

Research

Mindfulness Meditation Research: Issues of Participant Screening, Safety Procedures, and Researcher Training

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ABSTRACT

Increasing interest in mindfulness meditation (MM) warrants discussion of research safety. Side effects of meditation with possible adverse reactions are reported in the literature. Yet participant screening procedures, research safety guidelines, and standards for researcher training have not been developed and disseminated in the MM field of study. The goal of this paper is to summarize safety concerns of MM practice and offer scholars some practical tools to use in their research. For example, we offer screener schematics aimed at determining the contraindication status of potential research participants. Moreover, we provide information on numerous MM training options. Ours is the first presentation of this type aimed at helping researchers think through the safety and training issues presented herein.

Support for our recommendations comes from consulting 17 primary publications and 5 secondary reports/literature reviews of meditation side effects. Mental health consequences were the most frequently reported side effects, followed by physical health then spiritual health consequences. For each of these categories of potential adverse effects, we offer MM researchers methods to assess the relative risks of each as it pertains to their particular research programs.

The list of benefits associated with mindfulness meditation (MM) is growing. Interest in this ancient practice rooted in Buddhist philosophy seems to know no cultural or religious boundaries. Walsh and Shapiro write, "Meditation is now one of the most enduring, widespread, and researched of all psychotherapeutic methods."¹ Yet, while safety guidelines, participant screening procedures, and standardized researcher training exist for

some behavioral medicine practices (eg, exercise per the American College of Sports Medicine [ACSM] guidelines²), these have yet to be developed and disseminated in the MM field of study.

To assist those planning studies of MM, our goals in this paper are to (1) define categories of side effects of meditation with possible adverse reactions raised in the literature and by clinicians with extensive experience in the therapeutic delivery of MM, (2) propose a procedure for screening potential research participants and suggest safety procedures within each category, and (3) reduce the risk of potential iatrogenic harm to research participants by offering suggestions for researcher training in MM. Together, the authors contributing to this paper cover a broad range of expertise, including clinicians who regularly employ MM in their practices, specialists in MM facilitation from the *Theravada* tradition, and senior research scholars skilled in intervention, laboratory, and behavioral neuroscience methods.

MINDFULNESS MEDITATION DEFINITION

Mindfulness meditation (MM) involves completely attending to experiences on a moment-to-moment basis in an effort to cultivate a nonjudgmental, nonreactive state of awareness.³ MM is rooted in the traditional Buddhist practice of Vipassana, which translates literally as "seeing things as they really are."⁴ MM practice begins with sustained observation of the breath and expands to include awareness of physical sensations, thoughts, and emotional states as they arise in the present moment. This focus on present moment experiences trains attitudinal, relational, and cognitive capacities in practitioners with supporting changes in neurobiological substrates.⁵⁻⁷ According to Shapiro,⁸ this shift in focus from the breath to a variety of phenomena is what distinguishes MM from purely concentrative forms of meditation such as Transcendental Meditation (TM), which uses a mantra to centralize cognitive focus. Still, both MM and TM do involve concentrating on a specific object (eg, the breath); however, with MM this unified focus is then directed toward the entire field of awareness. Although meditation practices vary in the specific techniques employed, all involve a form of mental/attentional training.^{8,9}

This overlap in meditation techniques has recently been addressed by Lutz et al,⁹ who offer the description of 2 meditation styles, namely focused attention and open monitoring, noting that with MM, practitioners may include both styles in their practices, whereas techniques such as TM primarily involve focused attention. We have considered this overlap in MM styles in our presentation of potential adverse effects by drawing upon MM studies as

well as those reporting on related meditation techniques. We posit that when designing a study in an area of research where empirically tested safety procedures and standardized protocols are lacking, it is particularly important to consult the literature for reports of potential adverse effects attributed to the technique under investigation as well as any related techniques to maximize participant safety and facilitator awareness. As this is the case with MM, reports from small-n studies, secondary analyses, and the like involving MM-related forms of mediation warrant consideration. Beyond this, anecdotal evidence from clinicians who have observed negative consequences from MM with their patients is worth considering as well.

Please note: it was not our intent to evaluate the validity of the stated side effects reported in each of the articles cited herein. Such evaluations would require assessing how predictive each potential adverse outcome was from the meditation performed, how accurate the reporting author's analyses were, and determination of mitigating circumstances. Our intent was simply to report the possibility of these outcomes so future study designers may be aware of them and plan accordingly.

MINDFULNESS-BASED THERAPEUTIC APPROACHES

MM has been incorporated into various therapeutic interventions. These interventions are associated with beneficial therapeutic effects in cases of chronic pain,^{10,11} substance use disorders,¹²⁻¹⁹ depression,²⁰⁻²³ anxiety,^{24,25} and binge eating disorder.^{26,27} Therapeutic interventions that involve formal training in mindfulness skills include Mindfulness-Based Stress Reduction (MBSR),²⁸ Mindfulness-Based Relapse Prevention (MBRP),^{29,30} Mindfulness-Based Cognitive Therapy (MBCT),^{31,32} and Mindfulness-Based Eating Awareness Training (MB-Eat).³³ Other approaches that incorporate components of mindfulness into their therapeutic tenants include Dialectical Behavior Therapy (DBT)³⁴ and Acceptance and Commitment Therapy (ACT).³⁵

