Empowerment as a process of becoming stronger, being more confident, and gaining abilities was a topic that virtually all participants raised in one way or the other. They reported more self-confidence and self-acceptance, which was expressed by being more direct and courageous, more self-reliant, and by having a more positive self-image.

"The biggest insight in the course was for me: I do not have to pretend to others. I am as I am." (woman, aged 56)

"My self-love has grown. I can also accept the love of others more. People who like me like me the way I am ... I pay more attention to myself. I say more what I want or do not want anymore." (woman, aged 56)

Participants repeatedly referred to an increased ability to self-regulate. This was most commonly mentioned in relation to applying mantra meditation in everyday situations to control negative thinking and emotional distress. The ethical aspects of yoga also made it possible to handle difficult situations in a more satisfying way.

"I have learned more thought control. Through the mantra one can come back and a space opens—I can withdraw from the carousel of thoughts and calmness arises." (woman, aged 44)

"However, with the knowledge of the course and the ethical recommendations, I could handle the situation differently." (woman, aged 59)

Participation in the MBLM course also led to positive interpersonal exchanges. Participants reported benefiting from more honest and direct communication with other people, blaming others less, and finding an overall more relaxed attitude toward others.

"I have stopped judging myself so much and I also blame others less, I am more forgiving ... now I share more openly. I say frankly when I feel bad. Being honest with myself and others was a relief." (woman, aged 59)

"It helped me let go and leave others as they are. I did not want to change the others anymore. Other people lead a different life." (woman, aged 56)

Many participants also communicated a feeling of inner growth. Different facets were mentioned in this sub-theme, such as broadening ones horizons, more clarity and better acceptance for the flow of life.

"I began to see my environment differently and could think outside the box. The life ethics have broadened my horizons." (woman, aged 60)

"I started to ask: what am I in the world for? What am I good at? Much that was buried has come back." (woman, aged 37)

"I used to think: life always has to be beautiful, otherwise it's not right. What I had 'lost' is that I never got to know how it is to be content with myself and the life I have. To understand life as a flowing river and difficulties as being part of it." (woman, aged 55)

3.6. Quantitative results

The results of $n = 20$ patients who attended at least 6 group sessions were included in quantitative analysis (per protocol analysis). All returned questionnaires were analyzed. Overall, 2.0 % of answers to the questions were missing completely at random⁵² and were imputed before analysis. Regarding the BDI, pre-test ($M = 20.90$, $SD = 11.37$) and post-test ($M = 12.12$, $SD = 7.55$) results indicated an improvement in depression levels, $t(19.00) = 0.80$, $p = .003$. Individual changes are depicted in Fig. 4A. As anticipated, there was also a significant increase in mindfulness as assessed by the FMI after the end of the MBLM course ($M = 38.38$, $SD = 7.06$) compared to baseline ($M = 31.40$, $SD = 5.43$), $t(19.00) = -1.24$, $p = < .001$. In the assessment of spirituality, only the *Search for Insight* sub-scale of the ASP questionnaire increased significantly from pre-test ($M = 57.99$, $SD = 22.99$) to post-test ($M = 72.92$, $SD = 18.76$), $t(11.00) = -4.02$, $p = .002$. Pre- and post-test changes in the sub-scales in the sub-scales *Religious Orientation*, *Conscious Interactions*, and *Transcendence Conviction* remained non-significant. Eudaemonic well-being as assessed by the TGS increased. In the metaphysics underlying yoga, three qualities (*gunas*) constitute the world and therefore also reflect states of mind: purity and wisdom (*sattva*), activity and passion (*rajas*), and ignorance and inertia (*tamas*). One of the goals of yoga practice is to increase *sattva* and to decrease *tamas* and *rajas*. In

general, these patterns of change could be seen in the participants of the MBLM course a, comparing character traits as measured by the TGS from baseline to 8 weeks (see Fig. 4B). Changes were significant in the majority of t-tests performed: for details see Table 3.

