Empirical Article

Clinical Psychological Science
1–20

DOI: 10.1177/2167702621996340
www.psychologicalscience.org/CPS

Defining and Measuring Meditation-Related Adverse Effects in Mindfulness-Based Programs

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Abstract

Research on the adverse effects of mindfulness-based programs (MBPs) has been sparse and hindered by methodological imprecision. The 44-item Meditation Experiences Interview (MedEx-I) was used by an independent assessor to measure meditation-related side effects (MRSEs) following three variants of an 8-week program of mindfulness-based cognitive therapy (n = 96). Each item was queried for occurrence, causal link to mindfulness meditation practice, duration, valence, and impact on functioning. Eighty-three percent of the MBP sample reported at least one MRSE. Meditation-related adverse effects with negative valences or negative impacts on functioning occurred in 58% and 37% of the sample, respectively. Lasting bad effects occurred in 6% to 14% of the sample and were associated with signs of dysregulated arousal (hyperarousal and dissociation). Meditation practice in MBPs is associated with transient distress and negative impacts at similar rates to other psychological treatments.

Keywords

mindfulness, meditation, adverse effects, harms monitoring, preregistered

Received 3/28/20; Revision accepted 1/16/21

Although mindfulness-based programs (MBPs) have emerged as a promising treatment for a range of conditions with comparable efficacy to established psychological treatments (Goldberg et al., 2018; Hofmann et al., 2010), very little is known about negative or adverse effects (AEs; Baer et al., 2019). Although distressing and functionally impairing effects of meditation have been reported in textual sources, clinical literature, and multiple research studies (Lindahl et al., 2019), adverse event monitoring in MBPs remains inadequate and inconsistent, producing widely varying frequency estimates depending on how adverse events are defined and measured. As a result, the widespread dissemination of MBPs into schools, hospitals, prisons, and mobile apps has proceeded without sufficient information about potential harms. In the current study, we aim to clarify the nature and frequency of meditation-related AEs (MRAEs) in MBPs by implementing 24 updated harms-assessment recommendations of what to measure (severity, types of events, expectedness) and how to measure (mode, independence, patient-based, relatedness; Ioannidis et al., 2004; Lineberry et al., 2016; Office for Human Research Protections, 2016; Rozental et al., 2018). See Table 1 for a list of harms monitoring recommendations addressed in this article.

Adverse Effects: What to Measure?

The World Health Organization (WHO) International Classification for Patient Safety uses the term *side effect* to indicate any effect of a treatment that was not the intended goal or that deviates from package labeling or advertising (Edwards & Aronson, 2000; WHO, 2010). Side effects that are negatively valenced or "subjectively unpleasant" are called *adverse effects* and may vary in

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Table 1. Harms Monitoring Recommendations

No.	Issue	Description and recommendation	How the current study addresses
		What to measure	
Degree of harm			
1	Severity	Studies limited to serious AEs inadequate; include all clinically relevant events	Three-tiered approach: valence, impact, LBEs
2	Duration	Clinically relevant events can have different durations	Durations of all events assessed, LBEs are reported according to three different durations of negative impacts
3	Transient distress vs. harm	Differentiate transient distress from negative impact on life and functioning	Separate ratings for valence and impact
Types of events			
4	Deterioration of target symptoms inadequate	Misses novel or unexpected symptoms	MedEx-I measures wide range of meditation-related side effects
5	General deterioration vs. multiple domains	Treatments can improve some symptoms and some domains while making other worse	MedEx-I measures across six different domains
6	Treatment-specific	Different treatments have different types of AEs	MedEx-I based on previous research of meditation-related challenges
7	Expectedness	Prior research of meditation can inform what types of AEs may be expected	MedEx-I based on previous research of meditation-related challenges, including > 40 published reports
		How to measure	
Mode (how)			
8	Active vs. passive monitoring	Accurate estimates require active monitoring; passive monitoring underestimates AEs	MedEx-I is active and systematic; all participants were queried
9	Open-ended vs. specific questions	Open-ended questions underestimate frequencies; query specific symptoms	MedEx-I contains both open-ended and specific questions
10	Detailed case reports	Detailed case reports are more informative than group comparisons to detect harms signals	MedEx-I is a detailed qualitative interview embedded in a prospective trial
11	Hawthorn effect-like scripting	Repeatedly asking questions about specific experiences can make them more likely to happen or be reported	MedEx-I was administered retrospectively as last assessment
Mode (who)			
12	Independence	Researchers/clinicians underestimate harms; use an independent assessor	MedEx-I was conducted by independent assessor unrelated to trial
13	Diverse perspectives	Different participants can view the same experience in different ways	Multivalent (positive, negative, neutral/mixed) ratings of valence and impact
Relatedness			
14	Prior published reports	Use reports of AEs of the treatment agent	MedEx-I is consistent with more than 40 published reports of MRAEs
15	Expert judgment	Causal attribution to treatment by experts	MedEx-I is based on interviews with meditation teachers who attributed the cause to meditation
16	Subjective attribution	Causal attribution to the treatment by the subject	MedEx-I asks about experiences that the participant attributes to meditation
17	Temporal proximity (challenge)	Event occurs during or immediately following treatment agent	MedEx-I queries if experience occurred during or immediately following meditation practice

(continued)

Table 1. *(continued)*

No.	Issue	Description and recommendation	How the current study addresses
18	Exacerbation	Exacerbation of preexisting symptoms during or immediately following treatment agent	MedEx-I queries whether preexisting symptoms got worse during or immediately following meditation practice
19	De-challenge	Decrease when treatment is reduced	Established in VCE study (see Lindahl et al., 2017)
20	Rechallenge	Reappearance when treatment agent is reinstated	Established in VCE study (see Lindahl et al., 2017)
21	Dose-response, biological gradient	Greater exposure leads to higher incidence	Statistical correlations with meditation practice
22	Intrasubjective consistency	Occurrence of same event following treatment on more than one occasion in the same individual	Established in VCE study (see Lindahl et al., 2017)
23	Intersubjective consistency	Occurrence of same event following treatment in different individuals	Established in VCE study (see Lindahl et al., 2017)
24	Specificity	Rule out alternate causes	Experiences that did not appear for first time or worsen during program were not counted

Note: AEs = adverse events; LBEs = lasting bad effects; MRAEs = meditation-related adverse effects; MedEx-I = Meditation Experiences Interview; VCE = Varieties of Contemplative Experience.

degree of harm (WHO, 2010, p. 16). *Harm* is any physical, psychological, or social suffering or impairment in functioning and is measured on a continuum (WHO, 2010).

Degree of harm is determined by AE severity and duration and any resulting treatment implications (WHO, 2010). AE reporting in MBP trials has typically been limited to extremely severe or "serious" AEs that are "fatal or life threatening, resulting in significant incapacity" because only serious AEs are required to be reported (Food and Drug Administration [FDA], 2010; Wong et al., 2018). However, new guidelines recommend "broaden[ing] adverse event reporting beyond what is mandated by regulators" to include clinically relevant events that influence treatment decisions, tolerability, adherence, functioning, and quality of life (Lineberry et al., 2016, p. 3). This new definition includes not only events of moderate severity that require countermeasures (including reducing dose of treatment) or involve impairment in at least one domain of functioning but also mild events (transient distress) that require no intervention. Although mild events have been considered "nuisances," expected, or necessary for progress (Baer et al., 2019; Peterson et al., 2013), they still affect risk-benefit assessment, treatment tolerability, and quality of life and therefore remain clinically relevant (Linden, 2013; Lineberry et al., 2016).