The developers of each of these therapeutic interventions are well-established scholars and skilled healthcare providers. As such, these developers and/or members of their research teams have specific training in patient/participant intake procedures and methods of responding to mental health-related adverse effects. Yet, with the favorable findings being reported with MM interventions, research interest is growing rapidly and, consequently, MM effects are being investigated by members of various guilds including neuroscience, cognitive, social and physiological psychology, medicine, and nursing under the supposition that MM is by-and-large a safe behavioral medicine practice. However, systematic evaluations of its safety have not been reported in the literature. One possibility is that the absence of reported adverse effects is taken as support for MM safety. We posit the following: (1) The absence of reported procedural cautions/warnings, side effects, or adverse events in well-controlled MM clinical trials does not necessarily mean that none exist. (2) Such reporting absence may simply represent the lack of a standard for reporting these issues/events within a new and rapidly growing field of study. (3) Moreover, consent and safety procedures do not routinely get reported in clinical trials,

leaving open the possibility that new MM researchers who seek to replicate published procedures may not go into the study fully prepared for what may occur nor include adequate protection for participants. It is this third effect that is our major concern and, hence, the focus of this paper.

CATEGORIES OF POTENTIAL ADVERSE EFFECTS

As demonstrated in Table 1, side effects of meditation with possible adverse reactions do occur. In light of research reports cited in Table 1 and recent reviews that discuss potential negative consequences of meditation, we thought it important to categorize potential adverse effects into (1) mental, (2) physical, and (3) spiritual health considerations. Within each category, we offer examples of specific side effects, cite cautionary reports for potential adverse effects, and label each effect as an absolute contraindication, a relative contraindication, or an issue worthy of consideration. Similar to the rationale applied to assessing safety in exercise research,² we define an absolute contraindication as a condition or circumstance under which it is inadvisable to include a participant in a research study or carry out the research altogether. With a relative contraindication, participation may be inadvisable under some circumstances but not others. Matters worthy of concern are so named due to the theoretical/anecdotal nature of support for their consideration. To assist researchers in determining contraindication status of potential research participants, we offer step-by-step sample screener schematics to guide researchers as they develop their own research screening protocols.

Category 1: Mental Health Considerations

As can be seen in Table 1, adverse effects on mental health are the most frequently reported negative consequences from meditation. Of those mental health consequences listed in Table 1, the reports of severe affective and anxiety disorders as well as temporary dissociative states and psychosis give primary cause for concern.³⁶⁻³⁸ One example of a severe anxiety disorder is Posttraumatic Stress Disorder (PTSD). PTSD is a diagnosis characterized by the aftermath of a traumatic event (eg, combat, sexual assault), during which a person experiences feelings of intense fear, helplessness, and horror. Symptoms include intrusive recollections and re-experiencing in the form of distressing memories and flashbacks; avoidance of thoughts, feelings and situations associated with the traumatic event; emotional numbing; and hyperarousal.³⁹ Because the practice of MM is contrary to the avoidance that is characteristic of PTSD,⁴⁰ when individuals initially engage in MM they may, thus, encounter avoided affect and experiences in a form that is extremely distressing (eg, flashbacks, intrusive thoughts and memories) and may put them at risk for potential retraumatization. In order to address contraindication status (eg, absolute, relative, matter worthy of consideration) for participants with a history of trauma or a diagnosis of PTSD, we

*As mentioned, we do not provide a systematic review of this literature here. Three current reviews are referenced in Table 1 and sources for each are provided in the Table Note. Interested readers are referred to those sources.

