Online Yoga for Individuals with Mood Disorders

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Background and Significance

Hatha yoga is a promising adjunctive treatment for depression given its acceptability, affordability and availability. Hatha yoga focuses on training the body with the ultimate goal of promoting physical and emotional well-being. Yoga involves breath control (pranayama), physical postures (asanas), and meditation (dhyana). Yoga practitioners assert that it can be helpful for depressed individuals, and there is preliminary evidence for its efficacy in treating depression, as well as plausible mechanisms by which yoga might have an impact on depression. In particular, yoga promotes mindfulness and physical activity, which may help one manage depression. Other mechanisms by which yoga may have an impact on depression include: a) decreased rumination, b) decreased stress reactivity (via the hypothalamic-pituitary-adrenal axis), and c) decreases in markers of inflammation that have been associated with depression. Further, Hatha yoga may have additional benefits that are important for overall health and well-being, such as improved physical functioning.

Dr. Uebelacker is PI on a randomized controlled trial of yoga vs. health education for individuals with persistent depression (R01NR012005). In this study, entitled Holistic Approaches to Depression (HAD), she recruited individuals with major depression who were stable on an antidepressant medication. Participants were randomized to either 10 weeks of twice weekly hatha yoga (involving moderate physical activity; see Appendix 1) or health education (HE) classes. For this study, she trained yoga instructors in a manualized yoga protocol and rated adherence to that protocol. She recruited 125 individuals. Data analyses are underway, but preliminary results suggest a positive impact for yoga (vs. HE) on depression symptoms.

Regarding bipolar depression, early qualitative pilot research conducted by Drs. Uebelacker and Weinstock (2014) revealed self-reported positive emotional, cognitive, and physical effects of yoga in a sample of yoga practitioners with bipolar disorder. Following from this early pilot data, they are currently conducting a small, pilot randomized controlled trial of a gentle Hatha yoga vs. self-directed therapy with a workbook (bibliotherapy) for bipolar I/II depression, delivered over 10 weeks. Participants in this trial attend a weekly yoga class with in home practice, using the same video that we propose to use in the current study. Although symptom outcome data are not yet available for analysis, experiences in this pilot trial support the preliminary feasibility, acceptability, and safety of the gentle Hatha yoga in a bipolar disorder sample.

Despite promising preliminary results, further studies are needed to determine the acceptability, feasibility, and efficacy of yoga interventions for individuals with mood disorders. Yoga practitioners view yoga as a way to promote good physical and mental health, rather than as a treatment for poor health (1). This world view may be appealing to patients, especially those concerned with the stigma of conventional mental health treatment (2), or with the narrow focus on decreasing symptoms (instead of a broader focus on living to one′s full potential) that defines much of conventional mental health treatment. Yoga classes are widely available and relatively inexpensive compared to other depression treatments. Yoga can be practiced at home with the

aid of video recordings or books. We propose to examine the acceptability and feasibility of online yoga practice for individuals with depression, mania, or hypomania.

Overview of MoodNetwork

The MoodNetwork is a PCORnet funded patient-powered research network (PPRN; www.moodnetwork.org) approved by the Partners IRB. Its aim is to create a community of individuals with mood disorders interested in patient-centered research. A robust data infrastructure has been built that allows participants to state their research interests, complete online questionnaires, and sign-up for other studies. To become a study participant of the MoodNetwork, individuals visit www.moodnetwork.org, complete the IRB approved electronic consent, answer demographic and clinical questions and are then enrolled in MoodNetwork.

Overview of Yoga

The yoga practice will be one 30-min video of an instructor teaching gentle yoga to other participants. The style of yoga demonstrated is Hatha yoga, which is a yoga practice designed to include physical postures, breathing exercise, and brief meditation. This is a low-intensity yoga video that was created for and used in Dr. Uebelacker's study described above.

Specific Aims

The purpose of the proposed study is to examine the feasibility and acceptability of a 30-min online Hatha yoga video as well as explore changes in positive and negative affect from pre- to post-viewing for individuals with mood disorders.

Subject Selection

We propose to recruit 200 patients from the MoodNetwork study population who self-report that they have experienced depression, mania, or hypomania.

Inclusion criteria: Fluent in English; over age 18; self-report of having experienced depression, mania, or hypomania in their lifetime.

Exclusion criteria: Any contraindication to exercise (e.g., pregnant, physical injuries or any other reason prohibiting exercise).

