Mindfulness During Coronavirus

IRB00064587

8.12.2020

NCT04319445

Principal Investigator: Rebecca Erwin Wells, MD, MPH, Associate Professor
Department of Neurology, Wake Forest University Health Sciences

Mindfulness During Coronavirus

Principal Investigator: Rebecca Erwin Wells, MD, MPH, Associate Professor
Department of Neurology, Wake Forest University Health Sciences

Supported by: Wake Forest Baptist Medical Center Department of Neurology, Headache Program

Study Intervention Provided by: N/A

Sponsor of IND (IDE): N/A

Study Site

Wake Forest School of Medicine

Department of Neurology

Objective:

The objective of our study is to provide remote mindfulness session(s) to help during the COVID-19 pandemic. We are interested in targeting patients with migraine, providers, faculty and staff. We are hopeful that this will positively impact overall well-being at this stressful time. We are interested in assessing feasibility, accessibility, and overall interest of an online mindfulness intervention in these populations at this time.

Background & Rationale:

With the COVID-19 pandemic ongoing, anxiety, stress, and uncertainty is at an unprecedented level. Further, in order to prevent transmission and further spread, “social distancing” is recommended, which can lead to isolation and a sense of helplessness.

Mindfulness meditation is a treatment approach that can target anxiety and stress.[1] Mindfulness practice teaches individuals to focus on the present moment.[2] Mindfulness is an intervention that can be taught remotely, over the phone, or online. A meta-analysis of 15 RCTs showed that online mindfulness based interventions (MBIs) have a positive effect on depression, anxiety, and well-being. [3]

Stress is the number one trigger for migraine, [4-7] so targeting stress is important for patients with migraine.[8] Mindfulness may be helpful for patients with migraine.[9]

Providers, faculty and staff are also under tremendous stress during this pandemic, with the additional stressor of setting up an effective remote work environment and making decisions about priority of care. Mindfulness may be helpful for working adults as well.[10]

The PI has experience conducting research with this intervention, having conducted three randomized controlled trials of a mindfulness intervention; two in adults with migraine and one in adults with mild cognitive impairment.

Methods:

Recruitment:

Migraine patients:

Potential migraine participants will be notified in a multitude of ways. We will send a MyWakeHealth message of this opportunity. We will also recruit online via social media, MigraineWorldSummit, and other online avenues to patients in the Winston Salem area and across the country. Other healthcare providers across the country may be interested in sharing this with their patients as well.

Interested participants can click on a link that will take them to a REDCap survey. Or they can email us at the WFBH_Mindfulness@wakehealth.edu email account expressing their interest and we can then notify them of the details of the mindfulness session. Participants will be consented with this statement at the beginning of the survey document, "These surveys are completely voluntary… By proceeding with this survey, you are agreeing to participation."

Providers/Faculty/Staff:

Potential providers/faculty/staff will also be notified of this opportunity with online recruitment (through a variety of mechanisms, including Intranet, email, etc). A link to the survey will be included in the online recruitment/announcement, or they can respond to us via email. We will then notify them of the details of the mindfulness session.

Others interested:

Nearly everyone has been affected by this pandemic, and anyone may find benefit from this mindfulness session. The session will be made available more broadly to the public via social media, email, and other online resources.

ResearchMatch.org will be utilized as a recruitment tool for this protocol. ResearchMatch.org is a national electronic, web-based recruitment tool that was created through the Clinical & Translational Science Awards Consortium in 2009.

Mindfulness session(s)

The sessions will be hosted online using an online platform (such as through webex, private YouTube page, Facebook live, etc). The sessions may be live or pre-recorded. The live sessions will be recorded and may be made publically available. For the first live session, all those who participated will be contacted to sign a consent acknowledging and releasing the matieral to be made publically available. For future live sessions, the main consent form has been adjusted to include this information.

We will begin with an initial session and assess level of interest in order to determine whether to continue with follow-up sessions on a daily, weekly, or monthly basis.

Information about additional sessions will be made available to participants who have already participated in the first session, and may be advertised to new participants as well.