Although duration is related to harm, there is no specific or required duration that makes an event clinically relevant or harmful (Lineberry et al., 2016; WHO, 2010). Instead, duration interacts with other contextual factors to constitute harm. Higher levels of impairment or risk require shorter durations for clinical relevance (e.g., suicidality is serious regardless of duration). Conversely, mild events (headaches) that last for months also constitute harm. Thus, degree of harm is best understood as a combination of duration, distress, impairment of functioning or quality of life, and risk to self/other.

In the context of MBPs, definitions of AEs typically include "deteriorations" on preexisting target outcomes (Baer et al., 2019; Hirshberg et al., 2020; Wong et al., 2018). However, this approach fails to capture unexpected or novel treatment-emergent effects (Dimidjian & Hollon, 2010; Linden, 2013). Likewise, global, summed, or averaged deterioration scores also obscure the fact that treatments can improve some symptoms and some domains of functioning while making others worse (Dimidjian & Hollon, 2010; Lilienfeld, 2007). For this reason, current guidelines recommend assessing different domains of functioning independently (Dimidjian & Hollon, 2010; Lineberry et al., 2016).

Current guidelines recommend assessing all potential AEs that are linked to the central mechanism of action for a treatment (e.g., meditation; Dimidjian & Hollon, 2010; Lineberry et al., 2016; Mayo-Wilson et al., 2019), which requires knowledge of previously published reports about MRAEs. Undesirable side effects and risks of meditation have been documented in more than 40 scientific reports (for reviews, see Baer et al., 2019; Kuijpers et al., 2007; Lindahl et al., 2019; Lustyk et al., 2009; Van Dam et al., 2018). Many MRAEs are listed as

potential risks in MBP guidelines (Kuyken et al., 2012; Santorelli et al., 2017) and are linked to known mechanisms of action of MBPs. For example, the MBP mechanism of increased body awareness and/or activation of the insula cortex can be associated with increased anxiety, panic, and flashbacks; the MBP mechanisms of decentering, or increased psychological distance from experience, and prefrontal control over the amygdala can be associated with disembodiment, affective blunting, and dissociation (Britton, 2019).

Available frequency estimates of MRAEs have varied widely, depending on how AEs were defined and measured. A recent meta-analysis of meditation studies found that AE rates ranged from 4% to 33% depending on study design (Farias et al., 2020). In MBP trials, nonsystematic and passive monitoring of serious AEs produced rates of < 1% (Wong et al., 2018), systematic queries of "unpleasant experiences" produced rates of 67% to 73% (Baer et al., 2021), and percentage of "participants with increased symptoms" produced rates of 15% to 44% (Hirshberg et al., 2020). In addition, some RCTs have found that average symptom severity significantly worsened in MBP arms compared with control arms (Britton et al., 2010; Johnson et al., 2016; Lomas et al., 2017; Reynolds et al., 2017). However, none of these studies formally assessed the relationship of AEs to meditation practice. Systematic queries of *meditation-related* AEs (MRAEs) that were "particularly bad or frightening" or "unwanted" produced MRAE rates of 20% to 25% (Anderson et al., 2019; Cebolla et al., 2017; Schlosser et al., 2019). More common, less serious MRAEs that have been reported in surveys of meditators who meditate less than an hour per day include increased depression, anxiety, or panic; reexperiencing of traumatic memories; dissociation; executive dysfunction; headaches or body pain; insomnia; and social impairment (Cebolla et al., 2017; Farias et al., 2020; Lindahl et al., 2017; Lomas et al., 2015). More serious MRAEs including mania, psychosis, and suicidality have also been reported, often in the contexts of intensive retreats (> 5 hr/day) or in conjunction with preexisting psychopathology (Kuijpers et al., 2007; Kuyken et al., 2012; Lindahl et al., 2017; Yorston, 2001).

Adverse Effects: How to Measure?

Consolidated Standards of Reporting Trials (CONSORT) guidelines define safety as "substantive evidence of an absence of harm" and not "when there is simply absence of evidence of harm" (Ioannidis et al., 2004). In pharmacology treatments, the most detailed harms assessments occur in early preclinical and basic science phases of treatment development (Phases 0–1) in the form of case reports, dose-response curves, and observational studies before proceeding to randomized controlled trials (RCTs; Gitlin, 2013). MBPs, however, have largely omitted in-depth harms assessments in both treatment development and RCTs. Thus, despite CONSORT requirements (Moher et al., 2001), and compared with 100% of pharmacology trials (Vaughan et al., 2014), less than 20% of meditation trials actively measure AEs (Wong et al., 2018).

The majority of MBPs rely on passive monitoring—that is, spontaneous participant reports. However, it is well known that research participants and psychotherapy clients are unlikely to spontaneously report negative treatment reactions because of demand characteristics (the desire to please the therapist or researcher; Horigian et al., 2010; Nichols & Maner, 2008). As a result, relying on passive monitoring may underestimate AE frequency by more than 20-fold (Kramer, 1981). AE accuracy can be improved by active and systematic monitoring (Horigian et al., 2010), but only if active monitoring scales that assess specific symptoms—which have more sensitive detection rates than either open-ended queries (Allen et al., 2018; Bent et al., 2006) or passive monitoring (Talbot & Aronson, 2012)—are used.

Treatment providers and researchers are not good sources of harms estimates. Providers often overestimate their success rates, underestimate harms, and fail to recognize deteriorations when they occur (Hatfield et al., 2010; Walfish et al., 2012). Providers tend to dismiss patient complaints and their credibility as reliable reporters (Crichton et al., 2017) and deny that patient-reported symptoms were caused by the treatment, even for known side effects (Golomb et al., 2007). Providers are also prone to the fallacy that "worsening is to be expected and is a positive sign that the therapy is working" (Hannan et al., 2005, p. 156) even though less than 10% of deteriorations result in positive treatment response and intervening on deteriorating patients improves treatment outcomes (Lambert et al., 2003). Researchers may be motivated to downplay AEs because of reporting burden or because continued funding depends on treatment success (Ioannidis, 2009). Researcher conflicts of interest have been found to significantly predict fewer AEs in the MBP arm (Wong et al., 2018). Thus, because researchers and providers are reliably biased, recent guidelines recommend patient-based reports elicited by an independent party for identifying sensitive or socially undesirable information such as negative reactions to treatment (Dimidjian & Hollon, 2010; Fowler, 1998; Weissman et al., 2008). Although patient-centered assessments protect against motivated minimization by researchers and providers, different patients may view the same experience in different ways (Dimidjian &

Hollon, 2010; Rozental et al., 2018). One patient may experience crying or traumatic reexperiencing as destabilizing, whereas another patient may experience it as part of healing. Thus, it is necessary to assess the valence and impact of each experience for each patient independently.

Contrary to the assumption that RCTs always convey the best evidence, they are not the best design for detecting AEs (Hammad et al., 2011; Vandenbroucke, 2006) and have instead been called "the gold standard way to miss adverse events" (Healy & Mangin, 2019, p. 1). RCTs are powered for efficacy but underpowered for detecting AEs, which are typically rare, outlier events (Edwards, 2012; Hammad et al., 2011; Lineberry et al., 2016) that are easily obscured by lack of patient or assessor blinding, lack of intent-to-treat analyses, or author conflict of interest (Chou et al., 2007, 2010; Hammad et al., 2011). These limitations of RCTs to detect AEs or make causal inferences are further compounded in behavioral intervention studies, including MBPs, in which harms assessment and methodological rigor lag far behind pharmaceutical trials (Goldberg et al., 2017; Jonsson et al., 2014; Wong et al., 2018). Widespread use of waitlist control participants and lack of patient blinding result in global overestimation of treatment efficacy and underestimation of AEs (Hrobjartsson et al., 2014). Waitlist control participants are prone to nocebo effects and cannot be used to estimate base rates of AEs without treatment (Cuijpers et al., 2018; Freedland et al., 2019; Furukawa et al., 2014; Van Dam & Galante, 2020).