There will be no exclusion criteria based upon gender or minority status. We anticipate that at least 50% of the participants will be women. The percentage of minority participants is expected to be at least 15% given the current demographics on the MoodNetwork online community (i.e., 84% White; 3.8% Asian; 1.8% African American; 5.5% Mulitracial; 4% unknown) with at least 20% Hispanic or Latino. Pregnant women will be excluded given the mixed results on the benefits of exercise for pregnant women (3, 4). Non-English speaking subjects will not be recruited as they cannot give informed consent as it is in English and only available online (i.e., translation services are not available).

Fetuses, children, prisoners, and institutionalized individuals will not be recruited because they are beyond the scope of the objectives. Hospital employees may be recruited if convenient,

because the study confers low risk, and there will be no penalties should any subject refuse to participate or discontinue participation. We will emphasize that the participation in this study is completely voluntary. There will be no direct benefits to subjects from participation, thereby eliminating the issue of their distribution.

Subject Enrollment

Participants will be recruited from those already enrolled in the online MoodNetwork study (www.MoodNetwork.org). Participants will be recruited from Facebook and other social media outlets. MoodNetwork will send an email notification to their participants who have self-reported that they have experienced depression, mania, or hypomania indicating that they may be eligible to participate in a new study available through the Network.

Interested participants will login into their MoodNetwork accounts to access the informed consent form for this study via a computer, tablet or mobile device. A waiver of written documentation of informed consent will be obtained electronically through the web portal via a consent fact sheet. We will advise participants to print or save an electronic copy of their consent form. Participants will be given an email address (Moodnetwork@partners.org) and phone number (617-643-2076) to contact study personnel should any questions arise regarding the project. The phones will be answered weekdays between the hours of 9:00am and 5:00pm, and participants can expect a response within 2 business days.

MoodNetwork participants will be emailed about this yoga study if they are over the age of 18 and have responded "yes" to either a) having ever experienced depression or b) having ever experienced mania or hypomania. In the email, a link will be provided to the login page of MoodNetwork. The email will then tell them to access the consent form for this study under the "Research Studies" tab on the Study Participant home page of MoodNetwork. They will then be instructed to click on the "Yoga Study" link which will bring them to the consent form for this study which will determine their eligibility and consent by selecting yes or no to the following 2 questions:

- I do not have any medical problems that would interfere with my participation in a mild to moderate physical activity. (If you are not sure, please check with a physician before continuing with this study.)
- I consent to participate in this study.

Participants must say yes to both questions in order to gain access to the study materials. If participants indicate that they do have medical problems, there will be an automatic response stating that they cannot participate in this study at this time.

Participants will be advised to print or save an online copy of the informed consent for their records prior to continuing.

Study Procedures

Participants (n = 200) will be recruited from MoodNetwork.org. Participation will take approximately 40 min and will involve completing a series of questionnaires, watching and participating with one 30 min video, and completing another set of questionnaires. Participants

will use desktop computers, laptops, tablet devices, or phones to participate in this study. These procedures are described in detail below.

Participants will access the consent form through MoodNetwork.org on a personal computer or electronic device. Once the participant has read and electronically signed the consent form, participants will complete a series of questionnaires, including the Mood Disorder Diagnosis, Yoga Experience Questionnaire In Class, and Positive and Negative Affect Scale.

After completing the questionnaires, participants will be shown a 30 min yoga video that they will be invited to follow along with. After completing the 30 min yoga video, participants will complete a follow-up series of questionnaires, including: Positive and Negative Affect Scale, Feasibility/Acceptability Questionnaire, and Adverse Event Questionnaire.

Data previously collected as part of the participant's involvement in MoodNetwork, including the New Participant Registration form, will be accessed by study staff and integrated into the study database. This data includes demographics and lifetime depression and mania/hypomania screening questions.

Diagnostic and Clinical Assessments:
Mood Disorder Diagnosis. The Mood Disorder Diagnosis is a 3 item self-report questionnaire that assesses overall mood disorder diagnosis and current symptoms.
Yoga Experience Questionnaire In Class. The Yoga Experience Questionnaire will measure the extent to which the participant has practiced yoga in a class setting and in an outside of class setting.
Positive and Negative Affect Scale (PANAS)(5). The PANAS is a measure of positive and negative mood.
Feasibility/Acceptability Questionnaire(6). The Feasibility/Acceptability Questionnaire assesses reactions to video and willingness to participate in video intervention similar to this on a weekly basis.
Adverse Event Questionnaire. The adverse event questionnaire will ask participants whether they sustained any injuries during the yoga practice and, if so, what these injuries entailed.