Assessments:

We will assess value and interest of this type of intervention using this platform with a pre-post survey. The participants will complete the surveys via REDCap. Links to the surveys via

REDCap will be available in the announcements/recruitment information and/or sent to their emails. Data will be stored via REDCap electronic data system. Each participant will create a unique identifier number to ensure matching of all pre/post surveys completed by that participant. If a participant completes a pre-survey but not a post-survey, they may be emailed to thank them for their participation and sent the link to complete the post-survey as a reminder.

Pre/post surveys may be available for each mindfulness session.

A single post-survey will also be sent after the live sessions to assess participants overall experiences with the live mindfulness sessions.

Participant Selection:

Any person interested in participating in the mindfulness session will be eligible to complete the pre/post surveys and participate in the mindfulness session(s).

Sample Size
The estimated sample size for survey completion is 200. This is the number of individuals who are expected to participate in the mindfulness session and complete the surveys, although online recruitment is highly variable and may result in more participants than expected.

Human Subjects Protection

Informed Consent
Participants will be informed of the voluntary nature of the surveys at the beginning the survey. Participants will be informed of the possibility of additional mindfulness sessions and surveys, so that the original consent will include participation in additional sessions/surveys. Written informed consent will not be obtained.

Risks
The risk of harm or discomfort that may occur as a result of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests. This study overall poses minimal risks. The intervention of mindfulness is a non-drug intervention with rare side effects. The recruitment, surveys, and intervention will all be conducted remotely to avoid face-face interaction during this time of the COVID-19 pandemic. The rights and welfare of study will be protected through the use of measures to maintain the confidentiality of study information.

Confidentiality and Privacy
Confidentiality will be protected by collecting only information needed to assess study outcomes, minimizing to the fullest extent possible the collection of any information that could directly identify subjects, and maintaining all study information in a secure manner. To help ensure subject privacy and confidentiality, only a unique study identifier will be assigned to each data collection form. Any collected patient identifying information corresponding to the unique study identifier will be maintained on a separate master log. The master log will be kept secure, with access limited to designated study personnel. Following data collection subject identifying information will be destroyed at the earliest opportunity, consistent with data validation and study design, producing an anonymous analytical data set. Data access will be limited to study staff. Data and records will be kept locked and secured, with any computer data password protected. No reference to any individual participant will appear in reports, presentations, or publications that may arise from the study.

Data and Safety Monitoring

The principal investigator will be responsible for the overall monitoring of the data and safety of study participants. The principal investigator will be assisted by other members of the study staff.

REFERENCES:

[1] Ludwig DS, Kabat-Zinn J (2008) Mindfulness in medicine. *Jama* **300**, 1350-1352.

[2] Kabat-Zinn J (1990) *Full Catastrophe Living: Using the WIsdom of Your Body and Mind to Face Stress, Pain, and Illness*, Random House, New York.

[3] Spijkerman MP, Pots WT, Bohlmeijer ET (2016) Effectiveness of online mindfulness-based interventions in improving mental health: A review and meta-analysis of randomised controlled trials. *Clin Psychol Rev* **45**, 102-114.

[4] Peroutka SJ (2014) What turns on a migraine? A systematic review of migraine precipitating factors. *Current Pain and Headache Reports* **18**, 454.

[5] Houle TT, Butschek RA, Turner DP, Smitherman TA, Rains JC, Penzien DB (2012) Stress and sleep duration predict headache severity in chronic headache sufferers. *Pain* **153**, 2432-2440.

[6] De Benedittis G, Lorenzetti A (1992) The role of stressful life events in the persistence of primary headache: major events vs. daily hassles. *Pain* **51**, 35-42.

[7] Peroutka SJ (2014) What turns on a migraine? A systematic review of migraine precipitating factors. *Curr Pain Headache Rep* **18**, 454.

[8] Martin PR (2016) Stress and Primary Headache: Review of the Research and Clinical Management. *Current Pain and Headache Reports* **20**, 45.

[9] Wells RE, Seng EK, Edwards RR, Victorson DE, Pierce CR, Rosenberg L, Napadow V, Schuman-Olivier Z (2020) Mindfulness in migraine: a narrative review. *Expert Rev Neurother*.

[10] Hilton LG, Marshall NJ, Motala A, Taylor SL, Miake-Lye IM, Baxi S, Shanman RM, Solloway MR, Beroesand JM, Hempel S (2019) Mindfulness meditation for workplace wellness: An evidence map. *Work* **63**, 205-218.