Table 1. Side Effects of Meditation With Possible Adverse Reactions

Source and Study Design	Adverse Effects	Category of Side Effects*	Meditation Type	Meditation Duration/ Intensity Description
Castillo ⁴³ : multiple case study	<ul style="list-style-type: none"> In all cases there were reports of <ul style="list-style-type: none"> Depersonalization Derealization Note: 3 of the 6 cases experienced symptoms after extended residential courses	MH	TM	Individual practices (daily frequency/duration not reported) and extended residential courses.
Chan-Ob and Bonnyanarunthee ³⁶ : multiple case study ^a	<ul style="list-style-type: none"> Case 1: Reports of psychotic symptoms, including <ul style="list-style-type: none"> Hallucinations Fear of persecution Disorientation Poor insight and judgment Reduced food intake (note: patient's prior history of hypophagia not reported) Insomnia reported as complete sleep loss (note: patient's prior history of insomnia not reported) Case 2: Reports of psychotic symptoms, including <ul style="list-style-type: none"> Hallucinations Delusions of grandeur Thought disorder Loss of appetite (note: patient's prior history of hypophagia not reported) Inability to sleep (note: patient's prior history of insomnia not reported) 	MH PH/MH PH/MH MH PH/MH PH/MH	specific type not reported	Case 1: symptoms reported after a 7-day intensive meditation retreat where it was suggested that one "...meditate all the time" (p 926). Case 2: symptoms reported after 3 consecutive nights of walking meditation throughout the night.
French et al ⁷⁹ : single case study	<ul style="list-style-type: none"> Feelings of anxiety Feelings of intense dysphoria Feelings of mania, including euphoria/grandiosity Reports of psychosis-like behavior 	MH MH MH MH	TM	Individual practice (daily frequency/duration not reported)
Jaseja ⁵¹ : review	<ul style="list-style-type: none"> Increased epileptogenesis susceptibility 	PH	Various methods	This is a theory paper reporting EEG and neurochemical meditation effects.
Kennedy ⁸⁰ : multiple case study	<ul style="list-style-type: none"> Case 1: Reports of depersonalization and derealization, including <ul style="list-style-type: none"> Autoscopy Double vision Grandiosity/elation Case 2: Reports of depersonalization and derealization Feelings of anxiety 	MH MH	MM	Two cases with individual practices. Case 1: meditation described as awareness training and yoga (daily frequency/duration not reported); Case 2: regular Arica practice ^b (reports practice on most days of the week for an unspecified duration)
Lazarus ⁸¹ : multiple case summary	<ul style="list-style-type: none"> Feelings of depression, including <ul style="list-style-type: none"> Attempted suicide following a weekend training course in TM (note: details of the attempt and patient's history of prior suicide attempts not reported) Feelings of anxiety, including <ul style="list-style-type: none"> Tension Restlessness/extreme agitation Reports of severe depersonalization 	MH MH MH PH	TM	The author summarizes a collection of clinical observations precipitated by individual TM practice (daily frequency/duration not reported).
Persinger ⁴⁹ : single case study	EEG revealed focal, temporal lobe, epileptic-like electrical changes recorded after 19 minutes of TM.	PH	TM	10-year TM veteran observed during a 30-minute session
Persinger ⁸² : survey study	Significantly more complex partial epileptic-like signs (ascertained from an author generated inventory ^c) observed in meditators compared to nonmeditators.	PH	TM	1081 university students were surveyed; 221 of those surveyed were experienced meditators

Table 1 continued. Side Effects of Meditation With Possible Adverse Reactions

Source and Study Design	Adverse Effects	Category of Side Effects*	Meditation Type	Meditation Duration/ Intensity Description
Sethi and Bhargava ⁸³ : multiple case study	<ul style="list-style-type: none"> • Case 1: Reports of psychosis, including <ul style="list-style-type: none"> - Delusions of persecutions/reference - Auditory hallucinations • Case 2: Reports of religious delusions 	MH MH/SH	Type not specified	Case 1 participated in 4 days of intensive meditation in isolation. Case 2 participated in a 6-day residential retreat
Shapiro ³⁸ : secondary analysis on a convenience sample	<ul style="list-style-type: none"> • Feelings of depression, including <ul style="list-style-type: none"> - Decreased life motivation/boredom - Increased negativity/self-judgment • Feelings of anxiety, including <ul style="list-style-type: none"> - Panic and/or tension • Feelings of dissociation, including <ul style="list-style-type: none"> - Disorientation/confusion • Feelings of meditation “addiction” • Reports of pain 	MH MH MH MH PH	Vipassana	Residential retreat; 2-week or 3-month duration with formal practice occurring a minimum of 10 hours/day.
VanderKooi ⁸⁴ : multiple case study	<ul style="list-style-type: none"> • Case 1: Report of psychotic break with <ul style="list-style-type: none"> - Hallucinations - Religious delusions • Case 2: Report of psychosis, including <ul style="list-style-type: none"> - Hallucinations - Intense fear and loneliness • Case 3: Report of psychosis, including <ul style="list-style-type: none"> - Hallucinations - Religious delusions 	MH/SH MH MH/SH	Zen, TM, MM	Three cases of psychosis following residential retreats. Case 1: 7-day Zen retreat, Case 2: 10-day <i>Theravada</i> retreat, Case 3: weekend MM retreat.
Yorston ⁸⁵ : single case study	<ul style="list-style-type: none"> • Feelings of mania, including <ul style="list-style-type: none"> - Increased talkativeness - Overactivity/restlessness - Distractible - Sexual disinhibition • Reports of psychotic symptoms, including <ul style="list-style-type: none"> - Thought disorder with flight of ideas - Grandiose delusions • Insomnia involving 5-days of reported sleeplessness (note: prior history of insomnia not reported). 	MH MH	Yoga and Zen (<i>Sesshin</i>) meditation	Yoga was described as a weekend class. <i>Sesshin</i> was described as an intensive weekend event. The patient also participated in a 2-month Zen Buddhist retreat (frequency/duration of daily practice not reported).