Statistical Procedures

Baseline demographic and clinical characteristics will be examined. Frequency distributions will be produced. Measures of central tendency and variability will be estimated on each continuous measure; proportions estimated for categorical variables. Graphical displays (e.g., histograms and boxplots) will be produced. To examine feasibility, completers versus non-completers will be compared on baseline variables using t-tests, Mann-Whitney tests, or chi-square tests to examine. We will also conduct within-subject t-tests to examine changes in acceptability and affect from pre- to post-viewing of the yoga video.

Possible Risks and Discomforts

1. *Confidentiality and loss of privacy:* We will be collecting sensitive information about the subject that may create some distress and/or cause social and psychological risk if

released inappropriately. Although we consider it unlikely, it is possible when transmitting data on the Internet that responses could be intercepted or "hacked" by a third party.

2. *Potential for adverse events:* It is possible that some participants will have a negative emotional reaction to answering the survey questions.
3. *Potential for injury:* There is the potential for physical injury.

Minimizing Risks

Potential risks due to loss of confidentiality will be minimized by having all information collected and handled by research staff trained to deal appropriately with sensitive clinical issues. All research personnel will receive training in research ethics and be approved by the institution to conduct research. All information will be treated as confidential material and will be available only to research and clinical staff.

Computer data files will be available only to authorized personnel and no names or obvious identifying information will be stored in computer files. No subject will be identified in any report of this project. Although we consider it unlikely, there is a small chance, when transmitting data on the Internet, that responses could be intercepted or "hacked" by a third party, possibly exposing responses. We have disclosed this in the consent form. The consent form will indicate that participants may terminate their participation in the study without negative consequences.

The risk of physical injury will be minimized by several aspects of the study design. First, we will require all participants to agree that they do not have any medical problems that would interfere with participation in mild to moderate physical activity. Second, we are offering a low-intensity yoga video that was designed for people who may be new to yoga, thus, minimizing the risk of physical injury. Should an injury occur while participating in the online class, or at any time, participants will note this in the Adverse Event Questionnaire and will be advised to contact their primary care physician.

Any serious adverse events will be reported to the IRB as soon as possible within the required timeframe.

Potential Benefits

Participants may enjoy having an opportunity to participate in and provide feedback on the yoga class. Understanding the acceptability of online yoga classes for people with mood disorders could lead to more treatment options for this group in the future. Therefore, the benefits are anticipated to exceed the risks for participants.

Monitoring and Quality Assurance

Database will be housed on the Partners Research Computing Cloud Infrastructure (DIPR and RFA). The Discovery Information Platform for Research (DIPR) provides a set of virtual services within the Partners secure data center and within the Partners network which consist of

virtual servers for web or application hosting, file storage and database management. All systems are secured behind the Partners firewall and follow Partners Healthcare Information Security policies for authenticated, minimum access. All systems are patched, monitored and scanned routinely for vulnerabilities and intrusions by the systems administrator and PHS Information Security. The web server and database server are hosted within the Partners Firewall. The web server makes use of standard 128-bit Secure Socket Layer (SSL) encryption to protect data in transit.

Given that data is entered directly by participants, there will be no interaction with participants and data will not be reviewed in real time. Additionally, data will only be reviewed in aggregate (i.e., as in reports of data integrity and assessment of outcomes) and thus, item-level data will never be reviewed for content, but only for completeness (i.e., to ensure data integrity and for statistical analyses).

Participant is notified in consent form that the information provided does not in any way substitute for professional medical advice, diagnosis, or treatment that their doctor or other healthcare provider may give and that they should always ask the advice of their healthcare provider if they have any questions about a medical condition. They are urged not to disregard professional medical advice or delay in seeking care because of something they have read as part of this study. They are told that if they think they may have a medical emergency to call their doctor, go to the emergency room, or dial 911 immediately.

In accordance with MGH guidelines, and as outlined to the participants in the consent form, participant confidentiality will be ensured throughout the study. All data will be identified by code numbers only and no description of individual patients will be included in any publication. Any adverse event will be reported to the HRC according to the reporting guidelines.

Unique identifiers (UID) will identify all data. No data generated by this project will be inserted into MGH or Partners Healthcare medical records. MGH will handle the data management of this study on MoodNetwork. All data will feed into a secure database, which MGH researchers will query. Per MGH IRB regulation, all project research data will be stored for at least 7 years. Linking information will be destroyed as early as possible, at the end of project data analysis. Per Partners Healthcare regulations, all project research data will be stored for at least 7 years.

References

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