Rather than relying on RCTs, regulatory agencies such as the National Institutes of Health, WHO, and FDA rely instead on Phase 0–1 or postmarket observational studies and detailed case reports to identify treatment-related harms and make safety policy decisions (Council for International Organizations of Medical Sciences, 2010; Moore et al., 2012; Singh & Loke, 2012; Talbot & Aronson, 2012). Rather than trying to infer causality mathematically on the basis of group averages, causality can be more confidently and thoroughly established by assessing each event in each person with multiple causality criteria (Edwards, 2012; Hauben & Aronson, 2007). Standard causality assessment criteria are listed in Table 1 (relatedness items 14–24; Agbabiaka et al., 2008; Office for Human Research Protections, 2016; Turner, 1984; WHO, 2016). Because MBP development skipped this phase, it has been recommended that MBPs be "sent back" to Phases 0–1 to assess potential AEs properly (Dimidjian & Segal, 2015, p. 605). The *Lancet Psychiatry* Commission on psychological treatments recommend recouping Phase 0–1-level safety information by embedding in-depth qualitative interviews about AEs into clinical trials (Holmes et al., 2018).

Given these recommendations for the assessment of AEs, in the current study, we have several related aims. We provide an example of a harms assessment that incorporates the updated guidelines, with special attention to issues pertinent to behavioral interventions in general and MBPs in particular (see Table 1). In the current article, we use the terms *meditation-related side effect* (MRSE) to refer to all meditation effects that are unintended and *meditation-related adverse effect* to refer to meditation effects with negative valence and/or negative impacts. By using an empirically derived taxonomy of MRSEs (Lindahl et al., 2017), we aim to clarify the nature and frequency of MRSEs and MRAEs in the context of 8-week mindfulness-based programs. By asking each participant to rate the valence and impact of each MRSE that occurred, we clarify which side effects are experienced as "adverse" (i.e., are MRAEs) on a patient-centered, case-by-case basis. By taking a three-tiered approach to severity and degree of harm that incorporates valence, impact, and duration, we differentiate transient distress, negative-impact MRAEs, and lasting bad effects (LBEs). By identifying specific types of MRSEs that are associated with lasting bad effects, we aim to help meditators, meditation teachers, and MBP providers identify potentially problematic MRSEs that may warrant attention, corrective feedback, and/or intervention. By evaluating the performance of open-ended questions compared with specific questions, we provide information on how method of measurement affects frequency rates. By assessing MRAE rates across MBP variants, we begin to investigate whether frequencies are dependent on type of meditation practice.

Method

Participants

The target sample was intended to represent Americans seeking mindfulness meditation training for the management or alleviation of clinical, subclinical, and transdiagnostic expressions of affective disturbances, including anxiety, depression, and stress (Morone et al., 2017; Santorelli et al., 2017). Participants were English-speaking individuals, ages 18 to 65, with mild to severe levels of depression and persistently high levels of negative affect. Following MBP guidelines (Kuyken et al., 2012; Santorelli et al., 2017), exclusion criteria included lifetime history of bipolar, psychotic, borderline, or antisocial personality disorders; repeated self-harm or organic brain damage; current depression in

the extremely severe range or active suicidal ideation; current panic, posttraumatic stress disorder, obsessive compulsive disorder, eating disorder, or substance abuse; current psychotherapy; a regular meditation practice; or modification of antidepressant medication in the preceding 2 months (for details, see Britton et al., 2018).

Setting and oversight

The registered clinical trial (NCT01831362) took place at Brown University between November 2012 and March 2016. The study was approved and supervised by the Brown University Institutional Review Board (IRB), an independent Data Safety Monitoring Board (DSMB), and the National Center for Complementary and Integrative Health (NCCIH) Office of Clinical and Regulatory Affairs (OCRA) in accordance with the World Medical Association Declaration of Helsinki. Participants were recruited through community flyers advertising mindfulness meditation for stress, anxiety, and depression. Eligible participants provided written, informed consent and did not receive financial compensation. All AEs, both serious and nonserious, were reported to the IRB, DSMB, and OCRA according to NCCIH reporting requirements.

Design and training programs

As reported in Britton et al. (2018), the treatment programs were three variants of mindfulness-based cognitive therapy (MBCT): open monitoring (OM), focused attention (FA), and standard MBCT. Standard MBCT combines components of cognitive behavioral therapy and mindfulness-based stress reduction (MBSR) in a group-based psychoeducational format (Segal, Williams, & Teasdale, 2002) and employs a combination of both OM and FA meditation techniques. The OM variant included only OM meditation, during which participants bring unbiased, receptive, and open attention to their experience without focusing on any single object. The FA variant, by contrast, included only FA meditation, during which participants focus attention on an anchor (e.g., the breath). Detailed descriptions of treatment development and validation with session-by-session treatment manuals can be found in Britton et al. (2018). All treatments met for 3 hr once per week for 8 weeks and for a full-day silent retreat during Week 7. Prescribed formal meditation practice homework was 45 min per day, 6 days per week, with additional informal practice as needed. Participants received basic training in targeted practices (FA, OM, or the combination in MBCT) during Weeks 1 through 4 and then learned how to apply these practices to regulate negative emotions in Weeks 5 through 8. All treatments were equivalent for program structure, duration, instructor training/fidelity, and participant compliance (e.g., attendance, meditation frequency and duration; Britton et al., 2018).

Four meditation teachers taught the MBPs: three men and one woman. All instructors had graduate degrees (three PhDs, one MA, two clinical) and more than 20 years of personal meditation experience in one or more meditation traditions. Three were trained MBSR and/or MBCT instructors; three had training as teachers of Buddhist meditation. Treatment adherence was 93.3% ($\kappa = .71$), as assessed by adapted versions of the MBCT adherence scale (Britton et al., 2018; Segal, Teasdale, et al., 2002).

Measures

Baseline diagnostic status and exclusion criteria were established with the Structured Clinical Interview for DSM-IV for Axis I (SCID-I) and Axis II (SCID-II) disorders (Frist, 1997). Depression symptom severity was assessed with the clinician-administered Inventory of Depressive Symptomatology (IDS-C; Rush et al., 1996; $\kappa = .89$) and was interpreted as follows: 12 to 23 = mild, 24 to 36 = moderate, 37 to 47 = severe, 48 or greater = very severe.

The Meditation Experiences Interview instrument design. The Meditation Experiences Interview (MedEx-I) was derived from the Varieties of Contemplative Experience (VCE) research project, a mixed-methods study about meditation-related challenges based on interviews with practitioners of Buddhist meditation and meditation teachers (Lindahl et al., 2017). The VCE study yielded 59 types of meditation-related experiences that were described by meditators and teachers as unexpected, challenging, distressing, and/or associated with impairment of functioning. Relatedness to meditation was established by using 11 causality criteria (Agbabiaka et al., 2008; Office for Human Research Protections, 2016; WHO, 2016; for details, see Table 1).

Because the VCE study and the current trial were concurrent, an earlier version of the VCE codebook was used as basis for the development of the MedEx-I used in the MBP. This "MedEx codebook" consisted of 44 categories across six domains. The affective domain (11 categories) included changes in the type, frequency, or intensity of emotions, such as anxiety, affective lability, blunting, suicidality, and reexperiencing of traumatic memories. The cognitive domain (six categories) included experiences related to mental processes and thought content, quality, and frequency, such as executive dysfunction, delusions, racing, or absence of thoughts or loss of concepts. The perceptual domain (eight categories) captured alterations in sensory processes, such as

vision, hearing, interoception, and perception of time, and included perceptual hypersensitivity, distortions, and derealization. The sense-of-self domain (four categories) included self-disturbances such as feelings of disembodiment and loss of sense of ownership or agency. The somatic domain (13 categories) included changes in bodily functioning or physiological processes, such as sleep, pain, appetite, digestion, and involuntary movements. The social domain (two categories) included social and occupational impairment. Detailed descriptions, inclusion criteria, and exclusion criteria for each category of the MedEx-I codebook can be found in the Codebook in the Supplemental Material available online.