*MH=Mental Health, MM=Mindfulness Meditation, PH=Physical Health, SH=Spiritual Health, TM=Transcendental Meditation
^aSymptoms for the third case are not reported due to the presence of a known psychotic illness prior to the meditation course. ^bArica is a multifaceted practice involving kath-channel breathing, mantrams, and yantras (see: <http://www.arica.org> for more information). ^cThe Personal Philosophy Inventory^{47,80} assesses 13 clusters of complex partial epileptic items, which identify temporal lobe phenomenology. In addition to the specific references listed, this table was compiled from the review articles of Arias et al⁶⁸; Perez-De-Albeniz and Holmes³⁶; Melbourne Academic Mindfulness Interest Group⁴⁴; Lansky & St. Louis.⁴⁸

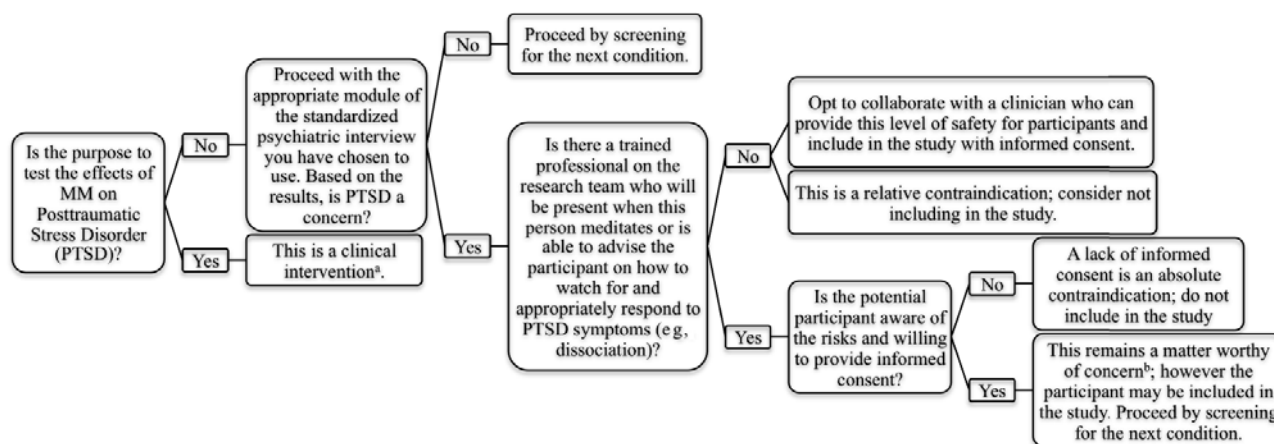
must first identify the specific research purpose.⁴¹ To illustrate, we provide a sample screener schematic for PTSD in Figure 1.

As depicted in Figure 1, if the purpose of the study is to improve symptoms for a clinically diagnosed condition such as PTSD, then the study is classified as a clinical intervention. We posit that it is highly unlikely that such studies would receive Institutional Review Board (IRB) approval or extramural funding without the necessary safety precaution of including a clinician trained to treat PTSD on the research team; this is due to the fact that PTSD is an absolute contraindication under such circumstances. This is not to say that MM interventions for PTSD should not be performed. Support for the contrary comes from reports of beneficial findings from empirically validated treatments for trauma and PTSD that include a MM component.⁴²

We address further positive MM outcomes in our discussion.

If, however, the purpose of the study is to investigate the effects of MM on a subclinical outcome (ie, not a diagnosable condition/illness) or to test an explanatory model (eg, a test of MM mechanisms of action), then including someone with PTSD in this example becomes a relative contraindication and screening at the outset of the study would assess inclusion: Basically, if conditions are met to provide adequate participant safety, such as inclusion of a trained clinician on the research team and obtaining informed consent, then inviting that participant to join the study may be appropriate if he or she meets all other inclusion criteria. For the researcher interested in exploring MM effects who is not clinically trained and does not have a member of their research team who is, we offer another option in our

Figure 1. Sample Screener Schematic for Posttraumatic Stress Disorder as an Example of a Mental Health Consideration for Studies of Mindfulness Meditation Effects



Note: ^aWe do not offer screening suggestions for a clinical trial. We believe it to be highly unlikely that such research would be funded or approved by an institutional review board (IRB) if an appropriately trained professional was not performing that work. ^bMatters worthy of concern will likely require an emergency/safety plan for IRB approval. We suggest that researchers prepare such a plan prior to running their study irrespective of IRB approval.

screening protocol (Figure 1) that will provide increased safety for potential participants. The option is to omit participants with mental health concerns such as PTSD in this example.

Finally, including a clinically trained person on the research team or having such a person available for consultation and referral throughout the duration of the study may achieve maximum safety in MM research. For each of the mental health consequences listed in Table 1, a screener schematic similar to Figure 1 could easily be generated by replacing PTSD with each condition of concern.

For example, another primary mental health concern associated with meditation as reported in the literature is temporary depersonalization, or feelings of being detached from one's mental processes or body. Certain types of meditation (eg, concentration practices like TM) have been found to induce depersonalization, possibly due to the related sensory deprivation.⁴³ Shapiro³⁸ reports on 2 incidences (i.e., 7% of the sample studied) in which attendees at *Vipassana* retreats experienced severe enough symptoms that they stopped meditating. One had practiced 2 years or less prior to attending a 10-day retreat, which left him "totally disoriented. . .confused, spaced out"³⁸. The other had 7 years or more of practice experience prior to attending a 3-month retreat. In a narrative he provided to the researcher he wrote "the mind set values that the retreat cultivated felt out of sync with the world. [Symptoms included]. . .lots of depression, confusion...severe shaking and energy releasing"³⁸. Still, a recent study by Michal et al⁴⁴ found an inverse relationship between mindfulness, which was operationally defined by self-reports using the Mindful Attention and Awareness Scale and depersonalization. It is unclear whether this association would generalize to interventions that involve MM practice. Until such time as empirical evidence is available, we offer our screener schematic to guide researchers in assessing contraindication status associated with depersonalization.