4. Discussion

MBLM is a new, complex mind-body intervention in mental health care to intensify and deepen meditation practice by implementing all major aspects of classical yoga. To investigate whether the MBLM program was feasible before a randomized controlled trial, we conducted a feasibility study of psychiatric outpatients with depressive symptoms, who participated in the program. We found MBLM to be a highly acceptable and feasible program for patients with mild to moderate depression, showing multiple benefits in terms of depressive symptoms, eudaemonic well-being, and personal empowerment. The retention rate in this study was 87.5 %, which is comparable to findings in other studies implementing 8-week yoga interventions.^{53,54} Satisfaction with the course was high, and when participants did not attend sessions, they usually had medical (but non-psychiatric) or social reasons not associated with the intervention itself. Home practice of yoga and meditation remained steady throughout the course: with an average of around 40 min of daily training it was around three times higher than the average stated in a national survey of people who practice yoga.⁵⁵ Supported by the qualitative findings, we interpret the sustained home practice as an indicator of higher motivation mediated by practicing the ethical aspects of yoga. Adverse events were reported more often in this study than in a large-scale survey of adverse events experienced in yoga classes for people who did not have a psychiatric diagnosis.⁴⁰ The adverse events reported by the patients in this study were mainly of psychological nature, typical during depression, and were associated largely with the *Ethical Living* domain. Our qualitative analysis showed that participants often found the topics of this domain disturbing, but generally in a thought-provoking and transformative way. This interpretation is supported by the fact that in the post-test assessment of spirituality, participants reported a greater search for insight than at baseline. None of the mentioned events—such as inner tension, recalling bad experiences, or feeling exhausted—lasted longer than two weeks. All of them can be seen as unavoidable side effects of the psychotherapeutic process within the *Ethical Living* domain. Nevertheless, these results should sensitize therapists to restrict MBLM to participants with

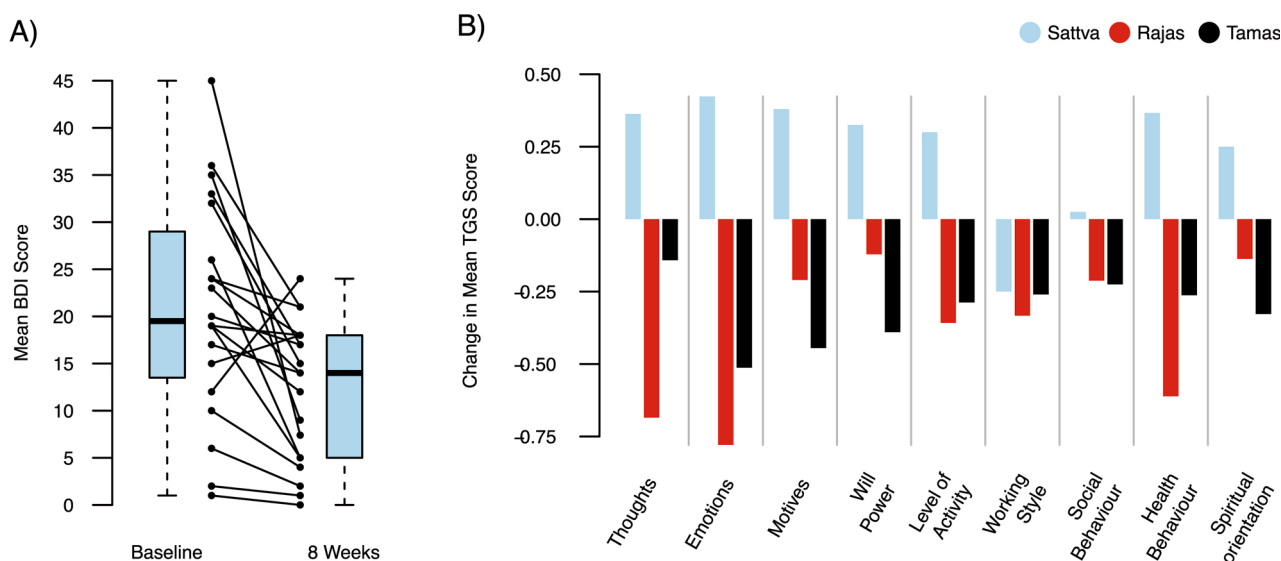


Fig. 4. A) Box-plot of depression levels at baseline and after the 8-week MBLM program. Lower and upper box boundaries 25th and 75th percentiles, respectively; line inside box median; lower and upper error lines minimum and maximum, respectively. Lines between the boxplots show individual changes. B) Bar graphs of mean differences in TGS scores for each subscale and each *guna*. Abbreviations: BDI, Beck Depression Inventory; TGS, Tri-Guna Scales.