Meditation Experiences Interview procedure. The MedEx-I was administered to participants in the MBP as the last part of the final assessment at the 3-month follow-up interview (Week 20). To meet the independence criterion, the MedEx-I was administered by an independent researcher (J. R. Lindahl) who was otherwise unaffiliated with the clinical trial (i.e., who had no contractual relationship with the sponsor or AE reporting responsibilities with the human subjects protection oversight committees; IRB, OCRA, DSMB). The interviewer was the primary coder for the VCE study and possessed expert-level familiarity with the phenomenology of MedEx-I categories.

Interview questions. The MedEx-I featured three types of questions: (a) one initial open-ended question, (b) 44 category-specific questions, and (c) five follow-up questions. The interview commenced with the open-ended query, "Have you had any unexpected, unpleasant, adverse, or challenging experiences as a result of mindfulness meditation practice during or following the program?" Under the overarching framework of subjective attribution to mindfulness meditation established in the open-ended question, category-specific queries asked about the presence of each of 44 MRSE categories in the MedEx-I codebook. Once the presence of an MRSE was established, five follow-up questions aimed to establish causality, relationship to specific practices, duration, valence, and impact:

1. *Preexisting experience.* Participants were asked whether they had experienced the codebook category before learning to meditate to rule out experiences that could plausibly be unrelated to meditation practice. An experience counted as plausibly causally related to meditation (i.e., was coded as "present") only if the experience emerged for the first time or if it increased in frequency, intensity, or duration during the mindfulness training program and was attributed to mindfulness meditation practice by the participant. Experiences that failed to meet these criteria were not counted.

2a. *Practice-related.* "Did the experience occur during or immediately following meditation practice?"

2b. *Specific practice.* If it occurred during/following meditation, participants were then asked, "Was the experience associated with a *particular* or *specific* practice or exercise?" To assess their unique contribution, we included experiences associated with the all-day retreat and the "working with difficulties" practice (in which a difficult emotion is deliberately invited) but coded them separately.

3. *Duration.* The participant was asked to describe the duration or how long the experience lasted in terms of minutes, days, weeks, months, or ongoing and whether it was limited to a meditation practice session or continued into daily life.

4. *Valence.* Participants were asked to rate the valence or emotional tone of the experience when it was occurring as positive, negative, or neutral/mixed. Experiences that changed valences (i.e., were initially negative but then became positive or vice versa) were classified as mixed.

5. *Impact.* "Did the experience have a positive, negative, or no impact on your life or functioning?" In contrast to valence, *impact* refers to the effect of the experience on daily life and domains of functioning (e.g., work, social, driving, decision-making), requirement for countermeasures (additional/modified treatment), or change in behavior (including willingness or ability to meditate).

Data collection and qualitative coding. All interviews were recorded, transcribed, and imported into NVivo software for qualitative data analysis and validation of categories. Qualitative coding was performed by the coders of the VCE study (J. R. Lindahl and D. J. Cooper). False positives (descriptions that did not meet criteria) were retained only as an index of the initial open-ended question performance but otherwise were not included. One third of the transcripts were coded by multiple coders to ensure interrater reliability ($\kappa = .77$). Validated data were imported into IBM SPSS for quantitative analysis.

Meditation practice. Home meditation practice during and after treatment was monitored daily with an online survey that queried both formal and informal practice frequency and duration. Formal practice included time

set aside from daily life for meditation or use of audio recordings of guided meditation practices, whereas informal practice occurred unscheduled, during daily activities, and without the use of audio recordings.

Data analysis

Outcomes. Outcomes included descriptive statistics of the following:

MRSEs are all meditation-related experiences or MedEx-I-derived events independent of valence or impact.

Duration indicates the longest lasting MRSE in each participant by measure of minutes, days, weeks, months, or ongoing.

MRAEs are MRSEs that are reported as having negative valence or negative impact on functioning and are arranged in three tiers: A *negative-valence* MRAE is experienced as unpleasant while it is occurring regardless of its impact on functioning. A *negative-impact* MRAE results in a negative impact in functioning and requires countermeasures or a change in behavior. LBEs were defined as negative-impact MRAEs with three possible durations: more than 1 day, more than 1 week, and more than 1 month.

Clinically relevant categories are MRSE categories that are constitutive and/or predictive of LBEs lasting longer than a week. Constitutive categories were rated by participants as the cause of impairment, whereas predictive categories significantly predicted increased risk of LBEs from other categories. Risk ratios (RRs) were used to assess whether the presence of any particular MRSE could signify an elevated risk for LBEs lasting longer than a week (Siegerink & Rohmann, 2018). The RR is calculated as the likelihood of LBEs in someone who reported a specific category divided by the likelihood of LBEs in participants who have not reported that category. Significantly elevated risk for LBEs is signified if the standardized value of the RR (z score) has a p value of $< .05$ (Sheskin, 2004). For details, see Table S2 in the Supplemental Material.

Relationship to meditation practice (i.e., causal attribution to meditation) was assessed in the current study in six ways (see Table 1): (a) by querying experiences that had previously established causal links to meditation, (b) emerged for the first time or intensified in the context of a meditation training program, (c) were subjectively attributed to meditation by the participant, or (d) occurred during or immediately following meditation practice; (e) by comparing meditation practice frequencies and durations between groups with LBEs lasting longer than a week and groups without (Wilcoxon-Mann-Whitney-U); and (f) by calculating Pearson correlations of practice frequency/duration and MRAE frequency.

Performance on open-ended questions was indexed by number of true (accurate) and false (inaccurate) positive ("yes") and negative ("no") responses to the open-ended question compared with results of specific queries for each MedEx-I category.

Between-groups differences were calculated to determine whether the frequencies of MRSEs, MRAEs, or LBEs differed across the three treatment variants. We used negative binomial regressions to model outcomes measured in number of events, and Firth's penalized likelihood logistic regression to model outcomes that were assessed dichotomously (i.e., presence vs. absence) while reducing bias due to rare events. For details, see Supplemental Treatment Analyses in the Supplemental Material.

Results

Participant characteristics

Ninety-six of the 104 (92%) randomly assigned participants completed treatment and all assessments. Eight participants dropped out: two before the first class, two after the second class, three after the third class, and one after the seventh class. Reasons for attrition included time commitment and scheduling issues ($n = 5$), moving away ($n = 1$), "not wanting to be in a study" ($n = 1$), and "increased stress" ($n = 1$). Participants attended 90% of all face-to face sessions, for an average of 8.1 ($SD = 1.0$) out of nine sessions; 91% attended the all-day silent retreat. During the 8-week treatment, participants practiced meditation at home for an average of 34 min/day, which represents 76% of the prescribed quantity (45 min/day). Between the end of treatment and the 3-month follow-up assessment, participants' average daily practice was 17 min/day (range = 0–67 min/day).

Participants were representative of Americans who use mindfulness meditation: predominantly White (97%), non-Hispanic (97%), middle-aged (mean age = 40.4 years, $SD = 12.9$), female (73%), and educated (mean education = 17.1 years, $SD = 2.7$) with clinical and subclinical levels of anxiety and depression (Morone et al., 2017). Forty percent of the sample met diagnostic criteria for major depression and 50% for generalized anxiety disorder. IDS-C scores indicated mild to moderate levels of depression, and one third (33%) of the sample took antidepressant medication. Participant characteristics and adherence did not differ between treatment variants.