Another primary adverse effect within this mental health category is psychosis, which represents a loss of contact with reality and is characterized by the presence of symptoms including delusions, hallucinations, disorganized speech, and/or disorganized behavior.³⁸ The sensory deprivation and lack of sleep that are sometimes associated with intensive meditation practice may serve as triggers for psychotic episodes among those who are predisposed to such a condition. As can be seen in Table 1, several case reports of psychotic episodes precipitated by meditation exist in the literature. While this may be attributed to meditation intensity, such as participation in residential retreats, the limited and preliminary nature of this evidence warrants a cautious approach to using meditation with individuals predisposed to psychosis. Cautions seem particularly important for individuals with acute psychosis, mania, or suicidality and those noncompliant with prescribed antipsychotic medications. For example, as detailed in Table 1, most reported instances of post-meditation psychosis followed very intensive meditation practices.^{36, 83, 85} The one report of attempted suicide following an intensive TM training course⁸¹ presented in Table 1 is hard to interpret given that the details of the attempt and the patient's history of prior suicidal attempts are not reported. Thus, the conservative approach to protecting research participants would be to adjust the screener schematic we provide in Figure 1 to assess acute psychosis, mania, or suicidality so that the contraindication status of such individuals can easily be determined.

If proposed study outcomes do not include assessment of mental health, the general consensus among MM investigators is to still screen for mental health concerns as precautions.⁴⁵ However, we must underscore that no standard exists for this practice nor do all empirical reports published provide details on this screening, leaving open the possibility that an investigator new to this field of research may fail to exercise such precautions. In addition, the means by which researchers determine the cur-

rent and/or past mental health status of potential research participants is with structured psychiatric interviews. There are a few types of structured interviews available for research purposes such as the Composite International Diagnostic Inventory.⁴⁶ Interviewer training is a prerequisite to use, in part, because the administration of these interviews is potentially harmful to respondents in and of themselves. For example, to screen for clinical levels of anxiety, participants are asked to recall stressful or potentially traumatic events, and these recollections may produce negative emotional reactions symptomatic of the anxiety condition. As we propose in our screener schematic, adding appropriately trained clinical professionals to the research team would improve participant safety.

Category 2: Physical Health Considerations

As reported in Table 1, adverse effects on physical health are the next most frequently reported negative consequence of meditation; these involve neurological and somatic problems. Based on the extant literature, the neurological concern surrounding meditation is increased epileptogenesis (ie, risk of seizures). Seizures are sudden disruptions in the brain's electrical activity that give rise to altered consciousness and/or behaviors. Epilepsy is the clinical diagnosis for a condition characterized by recurrent seizures. According to the Epilepsy Foundation of America, more than 3 million Americans suffer from seizure disorders, and it is estimated that 6% of the US population will experience a seizure in their lifetime.⁴⁷ While often scary to observers, most seizures are not life threatening. Conversely, status epilepticus, or long-lasting/continuous seizure, causes unconsciousness and respiratory distress.⁴⁸ Moreover, the burden associated with a seizure occurrence extends beyond the actual event in terms of lifestyle limitations (eg, loss of driving privileges).

As reported in Table 1, occurrences of seizures during meditation exist.^{49,50} An emergent body of literature evinces electroencephalographic (EEG) alterations from meditation including MM. According to Jaseja, meditation-induced neuronal hypersynchrony and neurochemical increases in glutamate and sero-

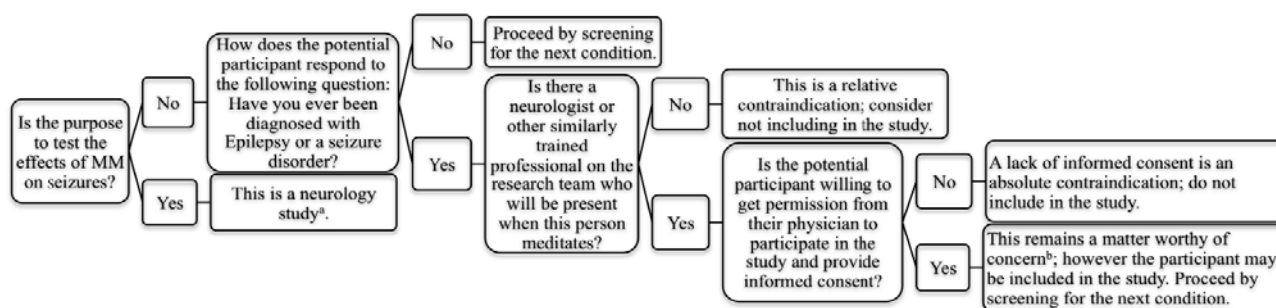
tonin may decrease the seizure threshold.⁵¹ Given that increased cortical gamma wave synchrony has recently been observed during MM in both experienced practitioners⁵² and meditation novices,⁵ screening for seizure history in potential MM research participants is warranted to maximize participant safety. Furthermore, the work of Jha et al⁵³ reveals that subsystems of attention including focusing components are implicated in MM. This is noteworthy given that focused attention is epileptogenic⁵⁴⁻⁵⁶ and is listed by the Epilepsy Foundation of America as a seizure trigger.⁵⁷

Therefore in Figure 2, we provide a screener schematic for this neurological concern in adults as an example for the physical health considerations category. In instances where the research question involves the use of MM therapeutically for epilepsy, we label this as a neurology study, which would be performed under the care of a physician.

