As eStudy Title: Adverse psychiatric effects of intense meditation practices

Protocol Version	Protocol Section	Current Protocol Language	Revised Protocol Language	Rationale for Change
2.0	All	Main focus of study = survey +/- interview	Changed language to prioritize interview first, then +/- survey	Current plan is to do interviews but may use survey in future

IRB Protocol

1. Title of the Research Project
Adverse psychiatric effects of intense meditation practices

2. Background/Problem Statement
Mindfulness interventions are based on a rich foundation of teachings and practices that span millennia. For decades, Eastern philosophical and medical teachings have been practiced by millions in the USA alone, and even integrated into modern Western medicine. Various methods from Hindu, Buddhist, Daoist, Zen and other traditions have been incorporated into protocols such as Mindfulness-Based Stress Reduction (MBSR), Mindfulness-Based Cognitive Therapy (MBCT), mind-body medicine, the relaxation response, and many others. A burgeoning number of randomized controlled trials have been conducted related to the efficacy of these meditative approaches for physical and mental health, and many, if not all, have shown some health-related benefit.

Considerably less research has been conducted and published on potential unintended or even 'negative' effects of meditation practices. Although a systematic review from 2018 noted very few adverse reactions or adverse events related to meditation practices. While very few prior trials have measured and reported adverse events, almost all of the very few trials that have measured and reported adverse events have relied on passive event reporting, which is extensively documented to greatly underestimate adverse event incidence. Most of the published research on the safety of meditation has been related to controlled clinical trials. In contrast, many meditation retreat centers conduct 3, 7, 10 day and longer retreats, but there are, to date, no reports that have systematically collected data on adverse effects that have arisen during such retreats. Therefore, much less is known about potential spiritual or psychiatric challenges that occur on such retreats. Prior case reports and case series have highlighted the potential for mania, psychosis, hallucinations, depression, dysphoria, and various other potentially undesirable effects of intense meditation.

Most experts assert that these events represent rare, though existent, phenomena. This research team recognizes that positive effects of mindfulness anecdotally far outweigh the negative ones. This study seeks to obtain survey and interview data from healthcare providers who have treated individuals who have had unwanted or negative reactions related to meditation.

3. Objectives:
A. To describe clinical manifestations of unintended/negative reactions to meditation.
B. To compare meditation-related symptoms and signs to other forms of psychiatric conditions, such as schizophrenia, psychosis, bipolar mania, depression, and drug-induced psychosis.
C. To collect data on treatment interventions in a patient population characterized by meditation-related events.

D. To collect data on treatment outcomes in a patient population characterized by meditation-related events.

4. Study Design/Methodology:
This will be a qualitative and quantitative interview & survey study on providers who have cared for patients / clients with unwanted or negative reactions/outcomes associated with meditation. This can include organized, intensive meditation retreats, or effects from short term mindfulness-based clinical intervention sessions. We intend to interview +/- survey 20-30 providers. We will collect audio and/or audio/video interviews communications with these providers to collect qualitative data. We will use electronic surveys via Redcap for further follow up if necessary.

5. Subject Recruitment Methods
We will recruit subjects based on proximity to major centers of meditation retreats. We will rely on the professional networks of our research team to locate providers. If a provider has no experience treating patients with these conditions, we will not complete the survey or conduct an interview. Initial contact will be made via email or phone call.

6. Informed Consent Process/Complete Waiver Process:
All subjects in this study will be healthcare providers or spiritual guides. We will use a preamble consent prior to administering the interview questions or survey.

7. Research Procedures:
We will not have any direct patient contact. We will not interview patients for this study, instead gathering de-identified background and clinical information from healthcare practitioners.

8. Minimizing Risks:
We anticipate no risks for the provider subjects. Interviews will be by phone or video conferencing.

9. Plan for Analysis of Results:
Due to the open-ended nature of questions for the survey and interview, we will utilize a qualitative analysis approach to gain insight to the study objectives. The broad inquiries will allow the respondents to provide their personal experiences in an unstructured open-ended format. For dependability two research team members will independently code the comments and conduct a thematic analysis. The two coders will provide the themes to the entire research team for discussion of which facets were prevalent from both coders for reliability. Based on an examination of the facets decided upon by the team, the set of themes will be provided to interviewees for credibility of the study and allow them to provide any feedback to ensure that their perspectives were accurately depicted. For transferability of the qualitative themes, for any research outputs in publication(s) or other outlets, we will provide direct quotations with thorough descriptions of the viewpoints.

10. Research Materials, Records, and Privacy:
Survey data will be stored in an online, encrypted database - Redcap. We will also enter notes in Redcap on interviews with the providers. We will not obtain any PHI on patients and will not record any of the video or audio interviews.

11. References

1. Brett C. Psychotic and Mystical States of Being: Connections and Distinctions. *Philosophy, Psychiatry, & Psychology.* 2002;9(4):321-341.
2. Bystedt S, Rozental A, Andersson G, Boettcher J, Carlbring P. Clinicians' perspectives on negative effects of psychological treatments. *Cogn Behav Ther.* 2014;43(4):319-331.