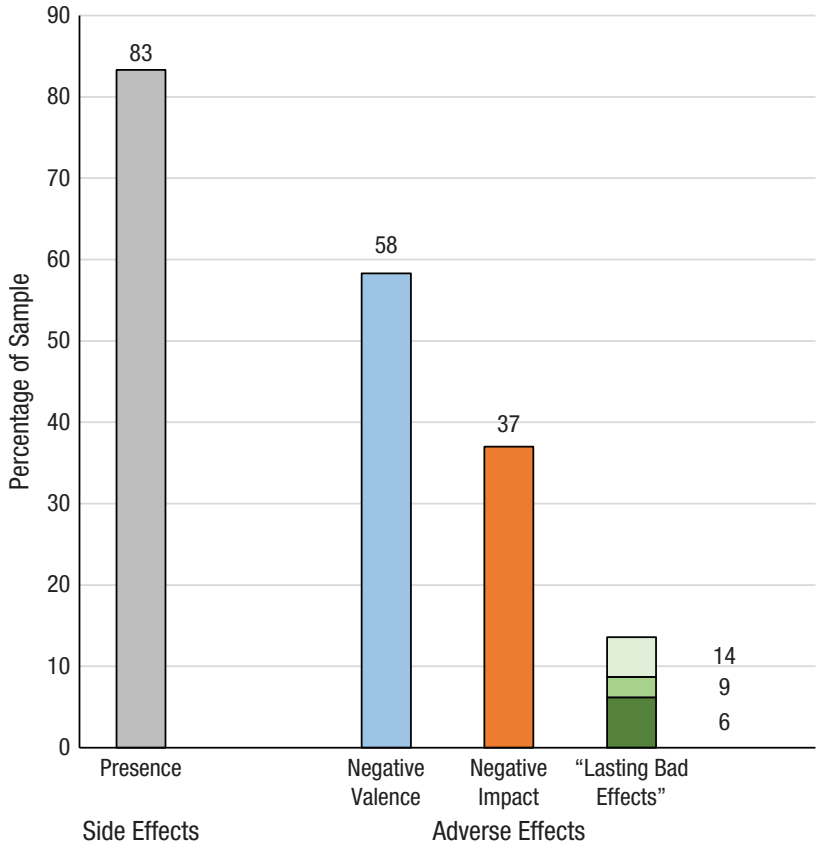

Fig. 1. Frequencies of meditation-related side effects (MRSEs) and meditation-related adverse effects (MRAEs). The gray bar indicates the percentage of the sample that reported the presence of any MRSE. MRAEs are displayed in three tiers: MRAEs with negative valence (blue), MRAEs with negative impact (orange), and lasting bad effects, or MRAEs with negative impacts lasting more than 1 month (dark green), more than 1 week (green), or more than1 day (light green).

Treatment efficacy

In terms of overall treatment efficacy, all three forms of mindfulness training produced large effect size improvements in IDS-C scores from baseline to posttreatment (*d*s = 1.48–1.65) and Week 20 follow-up (*d*s = 1.34–1.57) with no differences between groups (Cullen et al., 2021).

MedEx-I

Available data. Data for open-ended questions, MRSEs, and valence ratings were available for all 96 (100%) participants who completed the trial. Duration ratings were available for 90 (94%) participants, impact ratings for 81 (84%) participants, and LBEs data for 78 (81%) participants. Because denominators in percentages differ by outcome, they are explicitly reported, as specified by current guidelines (Ioannidis et al., 2004; Lineberry et al., 2016).

Replication of the VCE study. Eighty percent (35 of 44) of the VCE phenomenology codebook categories replicated in the context of an MBP. Nine categories from the 44-item MedEx-I codebook were not replicated: delusions, hallucinations, synesthesia, anomalous recall, cardiac changes, fatigue, sleep paralysis, gastrointestinal problems, and occupational impairment. In addition, 26 events that were categorized as "other" in the MedEx-I would either become five new categories in the final 59-item VCE codebook (14 events), be included in expanded versions of existing categories (seven events), or remain uncategorized (five events), yielding an 83% replication rate in relation to the final 59-item VCE phenomenology codebook.

Frequencies of MRSEs, MRAEs, and LBEs. Figure 1 and Table 2 display frequencies of MRSEs, MRAEs, and LBEs. Total number of events, percentage of sample with one or more events, mean, standard deviation, and ranges are displayed for the overall sample and for each treatment

Table 2. Frequencies of MRSEs, MRAEs, and LBEs

Variable	Total	MBCT	OM	FA	χ^2	*p*
		MRSEs				
Participants (*n*)	96	30	31	35		
MRSEs (*n*)	266	92	63	111		
Participants with ≥ 1 event (%)	83.33	83.33	87.10	80.00	0.54	.763
Events per person						
Mean	2.77 (2.64)	3.07 (3.40)	2.03 (1.40)	3.17 (2.66)	4.27	.119
Range	0–13	0–13	0–5	0–9		
		MRAEs				
Negative-valence events						
Participants (*n*)	96	30	31	35		
MRSEs (*n*)	109	35	29	45		
Participants with ≥ 1 event (%)	58.33	60.00	54.84	60.00	0.22	.895
Events per person						
Mean	1.14 (1.41)	1.17 (1.60)	0.94 (1.21)	1.29 (1.43)	1.10	.578
Range	0–7	0–5	0–5	0–7		
Negative-impact events						
Participants (*n*)	81	25	24	32		
MRSEs (*n*)	53	15	9	29		
Participants with ≥ 1 event (%)	37.04	32.00	29.17	46.88	2.11	.348
Events per person						
Mean	0.65 (1.07)	0.60 (1.00)	0.38 (0.65)	0.91 (1.33)	2.23	.328
Range	0–5	0–3	0–2	0–5		
		LBEs				
N	78	25	21	32		
LBE > 1 day (%)	14.10	16.00	9.52	15.63	0.41	.815
LBE > 1 week (%)	8.97	4.00	4.76	15.63	2.24	.326
LBE > 1 month (%)	6.41	4.00	4.76	9.38	0.52	.773

Note: Values in parentheses are standard deviations. χ^2 values are given for omnibus tests for differences between conditions; *p* values are for χ^2 tests. For details, see Treatment Analyses S1 in the Supplemental Material available online. MRSEs = meditation-related side effects; MRAEs = meditation-related adverse effects; LBEs = lasting bad effects; MBCT = mindfulness-based cognitive therapy; OM = open monitoring; FA = focused attention.

separately. Across all participants, a total of 266 MRSEs or events were reported. Eighty-three percent (80 of 96) of the sample reported experiencing at least one MRSE, and the majority (62.5%) reported multiple MRSEs. The mean number of MRSEs per person was 2.8 (*SD* = 2.6, range = 0–13). Note that not all MRSEs were negative or AEs; some events were neutral, mixed, or positive in either valence, impact, or both. Fifty-eight percent (56 of 96) of the sample reported at least one MRAE with a negative valence, and 27% (26 of 96) experienced more than one (range = 0–7). Thirty-seven percent (30 of 81) of the sample reported at least one MRAE with a negative impact, and 16% (13 of 81) reported more than one (range = 0–5). For the majority of participants (56.7%), the longest MRSEs lasted less than 1 hr; for 7.8%, less than 1 day; for 7.8%, less than 1 week; for 3.3%, 1 week to 1 month; and for 6.6%, 1 to 5 months or were ongoing at the time of interview. LBEs or negative-impact MRAEs with durations of 1 day to 1 week were reported by 11 (14.1%) participants, with durations of 1 week to 1 month by seven (9.0%) participants, and with durations of 1 to 5 months or ongoing by five (6.4%) participants. Frequencies of MRSEs, MRAEs, and LBEs did not significantly differ between treatment groups in any omnibus or pairwise comparisons (for details, see Table 2 the Supplemental Treatment Analyses in the Supplemental Material).