Based on the evidence referenced in Table 1, another physical health consideration with meditation is somatic discomfort or pain. In the manualized mindfulness-based therapies previously mentioned (eg, MBSR), consideration of discomfort is addressed by providing postural options for MM practitioners (eg, the use of a chair rather than sitting on the floor). Furthermore, some forms of MM involve physical activity (eg, walking meditation) that prevents the muscle/joint strain of maintaining a single posture during a MM session. Yet some scholars have begun to consider the need to deconstruct mindfulness-based therapy options in order to systematically investigate efficacy-effectiveness and explanatory models of the meditation components.⁴¹ With this movement, new considerations for participant safety are warranted. If, for example, a researcher wishes to systematically investigate the effects of a body-scan form of MM compared to Hatha yoga (a movement form of MM) on an outcome, kinesthetic concerns arise warranting participant screening for neuromuscular/joint-related illnesses negatively affected by maintaining a particular posture through the duration of a MM session.

One such neuromuscular/joint-related illness is arthritis, a

Figure 2. Sample Screener Schematic for Seizure Disorder/Epilepsy as an Example of a Physical Health Consideration for Studies of Mindfulness Meditation Effects in an Adult Sample



Note: ^aWe do not offer screening suggestions for a clinical trial. We believe it to be highly unlikely that such research would be funded or approved by an institutional review board (IRB) if an appropriately trained professional was not performing that work. ^bMatters worthy of concern will likely require an emergency/safety plan for IRB approval. We suggest that researchers prepare such a plan prior to running their study irrespective of IRB approval.

collective term used to label painful joint diseases. Common forms include rheumatoid arthritis, an autoimmune disease causing chronic pain, inflammation, and stiffness in several joints: and osteoarthritis, which is due to a loss of cartilage between joint bones typically affecting fewer joints more intermittently than the rheumatoid form. Immobility exacerbates both forms of arthritis, while moderate-intensity exercise is associated with symptom improvements.^{58,59}

Sedentary MM results in joints being held in a certain position for up to 30 minutes or more. This may result in uncomfortable kinesthetic sensations (Table 1) from inactivity or fatigue of postural muscles if a certain posture is held for the duration of the practice. This type of discomfort is exacerbated in persons with arthritis,⁶⁰ so to provide maximum safety for arthritic research participants active forms of MM (eg, walking) are advised. However, if the research goal is to test sedentary MM effects on some other outcome than arthritis symptoms, arthritis should be treated as a relative contraindication and would follow that pathway for screening in our Figure 2 schematic.

As also pointed out in Table 1, physical health concerns included loss of appetite, reduced food intake, and difficulty sleeping. These findings must be interpreted with caution as the reporting authors cited in Table 1 do not provide information on participants' prior history with hypophagia or insomnia. Moreover, such side effects may not be adverse events. For example, hypophagia may be health promoting if it is the result of reduced anxiety leading to reductions in stress-induced eating.

Category 3: Spiritual Health Considerations

In Table 1, we also reference studies in which negative consequences to spiritual health, specifically cases of religious delusions, have been reported. Spirituality can be defined as the subjective dimension of religious experience.^{61,62} As a measurable construct, spirituality is multifaceted with components, including a search for truth and meaning in life with some level of transcendence and personal transformation.⁶³ Spiritual well-being has been operationally defined as one's overall sense of life purpose and satisfaction and one's sense of well-being in relationship to God or other deity.⁶⁴ This interconnection between religious and existential well-being encompassing one's spiritual health may serve as a point of concern in MM research given the references to religious delusions we include in Table 1.

Protection from harm in this category is not a matter of screening per se; rather, it involves obtaining informed consent. For example, to adequately inform participants of their involvement in a study where they will engage in MM, the meditative components would be disclosed and questions regarding meditation are likely. Therefore, initially, it may be necessary to discuss with participants any negative associations of MM borne out of misunderstandings from history in an effort to abate any fears participants may have of violating their own foundational religious tenants by engaging in meditation. Briefly, MM practices are deeply rooted in the Buddhist tradition and are practiced in Buddhist monasteries throughout Southeast Asia. It was to these monasteries that Westerners began to travel to in the

1960s and 1970s specifically to learn to meditate. Some of these Western practitioners returned to the United States and pursued careers in psychology and medicine, and out of this fusion of Eastern and Western practices, the mindfulness tradition was acculturated.^{65,66} What may still linger in laymen's thinking are the associations of MM with the 1960s and the monastic lifestyle, which in Western culture may carry certain stereotypes and expectations. While researchers could point out that traditions other than Buddhism, such as Hinduism and Christianity, recommend meditation to their followers or incorporate meditation as a form of worship (ie, TM or centering prayer, respectively), further elaboration will require education on the part of the researcher. Therefore, there is no clear-cut schematic we can offer researchers to address these spiritual concerns. Instead, to maximally protect participants by facilitating the acquisition of informed consent, MM specific education would be helpful.