3. Cebolla A, Demarzo M, Martins P, Soler J, Garcia-Campayo J. Unwanted effects: Is there a negative side of meditation? A multicentre survey. *PloS one.* 2017;12(9):e0183137.
4. Jaseja H. Meditation potentially capable of increasing susceptibility to epilepsy - a follow-up hypothesis. *Med Hypotheses.* 2006;66(5):925-928.
5. Lindahl JR, Kaplan CT, Winget EM, Britton WB. A phenomenology of meditation-induced light experiences: traditional buddhist and neurobiological perspectives. *Front Psychol.* 2014;4:973.
6. Prakash R, Aggarwal N, Kataria D, Prasad S. Meditation induced psychosis: Case report. *Asian J Psychiatr.* 2018;31:109-110.
7. Schlosser M, Sparby T, Voros S, Jones R, Marchant NL. Unpleasant meditation-related experiences in regular meditators: Prevalence, predictors, and conceptual considerations. *PloS one.* 2019;14(5):e0216643.
8. Sharma P, Mahapatra A, Gupta R. Meditation-induced psychosis: a narrative review and individual patient data analysis. *Ir J Psychol Med.* 2019:1-7.
9. Sharma P, Singh S, Gnanavel S, Kumar N. Meditation - a two edged sword for psychosis: a case report. *Ir J Psychol Med.* 2016;33(4):247-249.
10. Wong SYS, Chan JYC, Zhang D, Lee EKP, Tsoi KKF. The Safety of Mindfulness-Based Interventions: a Systematic Review of Randomized Controlled Trials. *Mindfulness.* 2018;9(5):1344-1357.
11. Yorston GA. Mania precipitated by meditation: a case report and literature review. *Mental Health, Religion & Culture.* 2001;4(2):209-213.
12. Ruth Baer, Catherine Crane, Edward Miller, and Willem Kuyken. Doing no harm in mindfulness-based programs: Conceptual issues and empirical findings. Clin Psychol Rev. 2019 Jul; 71: 101–114. doi: 10.1016/j.cpr.2019.01.001.

13. Grabovac, A (2015). The stages of insight: Clinical relevance for mindfulness-based interventions. *Mindfulness, 6,* 589-600.

Data Collection Sheet

Questions for healthcare providers:
Common presenting symptoms and signs in patients presenting from meditation centers (or other settings) in psychiatric and/or spiritual crisis.
Issues that are most distressing to the patients and/or those bringing them in.
How many are an active danger to self or others vs just having altered mental processing?
How many require medications on arrival and for what specific symptoms?
Their best ideas about non-medication-based interventions.
What are the implications of presenting in spiritual crisis for nursing vs for other patients with more typical mental illness presentations: any difference?
What have meditation centers typically already tried to help stabilize these patients?
Do they see any similarities between patients presenting from meditation retreats vs those presenting on psychedelics, and what those differences are?
What do they typically keep on their dDx?
If they feel that the psychiatric presentation is directly related to the meditation retreat, do they capture this on the differential diagnosis? If so, how?
What tests do they typically feel they need to run to exclude other medical conditions?
Do they feel there are obvious differences in presentation between these patients and those presenting with non-meditation-related mental illness?
Do they feel there is a clear correlation between previous mental illness and/or trauma and the chances of the person having a meditation side effects or spiritual crisis?
Do they see patients that don't have any previous mental health history also having destabilizing meditation side effects or spiritual crises?
What diagnoses do they typically assign to them?
Are there discrepancies between what they feel is actually going on with these patients vs the options they have in the DSM-5 and ICD-10, meaning if they could edit or add additional codes or diagnoses in the DSM and ICD, what would they change or add?
What are the common management plans and decision trees for disposition?
How many patients receive some medication Rx, and if so, which medications?
Do clinical physicians feel there is adequate clinical data on which medications to prescribe them and in what doses?
Do they feel there are adequate follow up options for these patients and, if so, what are they?
What conceptual frameworks and language do they use to answer questions by patients and family about what might be going on with them, particularly regarding unusual symptoms, such as movements, energetic phenomena, and the like?
Are there any terms or concepts that they would like to be able to use that they wish were more accepted and supported by mainstream medicine?

Is there additional information they feel might be useful to obtain through further research to more optimally manage these patients?
Would it be possible to do a prospective study with that physician and their patients in spiritual crisis or with meditation side effects?

About the patients:
Basic demographic characteristics.
Basic mental health history.
Previous medications.
Previous therapy.
Previous trauma.
Previous possible undiagnosed mental health conditions.
Substance use history.
Family mental health history.
Common presenting symptoms and signs
Issues that are most distressing to the patients
Active danger to self or others vs just having altered mental processing
How many require medications on arrival and for what specific symptoms
Effective non-pharmaceutical interventions
Implications of presenting in spiritual crisis for nursing vs for other patients with more typical mental illness presentations: any differences in nursing care
What have meditation centers already tried to stabilize these patients
Similarities between patients presenting from meditation retreats vs those presenting on psychedelics
Differences in clinical presentation between these patients and non-meditation-related, non psychedelic mental illness
Diagnostic tests to exclude other medical conditions / What else on DDx?
Clear correlation between previous mental illness and/or trauma and the chances of spiritual crisis
Do any patients with no previous mental health history have destabilizing spiritual crises
What diagnoses do the providers give these patients
Any discrepancies between what providers believe is happening vs the options they have in the DSM-5 and ICD-10
If they could edit or add additional codes or diagnoses in the DSM and ICD, what would they change or add?
The common management plans and decision trees for disposition
Medication prescriptions given
If physicians feel there is adequate clinical data on which medications to prescribe and in what doses
The adequacy of follow up options
The conceptual frameworks they use to answer questions by patients and family about what might be happening, particularly regarding unusual symptoms (movements, energetic phenomena, etc).
Any additional information they feel might be useful to obtain through further research to more optimally manage these patients.