Clinically relevant categories. Frequencies of MRSEs, negative-valence MRAEs, and negative-impact MRAEs for each MedEx-I category can be found in Table S1 in the Supplemental Material. Figure 2 displays MedEx-I categories that were constitutive and/or predictive of LBEs. Executive dysfunction, insomnia, emotional blunting, and self-disturbance were reported in less than 5% of the sample and were both constitutive and predictive of LBEs, increasing the risk of LBEs by 6- to 14-fold. Anxiety, time-space distortions, and traumatic reexperiencing were reported in 10% to 25% of the sample, and although they *could* constitute LBEs, they were not predictive of LBEs because most instances were not associated with

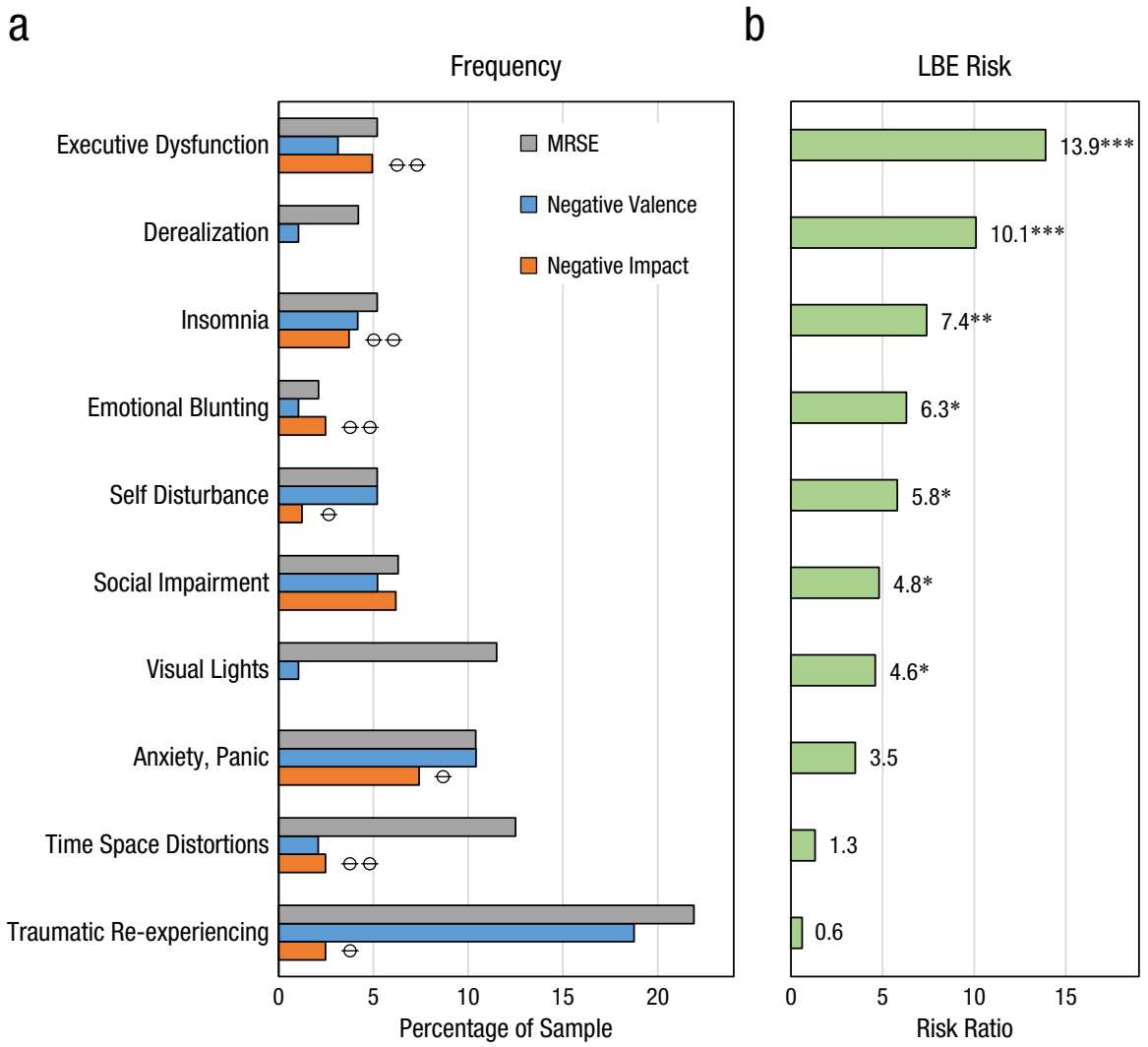

Fig. 2. Clinically relevant categories that are constitutive and/or predictive of lasting bad effects (LBEs). (a) Graph shows frequencies of meditation-related side effects (MRSEs; gray), negative-valence meditation-related adverse effects (MRAEs; blue), and negative-impact MRAEs (orange). ⊖ = LBEs lasting longer than 1 week; ⊖ ⊖ = LBEs lasting longer than 1 month. (b) LBE risk is displayed as a risk ratio that compares the probability of lasting longer than 1 week in the presence versus the absence of a category. For example, LBEs are 10 times more likely when derealization is present than when it is absent. Asterisks indicate significant predictors of LBEs lasting longer than 1 week (*$p < .05$, **$p < .005$, ***$p < .0001$). For details, see Table S2 in the Supplemental Material available online.

enduring impairment. Derealization, social impairment, and visual lights were predictive but not constitutive of LBEs. For details, see Table S2 in the Supplemental Material.

Relatedness to meditation practice. All 266 events met minimal causality criteria on account of either occurring for the first time or increasing in frequency, duration, or intensity during the mindfulness program and being subjectively attributed to meditation by the participant. Some common experiences such as fatigue, cardiovascular changes, and gastrointestinal symptoms were reported but failed to meet these causality criteria and were therefore not counted or included in the analysis.

Data on relationship to mindfulness meditation practice were available for 84% (225 of 266) of events. For 198 (88%) events, participants reported that the experience occurred during or immediately following mindfulness meditation practice, and for 140 (62%) of those events, participants were able to identify specific practices or exercises associated with the experiences. The majority of events occurred during daily home practice or class, whereas a small minority of events occurred in the context of the all-day retreat (6.2%) or the working with difficulty practice (6.2%). For 27 (12%) events, participants reported that the experience was more of a general or cumulative effect of participating in the

program rather than during practice, although many of these were experiences that could not have occurred during meditation (e.g., nightmares, social impairment).

The group with LBEs lasting longer than a week did not differ in the duration (minutes) of formal mindfulness meditation practice either during or after treatment. However, they did show a trend toward more informal practice minutes during treatment (70 min vs. 53 min/week; $p = .075$) as well as significantly more frequent informal practice sessions after treatment (13.5 vs. 4.3 times/week, $p = .028$). Frequency of informal practice after treatment was significantly correlated with number of negative-impact MRAEs ($r = .213$, $p = .037$).

Open-ended question performance

The open-ended question ("Have you had any unexpected, unpleasant, adverse, or challenging experiences as a result of mindfulness meditation practice during or following the program?") produced a roughly equal ratio of true positives (27%) to false positives (28%) but produced more than 3 times more false negatives (32%) than true negatives (10%). The open-ended question correctly identified only 26 of the 80 (32.5%) participants who experienced MRSEs, thus underestimating the true rate by nearly 70%.