It may also be necessary on occasion to address unrealistically positive associations or expectations associated with meditation, such as the attainment of blissful states or an escape from one's day-to-day experience. Although MM practices may lead to states of peacefulness and deep relaxation, these expectations are secondary to the goals of the MM, which are to encourage nonjudgmental openness and awareness of all phenomena, including those that are challenging or unpleasant. Thus, an understanding of these goals is extremely helpful in clarifying misconceptions. In Table 2, we provide the type, source, and contact information for numerous educational opportunities in MM. Even a trained clinician or other healthcare provider may lack the ability to address participants' questions regarding the spiritual nature of MM if their training did not include such study. We are not suggesting that knowledge of the dogma of all religious practices is necessary, rather the simple understanding of how MM differs from or compliments other techniques and practices would allow one to address concerns that may preclude garnering informed consent.

Another issue related to research safety, and one that is actively being debated among MM experts, is MM training for researchers. Although the general consensus is that training is needed, no standard exists.⁴⁵ In Table 2, we provide researchers with numerous training options. Formal training exists for the few mindfulness-based interventions developed thus far. For example, clinically-oriented researchers interested in investigating the effects of a mindfulness-based approach to preventing relapse related to depression or substance use have available to them course options for in-depth training in these therapeutic approaches (MBCT^{31,32} and MBRP,^{29,30} respectively). For researchers investigating MM effects using methods other than the formal mindfulness-based interventions, we list online courses and resources for informal training (Table 2).

We stress again, that currently no prerequisite training standard for researchers exists. As such, MM interventions may be taught and investigated by well-intentioned but inadequately trained researchers creating another safety issue: iatrogenic harm. Another option for researchers interested in investigating the effects of MM but lacking the personal skills and expertise

Table 2. Sources for Mindfulness Training

Type	Source	Web Address
Formal Training*		
MBSR	Center for Mindfulness in Medicine, Healthcare, and Society, University of Massachusetts Medical School (Jon Kabat-Zinn and Saki Santorelli)	www.umassmed.edu/cfm/index.aspx
MBCT	University of Toronto, Department of Psychiatry; University of Oxford, Department of Psychiatry (Zindel Segal, Mark Williams and John Teasdale)	www.mbct.com
MBRP	Addictive Behavior Research Center, University of Washington, Department of Psychology (G. Alan Marlatt)	http://depts.washington.edu/abrc/MBRP.htm
MB-EAT	The Center for Mindful Eating, Indiana State University, Center for the Study of Health, Religion and Spirituality (Jean Kristellar)	www.tcme.org
MB-CP	The Professional Development and Teacher Training Program at The University of California San Francisco Osher Center for Integrative Medicine	www.osher.ucsf.edu
Informal Training Available Online		
eMindful.com		www.emindful.com
Mindful Healing Series		www.aliveworld.com
Dharmaweb		www.dharmaweb.org
Other Organizations That Offer Seminars/Educational Opportunities		
Insight Meditation Society		www.dharma.org
Mind and Life Institute		www.mindandlife.org
Dharma Ocean Foundation		www.dharmaocean.org
Mindful Awareness Research Center	UCLA Semel Institute	http://marc.ucla.edu/
Omega	Institute for Holistic Studies	www.eomega.org
Mindsight Institute	Dan Siegel	http://mindsightinstitute.com
Other Organizations That Offer Residential Retreats		
Plum Village Practice Center	Thich Nhat Hanh	www.plumvillage.org
Spirit Rock	Founded by Dharma Foundation	www.spiritrock.org
Shambhala Mountain Center	Founded by Chögyam Trungpa Rinpoche	www.shambhalamountain.org
Common Ground Meditation Center	Mark Nunburg	www.commongroundmeditation.org
ART	Awareness and Relaxation Training	www.mindfulnessprograms.com
Hollyhock		www.hollyhock.ca/cms
Dharma Ocean Retreat Center	Reggie Ray	www.dharmaocean.org
Santa Barbara Institute for Consciousness Studies	B. Alan Wallace	www.sbinstitute.com
Other Resources		
The Meditation Spot	Contains numerous resource links	www.aboutmeditation.com
The Institute for Meditation and Psychotherapy		www.meditationandpsychotherapy.org
*MBSR=Mindfulness-based stress reduction, MBCT=Mindfulness-based cognitive therapy, MBRP=Mindfulness-based relapse prevention, MB-EAT=Mindfulness-based eating awareness training, MB-CP=Mindfulness-based Childbirth and Parenting, ART=awareness and relaxation training, UCLA=University of California, Los Angeles.		

required to conduct these interventions is to hire an MM expert who can both deliver the intervention and guide the researcher in development and execution of the research protocol.

