What Are Adverse Events in Mindfulness Meditation?

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Abstract

Mindfulness meditation has become a successful treatment of both physical and psychosocial ailments over the past decade. Mindfulness-Based Stress Reduction (MBSR) and Mindfulness-Based Cognitive Therapy (MBCT) are now implemented in various clinical and hospital settings for the treatment of stress, depression, substance abuse, and chronic pain. However, given mindfulness meditation's exponential rise in popularity, scientific and media reports have called for the evaluation of mindfulness meditation's safety for those who participate in its programs. Studies have described adverse events, such as anxiety and pain, and more severe events like psychosis, that have been associated with mindfulness meditation. However, there has not been a consistent, systematic way to define and report adverse events in meditation randomized control trials. The objective of our viewpoint was to dispel the notion that these emotive feelings and sensations are adverse events due to mindfulness meditation. Instead, they are actually expected reactions involved in the process of achieving the true benefits of mindfulness meditation. For the more severe outcomes of meditation, for example, psychosis and mania, these events are confounded by other factors, such as the intensity and length of the meditative practices as well as psychological stressors and the psychiatric histories of those affected. Comparatively, mindfulness-based programs like MBSR and MBCT are shorter in duration and less intense. They are designed to be adapted to their participants' needs as to not induce pain or panic. Mindfulness meditation teaches its students to learn how to deal with their minds and bodies instead of using maladaptive coping techniques. Thus, we urge that further research in mindfulness meditation consistently use the definition of adverse events as those which lead to severe outcomes or hospitalization.

Keywords

mindfulness, adverse events, meditation, mindfulness-based programs

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The research evidence for mindfulness-based programs (MBPs) has grown in recent years, as has their popularity. However, scientific and media outlets have published cautionary reports about meditation's possible contraindications and potential for harm, stating that there is insufficient research regarding the safety of mindfulness meditation.[1,2] All human subject research must protect the safety of its participants and report intervention-related adverse events as required by the CONSORT guidelines. Yet, more than 80% of meditation trials do not describe whether there were study-related adverse events.[3] Several studies have attempted to define meditation-related adverse effects (MRAEs) in order to make reporting more systematic, but definitions remain inconsistent.[3,4] Similarly, harm caused by psychological interventions are well known, but defining and reporting adverse events uniformly in randomized controlled trials have been difficult given the wide variability.[5]

It is important to separate out the research study's reportable serious adverse events, such as hospitalizations or serious harm, that are associated with the mindfulness meditations vs the mild or moderate adverse events that are

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transient and not serious. Another complication in the evaluation of adverse events in MBPs is the reality that increased awareness, which is an important intention of mindfulness meditation, may include increased awareness of discomfort. Whether physical or emotional, this hallmark of mindfulness may appear to be a mild adverse event, but it is actually expected and may ultimately be part of the process of achieving a beneficial outcome of meditation practice. Mindfulness students are encouraged to turn toward their distress and suffering as they learn to examine, without judgment, their existing habits, with the aim of pausing and discerning new choices. Thus, it is important to be clear about definitions and expectations when describing adverse events, particularly non-serious and serious adverse events, as well as determining whether they are related to MBPs itself.

Several studies have recently emerged arguing against the classification of certain symptoms as adverse events due to mindfulness meditation. Baer et al. (2021) found that in their two samples (school teachers completing a personal mindfulness course, n=84, and university students completing a mindfulness course, n=74), about two-thirds of participants in each study reported unpleasant experiences, which included thoughts, emotions, and sensations.[6] These sensations however were consistent with the types of difficult experiences mindfulness teachers generally expect given the increased awareness of one's present situation. Participants also indicated that they did not perceive any worsening of symptoms or blame mindfulness for the symptoms they experienced. Only one participant in the student group at the 6-week follow-up (n=60) reported harm (defined in the study as "worse off, in any way, after the course, than you would have been if you hadn't done the course"), and this person also showed reliable deterioration in mental health. For the rare deterioration that may occur, it is not only important that mindfulness teachers communicate early with the participant and their healthcare provider to address concerns, but teachers should also be equipped with the necessary training and skillset to recognize and respond appropriately to participants. Mindfulness teaching programs have already used prior unwanted events as learning opportunities for their classes, but these teaching moments should further include safeguards for adverse events.[7] Difficult experiences are common, expected, and part of a mindfulness intervention. In terms of adverse event reporting, the experiences described above would have likely fallen into a non-serious event classification.