Discussion

In the current study, we used updated harms-assessment guidelines including an embedded qualitative interview to assess empirically derived MRSEs and MRAEs in the context of an MBP. Results indicated a high degree of replication of MRSEs previously identified in a sample of practitioners of Buddhist meditation (Lindahl et al., 2017). More than 80% of categories replicated in the MBP, and more than 80% of the MBP sample reported at least one MRSE. MRAEs with negative valences and negative impacts on functioning occurred in 58% and 37% of the sample, respectively. LBEs, or MRAEs with lasting negative impacts, were reported by 6% to 14% of the sample, depending on the duration. LBEs were associated with greater frequency of informal mindfulness practice and could be predicted by the presence of categories indicative of dysregulated arousal. Open-ended questions underestimated the prevalence of MRSEs by nearly 70%.

The current results demonstrated two forms of convergent validity with the VCE study. Eighty percent of the VCE categories were replicated in the current study, which confirms that many of the MRSEs documented in practitioners of Buddhist meditation also occur in MBPs. Some of the categories that were not replicated represent some of the more severe experiences reported in the VCE study, such as those related to psychosis (delusions and hallucinations) and occupational impairment. Other categories that were not replicated in the MBP were experiences that are extremely common and could not be established as being causally related to mindfulness meditation training. For example, fatigue, cardiac changes, and gastrointestinal complaints are experienced by most adults (Hinz et al., 2017). Exclusion of such commonly occurring symptoms from counting as MRSEs validates that the MedEx-I is not simply measuring symptoms that would have occurred without meditation (i.e., base-rate-level symptoms). Experiences that were categorized as "other" (i.e., those that were documented in the MBP but did not fit into existing categories of the MedEx-I) were subsequently identified in the VCE study sample and in the final version of the codebook. Similar to the Minnesota Multiphasic Personality Inventory F(p) scale, these items may serve as a validity check because they detect exaggeration or overreporting of unusual experiences (Arbisi & Ben-Porath, 1995).

All events were counted as meditation-related only if they were new or worsening since beginning the mindfulness meditation program and were attributed to mindfulness meditation by the participant. The vast majority (> 80%) of events occurred during or immediately following a mindfulness meditation practice. Only 6% of events occurred as a result of either the all-day retreat or the working with difficulty practice. This challenges the idea that negative experiences are more likely to occur at higher practice intensities or when intentionally bringing attention toward difficult experiences (Baer et al., 2019). To the contrary, the majority of events occurred during daily home practice or during class. Duration and frequency of informal meditation practice during and after treatment were associated with more negative impact events and a higher likelihood of LBEs, which indicates a dose-response relationship.

Nearly 60% of the sample experienced at least one MRAE with a negative valence, suggesting that at least some transient distressing experiences during meditation are the norm and should be expected for most participants. Likewise, Baer et al. (2021) found that 67% to 73% of MBP participants reported having unpleasant experiences associated with mindfulness practice during or after the course. High rates of transient mood deterioration (60%–65%) similarly have been found following a single session of group therapy for depression or anxiety (Schneibel et al., 2017).

Nearly 40% of participants reported at least one MRAE that had a negative impact on life outside of meditation practice, which is similar to the rates of new

or worsening symptoms caused by psychotherapy when measured systematically with a questionnaire (42%–51%; Moritz et al., 2015; Rozental et al., 2019; Schermuly-Haupt et al., 2018). Thus, although transient negative experiences during MBPs should be expected, they may also affect participants' quality of life and functioning, require countermeasures or additional treatment, or affect their desire or ability to meditate.

LBEs, or MRAEs with enduring negative impacts, were reported by 6% to 14% of participants depending on whether *lasting* is defined as more than a month, more than a week, or more than a day. Similar rates of LBEs (3%–14%) have also been reported in psychotherapy (Crawford et al., 2016; Hansen et al., 2002; Lambert, 2013). Thus, despite ambiguity in definitions, the rate of LBEs that impair life or functioning from days to months in MBPs appears to be similar to other psychological treatments.

Duration has often been used to indicate severity of AEs and to differentiate transient discomfort from *disorders*, or problems that warrant clinical attention or interventions (American Psychiatric Association [APA], 2013; Baer et al., 2019; Lindahl et al., 2020). However, different symptoms require different durations to be considered clinically significant. For example, acute stress disorder requires a duration of 3 days, mania requires a duration of 4 days, depression requires a duration of 2 weeks, and PTSD requires a duration of 1 month (APA, 2013). Some symptoms, such as suicidality, hallucinations, or delusions, warrant intervention regardless of duration because of the risk to self or others. In the current study, although MRAEs that lasted less than a day were not counted as LBEs, some short-duration MRAEs were nevertheless significant. At least three participants reported MRAEs that caused impairments in driving, which also poses a risk to self and others. Thus, although duration may be used as a rough guideline for when to intervene, short-duration MRAEs should not be discounted. As Crawford et al. (2016) explained, "Even when negative experiences do not turn out to be lasting, they are unpleasant for the patient and have the potential to erode the patient's confidence in the therapist or therapy process and limit further engagement with the treatment" (p. 264).

Clinical implications

The majority of MRAEs occurring in this study, particularly those with negative impacts, are consistent with signs of dysregulated arousal (i.e., hyperarousal and dissociation; Frewen & Lanius, 2006; Treleaven, 2018). Symptoms of hyperarousal (e.g., anxiety and insomnia) were some of the most likely to be appraised as negative in both valence and impact and therefore may be more likely to be voluntarily reported and identified by teachers. Conversely, although dissociation symptoms (e.g., emotional blunting, derealization, and self-disturbance) were both less frequent and less likely to be appraised as negative, they were still associated with more than 5 to 10 times greater risk for LBEs. These results parallel findings from the VCE study, in which greater attenuations in senses of self, although not always unpleasant, were associated with a greater impairment in functioning (Lindahl & Britton, 2019). This means that reappraisal of dissociative symptoms via nonjudgmental acceptance is not sufficient to prevent impairment in functioning and should not constitute the only response. Instead, training in how to recognize dissociative symptoms as potential indicators of the need for intervention, which have recently been added to some mindfulness teacher training programs (Britton et al., 2017; Treleaven, 2018), may be important.

Research implications

The deficient performance of the open-ended question parallels findings in psychotherapy research: AE rates are proportional to how well they are measured (Bent et al., 2006). Single open-ended questions about AEs in psychotherapy have yielded AE rates of 5% to 20%, but those rates rise to 40% to 60% when asked systematically with structured questionnaires about specific experiences (Moritz et al., 2015; Rheker et al., 2017; Rozental et al., 2019; Schermuly-Haupt et al., 2018). In meditation studies, single open-ended questions about "unpleasant" or "unwanted" meditation effects have yielded rates of 25% of meditating samples (Cebolla et al., 2017; Schlosser et al., 2019). Given that the open-ended question in this study failed to detect more than two thirds of the MRAEs detected by specific queries, more accurate estimates are probably in the 40% to 60% range, similar to psychotherapy. These findings highlight the need for a validated, meditation-specific questionnaire to produce accurate estimates.

In addition to mode of measurement, the frequency of AEs and whether they constitute harm depends on how the terms *adverse* and *harm* are defined. For example, Baer and colleagues (2021) found that when harm was defined as being "worse off, in any way, after the course, than you would have been if you hadn't done the course" (p. 3), 4% to 7% of MBP participants said they had been harmed. When harm was defined as "sustained deterioration" (Baer et al., 2019; Duggan et al., 2014), as indicated by LBEs in the current study, harm rates were 6% to 14%. By contrast, the WHO (2010, p. 16) defined harm on a continuum that includes all forms of suffering of any duration, including experiences that are "subjectively unpleasant" and/or clinically

relevant. Following this definition would include all negative-valence and negative-impact events, and the current study's rates of harm would be 40% to 60%, which are similar to psychotherapy. Until such definitions are harmonized across treatments and studies, differences in frequency, including declarations of "no adverse effects," are likely artifacts of measurement or the lack thereof. In the meantime, providing precise and detailed descriptions of definitions and methods of measurement, as modeled in the current study, will help to clarify the nature and frequency of AEs.