And finally, related to the subject of training is the issue of self-practice. While the popular opinion is that maintaining a MM practice is a necessary first step towards credible and safe MM instruction,⁴⁵ again, no standard for this exists. We suggest that just as it would be unrealistic to expect someone who had never exercised before to have the cardiorespiratory endurance, physical strength, and simple know-how to instruct a group exercise class, it is also unrealistic for someone with no meditation experience to have the mental endurance, flexibility, and ability to model MM for research participants. In the Buddhist tradition, MM teachers were seen as experienced guides escorting individuals on a deep inward journey.^{67(p74)} Keeping with this tradition then, if a MM researcher plans to conduct a research study without the guidance and support of an MM expert and has not visited this territory before, his or her ability to safely guide a research participant will be limited. The mindfulness-based interventions listed in Table 2 all consider modeling an attitude of openness and nonjudgement to be a foundational skill to teaching MM; these are skills that come from personal practice. Further, MM essentially involves private experience, and it is therefore quite difficult, if not impossible, to understand unless one has done it oneself. Therefore, an inexperienced researcher may be unable to answer participant questions, again preventing the acquisition of informed consent. Therefore in Table 2, we offer numerous resources to assist researchers in developing their own self-practice.

Furthermore, we suggest that those new to MM consult with a more experienced practitioner. Interestingly, this is how the practice of MM was shared historically within the *Theravada* tradition. *Theravada* means “way of the elders.” This tradition stresses the importance of passing foundational teachings along generational lines. The elders shared the guidelines regarding the training of teachers and students and the standards of safety built into this type of training. More advanced practitioners have years of personal experience from their own practice and instruction to draw upon in teaching novices. This leadership can help novices deal with their own insecurities or perceived barriers to MM such as feelings of skepticism, embarrassment, and self-judgment while offering tools to guide them on their paths.⁶⁸ While it appears that rich training from spiritual teachers has informed a few of the developers of mindfulness-based methods (eg, in *Coming to Our Senses*, Jon Kabat-Zinn writes of his studies with Zen master Seung Sahn,⁶⁹ and Alan Marlatt writes of numerous spiritual teachers including Pema Chödrön in his *Personal Journey*⁶⁸), this practice does not appear customary among MM researchers, which is curious given how common consulting and interdisciplinary collaboration has become in scholarly activities.

DISCUSSION

Our purpose was to address issues of participant screening, research safety, and researcher training in the MM field of study;

it was not to evaluate the validity of reported adverse events in the studies cited. Rather, the studies cited herein were used for the purposes of creating guidelines and assessing potential areas of difficulty. We summarize research that supports 3 categories of health-related concerns that may be negatively affected by MM, namely, physical, mental, and spiritual health considerations. Drawing upon the extant literature, we provide examples of risks within each of these categories, and we provide step-by-step participant screening schematics or offer research safety procedures applicable to MM research. Given that no standard for prerequisite training or self-practice exists for MM researchers we provide many resources for MM training and education in an effort to reduce iatrogenic harm.

We recognize that limitations to safety assertions exist at this time. For example, the majority of the reports cited in Table 1 are case studies or secondary analyses reporting adverse effects in a post-hoc fashion. For example, the cited case reports of psychotic episodes precipitated by meditation occurred in participants attending intensive meditation retreats rather than brief mindfulness interventions.⁷⁰ These retreats are not only rigorous in the intensity and duration of meditation practiced, but any adverse effects of MM are confounded by factors such as sensory deprivation, loss of sleep, and fasting, all of which may serve as precipitants for a psychotic episode. Thus, it is difficult to interpret the direct nature of the relationship between meditation and adverse outcomes based on these and similar reports.

The greatest limitation lies in the simple impracticability of directly and systematically investigating meditation-induced harm. Thus, as we posited earlier, a cautious approach to using meditation in research is warranted in the face of the limited and preliminary nature of current evidence in order to maximize participant safety.

It is important to note that MM practice is different from interventions such as MBSR that includes MM practices along with a discussion of the effects of stress or MBCT that is an integration of MM with cognitive-behavioral exercises and activities. However, the practices included in these interventions are traditional MM practices (eg, body scan, sitting meditation). Further, these practices are at the core of these programs and designate these programs as being “mindfulness-based.” Thus, it is our opinion that the considerations that exist for these interventions should be the same as those that exist for other MM practices.

As a show of our strong support for clinical investigations of MM therapeutic effects, we point out that an emergent body of research suggests therapeutic benefits for some of the risks we have listed here. To date, research evinces benefits from mindfulness-based interventions for several mental illnesses, including mood,⁷¹ psychotic,⁷² and anxiety disorders²⁴ as well as prenatal stress and depression.⁷³ Similarly, therapeutic benefits from mindfulness-based interventions exist for physical ailments including neuromuscular disorders,^{74,75} chronic pain^{10,76} and neurological conditions.^{77,78} Again we underscore that these clinical interventions are being carried out by those with specific training aimed at protecting the patients they serve. Furthermore, administrators of some mindfulness-based inter-

ventions (eg, MBSR), require that patients receive a complete medical examination prior to participating in the program.²⁸ Yet it is because of our support for and our active involvement in MM research that we recognize a lack of reporting of safeguards. In this paper, we summarize research safety concerns, offer participant screening guidelines, and provide information on MM training and education, in an effort to reach the scientific community-at-large. For it remains of utmost importance that scholars protect research participants, especially those who belong to high-risk/special populations, by appropriately assessing risk and determining contraindication status until such time as empirical evidence proves the safe inclusion of all persons in general MM research.

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