Table 3Paired *t*-test results comparing baseline to 8-week outcomes.

	BL Mean	BL SD	8 W Mean	8 W SD	p	Lower CI	Upper CI	df	t
BDI	20.90	11.37	12.12	7.55	0.00257	3.50	14.06	19	0.80
FFA	31.40	5.43	38.38	7.06	0.00003	−9.67	−4.28	19	−1.24
ASP									
Religious Orientation	35.57	30.39	48.61	24.29	0.03031	−24.60	−1.49	11	−2.48
Search for Insight	57.99	22.99	72.92	18.76	0.00202	−23.11	−6.75	11	−4.02
Conscious Interactions	76.56	18.87	83.85	12.35	0.11058	−16.54	1.96	11	−1.74
Transcendence Conviction	52.78	35.95	59.72	31.75	0.09601	−15.34	1.45	11	−1.82
TGS Thoughts									
Sattva	3.07	0.54	3.43	0.73	0.00951	−0.63	−0.10	19	−2.88
Rajas	3.39	0.92	2.70	0.74	0.00090	0.32	1.05	19	3.93
Tamas	2.78	0.77	2.63	0.65	0.23256	−0.10	0.38	19	1.23
TGS Emotions									
Sattva	2.68	0.77	3.10	0.76	0.00235	−0.68	−0.17	19	−3.51
Rajas	3.49	0.86	2.71	0.81	0.00054	0.39	1.17	19	4.15
Tamas	2.90	0.98	2.39	0.92	0.01815	0.10	0.93	19	2.59
TGS Motives									
Sattva	2.83	0.73	3.20	0.83	0.02104	−0.70	−0.06	19	−2.52
Rajas	2.51	0.71	2.30	0.59	0.14050	−0.08	0.50	19	1.54
Tamas	2.67	0.70	2.22	0.73	0.00390	0.16	0.73	19	3.28
TGS Willpower									
Sattva	2.55	0.92	2.88	0.89	0.08479	−0.70	0.05	19	−1.82
Rajas	1.88	0.48	1.76	0.44	0.16637	−0.06	0.30	19	1.44
Tamas	2.88	0.87	2.55	0.94	0.04024	0.02	0.64	19	2.20
TGS Level of Activity									
Sattva	2.94	0.76	3.24	0.60	0.06376	−0.62	0.02	19	−1.97
Rajas	3.32	0.71	2.97	0.57	0.00704	0.11	0.61	19	3.02
Tamas	2.72	0.90	2.44	0.76	0.07966	−0.04	0.61	19	1.85
TGS Working Style									
Sattva	4.00	0.60	3.75	0.65	0.05391	0.00	0.50	19	2.05
Rajas	3.29	0.64	2.96	0.69	0.04266	0.01	0.65	19	2.17
Tamas	2.66	0.88	2.40	0.63	0.09395	−0.05	0.57	19	1.76
TGS Social Behavior									
Sattva	3.88	0.58	3.91	0.57	0.75939	−0.19	0.14	19	−0.31
Rajas	2.19	0.63	1.98	0.74	0.09780	−0.04	0.47	19	1.74
Tamas	2.34	0.68	2.12	0.67	0.02924	0.03	0.42	19	2.36
TGS Health Behavior									
Sattva	3.37	0.93	3.73	0.79	0.00771	−0.62	−0.11	19	−2.98
Rajas	3.28	0.93	2.67	0.73	0.00524	0.21	1.02	19	3.15
Tamas	2.79	0.85	2.52	0.75	0.10093	−0.06	0.58	19	1.72
TGS Spiritual Orientation									
Sattva	3.72	0.87	3.98	0.85	0.19643	−0.64	0.14	19	−1.34
Rajas	2.28	0.59	2.14	0.52	0.08557	−0.02	0.30	19	1.81
Tamas	2.88	0.87	2.55	0.94	0.04024	0.02	0.64	19	2.20

Note. Abbreviations: BL, Baseline; SD, Standard Deviation; 8 W, 8-Week Follow-Up; CI, 95 % Confidence Interval; BDI, Beck Depression Inventory; ASP, Aspects of Spirituality; FFA, Freiburg Mindfulness Inventory; TGS, Tri-Guna Scales.