Limitations

This study is the first to conduct a Phase 0–1 in-depth assessment of AEs in an MBP, which is only the first of many stages toward understanding MBP-related harms. Although the current study met its objectives to assess the nature and frequency of MRAEs in an MBP, a number of questions remain. Predictors of MRAEs, including participant characteristics, type or intensity of meditation practice, and teacher characteristics, are all important questions.

Because "the same treatment can have both beneficial and harmful effects" (Dimidjian & Hollon, 2010, p. 22), it is important to consider the balance between benefits and harms in clinical decision-making. For example, in the current study, clinically relevant events associated with impaired functioning occurred within a context of overall efficacy on multiple outcomes (Cullen et al., 2021), high practice compliance, and low attrition, which suggests that participants found the difficulties worth tolerating in light of expected or concurrent benefits or in comparison with not receiving treatment.

Although the frequency of MRSEs, MRAEs, and LBEs did not significantly differ between MBP variants, these statistical findings do not preclude the existence of practice-specific MRSEs or clinically meaningful differences. Instead, these findings simply replicate earlier findings (Lindahl et al., 2017) that the types of meditation found in MBPs—concentration (FA) and insight (OM)—are capable of causing MRSEs. Given that different meditation practices produce different types of effects, they are also likely to produce different types of MRAEs even if the overall frequency is similar. Future studies with larger, adequately powered samples and systematic MRAE assessment will be needed to address these important questions.

In addition, future research may want to address some of the limitations of the current study. For example, the current study queried only a subset of possible AEs: new or worsening symptoms of physical and psychological health that are associated with meditation practice. Similar to other psychological interventions (Rozental et al., 2018), MBPs may have additional unwanted effects, such as relationship ruptures, dependency, and time burden, that may contribute to dissatisfaction and discontinuation (Anderson et al., 2019).

The current study can produce estimates about MRSEs and MRAEs that occur within the first 5 months of practicing less than an hour per day but not a practice with a longer time frame or a more intensive practice. Although 25% of the VCE sample encountered meditation-related challenges within the first 50 hours or practicing less than 1 hr per day, the majority required more years of practice or more intensive practice such as meditation retreats (Lindahl et al., 2017). This suggests that the principle of a biological gradient, or that greater exposure should lead to greater incidence of the effect (Hill, 2015; Schunemann et al., 2011), likely applies to MRAEs.

The current sample was aimed at representing the average adult American mindfulness meditator and included individuals with stress, anxiety, and depression who were self-selected (meditation-seeking) and then carefully screened according to standard MBP exclusion criteria (Kuyken et al., 2012; Santorelli et al., 2017). However, the findings may not extend to individuals not seeking a meditation-based program (e.g., individuals who are randomly assigned or required as part of school or employment), children or the elderly, people with other physical or mental health conditions, or MBPs that assess prospective participants through group orientation sessions rather than 2-hr individual clinical interviews. Because individuals from minority ethnic or otherwise marginalized groups are more likely to report LBEs of psychological treatments (Crawford et al., 2016), it is likely that more diverse MBP samples will report higher rates of harms than the current (predominantly White) sample.

The current study measured only treatment completers and not participants who dropped out. At least one participant left because of worsening symptoms, and because AEs tend to lead to treatment discontinuation (Warden et al., 2009), it is likely that the AE rates in the study would have been higher if data could have been attained from dropouts.

At the request of the sponsor, the MedEx-I was administered as the last assessment of the study, 3 months after treatment concluded. This time point was selected to minimize Hawthorne effect-based scripting, in which repeatedly querying about AEs increases the likelihood of having or reporting them (Braunholtz et al., 2001). However, there are limitations to retrospective recall that may result in underestimates of more distal experiences. Likewise, although frequency and duration of meditation practice were similar to those in other trials (Parsons et al., 2017), self-reported meditation adherence may be prone to reporting biases.

Although the MedEx-I improved on safety monitoring practices by querying MRSEs by an independent assessor, a validated self-report questionnaire of the same content is still recommended for several reasons. The MedEx-I required hundreds of hours of in-person assessments and qualitative coding by specially trained experts and is therefore both impractical and nonfeasible for most researchers or clinicians. In addition to meeting the updated harms-assessment guidelines described above, patient-based, treatment-specific AE questionnaires are low cost and low burden, require no special training to administer, and are the only method that supports direct quantitative comparisons between studies. Although many medical fields (Corso et al., 1992) have been using such standardized treatment-specific AE scales for decades, behavioral treatments have recently started to develop their own AE instruments (Linden, 2013; Parker et al., 2013; Rozental et al., 2018) to keep up with AE monitoring standards and journal requirements (Hopewell et al., 2008).

Conclusion

All treatments cause some harm some of the time, and multiple sources suggest that MBPs are no exception. The current study found that the active ingredient in MBPs, mindfulness meditation practice—including FA and OM practices alone or in combination—was associated with both transient distress and enduring negative impacts on life and functioning at similar rates to other psychological treatments. Principles of informed consent require that treatment choice be based in part on the balance of benefits to harms and therefore can be made only if harms are adequately measured and known. The passive monitoring-based "don't ask, don't tell" approach to treatment-related harms is being replaced by updated guidelines and validated treatment-specific harms assessment across physical, pharmacological, psychological, and behavioral interventions. The current study is an attempt to bring MBP harms monitoring up to the standards of other treatments so that providers can identify events that require monitoring and intervention to maximize the safety and efficacy of MBPs.

Transparency

Action Editor: Stefan G. Hofmann
Editor: Kenneth J. Sher
Author Contributions

W. B. Britton developed the study concept and study design and supervised data collection. J. R. Lindahl performed data collection. J. R. Lindahl and D. J. Cooper performed qualitative analyses. N. K. Canby and R. Palitsky performed statistical analyses. W. B. Britton and J. R. Lindahl drafted the manuscript, and N. K. Canby and R. Palitsky provided critical revisions. All of the authors approved the final manuscript for submission.

Declaration of Conflicting Interests

W. B. Britton is an MBSR and MBCT teacher and has received financial compensation for this role. She is nominally affiliated with the Mindfulness Center at Brown University, which generates income by offering mindfulness classes to the public. She is the founder of Cheetah House, a nonprofit organization that provides information about meditation-related difficulties, individual consultations, and support groups, as well as educational trainings to meditation teachers, clinicians, educators, and mindfulness providers. This interest has been disclosed to and is being managed by Brown University in accordance with its Conflict of Interest and Conflict of Commitment policies. The author(s) declared that there were no other potential conflicts of interest with respect to the authorship or the publication of this article.

Funding

This work was supported by National Center for Complementary and Integrative Health Grants K23-AT006328-01A1 and UH2-AT009145.

Open Practices

The design and analysis plans for the experiments were preregistered clinicaltrials.gov and are available at https://clinicaltrials.gov/ct2/show/study/NCT01831362. The trial protocol was published with the primary outcomes (Cullen et al., 2021). The Medex-I interview, the main measure in the current article, was described in the published protocol but was not a primary or secondary outcome and was not accompanied by a statistical analysis plan. Current guidelines recommend that adverse events be reported descriptively, but that statistical analysis is typically inappropriate. The data discussed in the current article are largely descriptive; the statistical analysis (differences between treatments) was requested by reviewers. This article has received the badge for Preregistration. More information about the Open Practices badges can be found at https://www.psychologicalscience.org/publications/badges.

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Supplemental Material

Additional supporting information can be found at http://journals.sagepub.com/doi/suppl/10.1177/2167702621996340

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