In clinical research studies involving human subjects, unwanted symptoms may have been reported as expected and transient adverse events. Aizik-Reebs et al. (2021) investigated the momentary and persistent adverse effects associated with a 21-day MBP (three weekly 90-min group mindfulness training sessions and three 30-min individual mindfulness training sessions delivered via web-based videos). They found that while 87% of participants experienced at least one momentary adverse event while mediating, namely, anxiety, they postulated that the 25% of participants who sustained post-intervention adverse events in daily living were due to an increased awareness of their internal pre-existing states.[8] In other words, there are actually no *increased* adverse events attributed to mindfulness meditation, and the events which *do* arise are managed by teachers because these experiences *should* be expected given the increased awareness of experience that typically occurs with mindfulness meditation. The Aizik-Reebs et al. (2021) study highlights the importance of teachers and research teams continuing to support the well-being of new meditators following the intervention.

With mindfulness, the aim is not to habitually suppress or avoid unpleasant emotions. It is to become aware of feelings and sensations using adaptive strategies, such as acceptance and reappraisal.[7] Similarly, mindfulness meditation per se does not generate chronic pain. The pain already exists for participants. The goal is to teach participants how to work with discomfort instead of using maladaptive techniques. MBPs are able to be adapted to participants' needs due to built-in flexibility. For instance, when participants are uncomfortable focusing on the breath (at the heart of many mindfulness methods), they can be invited to focus on another sensory object. If participants are uncomfortable focusing on specific body parts during the body scan, they can skip that body part. While participants learn to be in the present moment with discomfort during the course of an MBP, they also learn to discern the types of internal or external stimuli or discomfort that could trigger panic or other psychological distress and then choose a more compassionate response. Current mindfulness education also instructs teachers about trauma-sensitive approaches with relevant theories and modifications that can be incorporated into MBPs to avoid precipitating distress in patients with a history of trauma.[9] It is important however to clarify with participants that mindfulness is not synonymous with relaxation and positive thinking, and that it is possible to have uncomfortable experiences such as physical pain, uncomfortable thoughts, images, or memories and still be okay. We propose that this practice applies to participants new to mindfulness taking part in programs of 8-week duration or less. For more intensive meditation practices, it may be different.

Qualitative studies and anecdotal case reports over the years have described more severe adverse events, including the onset of psychosis and mania, that occurred in close temporal proximity to the meditation and could therefore be attributed to the meditation itself.[2,10] These reports, however, described periods of intensive (many hours per day with few breaks) or long-term (thousands of hours of committed meditation) practice, not the more benign engagement expected in everyday programs for the public like MBPs. The authors of such case reports even warn that psychosis related to meditation encompasses other factors besides meditation itself, such as past psychiatric history, sleep deprivation, and social stressors causing maladaptive behaviors. It is important to evaluate adverse events associated with intensive meditation practice separate from the comparatively shorter,

teacher-led MBPs. These courses typically consist of 8-weekly discussion and meditation instruction sessions each lasting 2–3 hours. Thus, we propose that MBPs not be classified as intensive meditation practice. Although meta-analyses on clinical and nonclinical populations indicate MBPs for a range of conditions, the lack of *extensive* data on harmful adverse events and misconceptions about these events have cast doubts for clinicians and the public. It is therefore important that the field of mindfulness be consistent in defining serious adverse events as those which result in hospitalizations or serious harm.

Multiple studies specifically looking at contraindications and adverse events experienced by participants learning meditation in MBPs reveal that serious adverse events are rare and mainly occur with intensive meditation practice.[2,10] Adverse events, as required to be reported in all human subject research, has not revealed serious outcomes that needed hospitalization or caused serious harm due to mindfulness meditation. This likely explains why MBPs are considered safe. Nevertheless, flexibility in mindfulness approaches and mental health-focused teacher training are critical to working with participants who need instruction on alternative methods to practice mindfulness without triggering panic, trauma memories, or other discomfort. Additionally, the reflective approach of mindfulness will not appeal to all persons, especially for those not ready to work with the increased awareness of thoughts, emotions, and sensations that occurs with mindfulness methods. Therefore, it is important to accept that mindfulness is not for everyone. While MBPs are readily adaptable and teachers are trained to respond to adverse events, patients with severe symptoms, such as untreated trauma, active suicidal ideation, or serious substance abuse, should be screened and excluded from MBPs given the risk of further deterioration or harm.[9] The majority of MBPs are short (8 weeks or less), do not have serious adverse events reported in research because they do not meet the definition put forth by regulators, and may have transient mild unwanted events that would be expected given the increased awareness that occurs with mindfulness meditation. As the field of mindfulness continues to progress, defining adverse events is critical and would allow for consistency across research studies and clinical practice.

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