sufficient psychological stability. Adverse events associated with mantra meditation were also higher than reported in healthy populations.⁴¹ This is in alignment with previous research, where participants with higher levels of repetitive negative thinking—a common symptom of depression—were more likely to report unpleasant meditation-related experiences. Again, reported events were mainly psychosomatic and only transitory during the 8 weeks of training. Depression levels as assessed by the BDI dropped from 20.90 (± 11.37) to 12.70 (± 7.80), which is a decrease of 39.23 %. Since we did not deploy a control group in this study, we can only compare this result with previously described courses of depression. A Minimal Clinically Important Difference (MCID) has been estimated as a reduction of 17.5 % from baseline.⁵⁶ Decreases of around 50 % in depression levels during an interval of 8 weeks are usually seen in treatment-naïve patients with major depression who receive a new drug.^{57,58} However, the patients in this study were not treatment-naïve, continued their existing treatment during their participation of the MBLM course, and hence were not so likely to show such a pronounced change in depression levels. Participants attributed different aspects of symptom relief (reduced emotional distress and rumination, physical well-being) and empowerment (self-confidence, self-acceptance, and self-regulation) to the course. Therefore, it is likely that MBLM has an antidepressant effect that is additive to their ongoing treatment. Lastly, one major finding of this study was that

eudaemonic well-being, understood in terms of *gunas* (general qualities and character traits) changed as predicted by yoga philosophy (e.g., *samkhya* philosophy). Participants largely changed their more imbalanced states of consciousness (*rajas* and *tamas guna*) into more harmonious states (*sattva*). Specifically, participants felt that they had a more relaxed attitude toward others and experienced inner growth. These results are in line with those of a behavioral intervention designed to increase *sattva guna*⁴⁵ and remarkable, as teachings of the underlying *samkhya* philosophy were not part of the MBLM program. The study has several limitations. Although we have argued that the results likely reflect the effectiveness of MBLM in depression, we could neither show this without a control group, nor given the small sample size in this study. The results should not be taken as evidence that the treatment was effective in the measures shown in Table 3. However, feasibility studies are, by design, underpowered and the main objective of the study was to show feasibility and acceptability, to gather information for a subsequent randomized controlled trial. Finally, 8 weeks is quite a short time to evaluate effects of interventions implementing yoga or meditation. Classical yoga is a way of living with the long-term goal of self-realization and short-term results may be different from those developing over a longer period. Strengths of this study include the novelty of the intervention type, mixed-methods design including the use of validated questionnaires, and defined inclusion/exclusion

criteria. Further studies should evaluate the MBLM program in terms of effectiveness, processes of change, and cost-effectiveness. Pilot trials in different populations, qualitative analyses, and a dismantling trial to analyze mechanism of action of the MBLM components are in progress (see ClinicalTrials.gov identifiers NCT03652220, NCT04089618, and NCT04252976).

5. Conclusion

Designed for Integral Mental Health Care, MBLM is a new intervention to improve eudaemonic well-being by establishing and deepening meditation practice based on a healthy lifestyle and on the ethical principles of classical yoga. This pilot study has indicated that MBLM is a highly acceptable and feasible program for outpatients with mild to moderate depression. Benefits included relief of depression-related symptoms, increase in eudaemonic well-being, and personal empowerment, including self-regulation, self-confidence, and spiritual growth. Attendance and adherence to home practice were high. This comprehensive, lifestyle-modifying approach to alleviating depressive and stress-related symptoms is also highly relevant to treating and preventing mental illness, and treating psychic comorbidities in patients with chronic somatic illness. Due to the modular structure of MBLM, its components can be adjusted to apply to other mental health conditions like addictions, anxiety disorders, or somatoform disorders.

Author contributions

HCB, AM and SB conceptualized and designed the study. HCB and NB were involved in the acquisition of data. PS supervised the data analysis. AM and SB supervised the clinical application in mental health care. HCB, NB and MJ contributed to qualitative analysis and reporting. HCB wrote the first draft of the manuscript. All authors worked on the final version of the manuscript.

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Declaration of Competing Interest

The Authors declare that there is no conflict of interest.

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Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:<https://doi.org/10.1016/j.ctim.2020.102598>.

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