MAYO CLINIC

General Study Information

Principal Investigator: Ivana Croghan, PhD

A Study Title: A Feasibility study evaluating Mindfulness-Based Intervention Assessing A Wearable Wellness Brain Sensing Device (Muse-S™) in Practicing Health Care Providers.

Protocol date: 23 Sept 2024

Research Question and Aims

Hypothesis: Healthcare providers (HCP) often deal with patients who are experiencing a variety of ailments, symptoms, and infections at the time of the face-to-face visit. There is an inherent stress that exists when one realizes the life of another being rests in their hands and capabilities. In addition, whereas the risk of contracting diseases in the course of caring for others has always existed, it has never been more evident than during this time of the Covid19 pandemic. The stress of caring for others while worrying about the potential ramifications of their care management decisions and the possibility of contracting Covid19 and inadvertently passing said disease to others (friend and family included) has significant physical and mental health ramifications for HCP. Whereas it has been touted that mindfulness can be a benefit to physicians in the front line[1], little guidance exists as to how this can be learned and practiced by HCP during such a busy time with little respite. We postulate that using a novel biofeedback-assisted meditation device (Muse-S™) often during the workday can provide mindfulness training to increase calm state brain activity in physicians during a busy practice in the midst of a pandemic[2]. We hypothesize that the greater amount of time the HCP uses this tool, the greater amount of resilience s/he builds, providing needed mental support.

Aims, purpose, or objectives:

1. To study the feasibility of HCP using a wearable brain sensing wellness device (Muse-S™) during a time of increased workload, patient volume and stressors.
2. To assess the association between duration of active state and calm state as measured by the wearable brain sensing wellness device (Muse-S™), and quality of life (QOL), subjective stress, sleep and resilience.

The primary outcome will be the adherence to the Muse-S™ by summarizing the frequency of use and duration of use each time it was accessed.

The secondary outcomes will include:

- change in stress score over time
- measures of QOL, resilience and coping score in HCP at specific time points post baseline.

Background:

Prior to the COVID 19 pandemic, physicians were experiencing high degree of burnout, which has consequence to physician health[3-5]. A multitude of causes result in physician burnout, such as adopting/learning new electronic medical records[5], administrative responsibilities taking time away from clinical practice[6], lack of autonomy, changes in reimbursement model[7] and other factors.

COVID 19 has added another dimension to the stress experienced by physicians. A recent study in JAMA[5], showed that front line healthcare workers in China were experiencing a high degree of stress. It was reported that "A considerable proportion of participants reported symptoms of depression (634 [50.4%]), anxiety (560 [44.6%]), insomnia (427 [34.0%]), and distress (899 [71.5%])[5]". Additional stressors include the rapidly changing way medicine is being practiced[8]. The use of barrier-protection, adoption of telemedicine, and decrease of income has affected the way physicians practice medicine. This along with fear of infection and passing along to family members add additional pressure on physicians[9].

Integrative Medicine has introduced many mind-body therapies for addressing mental stress. The top stress relievers recommended by Mayo Clinic include: getting active, eating a healthy diet, avoiding unhealthy habits, meditation, laughing more, connecting with others, asserting yourself, practicing yoga, getting enough sleep, keeping a journal, exploring music and being creative, seeking counseling[10]. Among all of these potential options, meditation is the easiest to incorporate in a current lifestyle yet most difficult to undertake without proper training and guidance at the beginning. Muse-S™ is a clinical grade, headband-style wireless EEG system designed to interact with a mobile device (a smartphone or tablet) (https://choosemuse.com). In combination with the Muse-S™ APP running on iOS or Android smartphones, Muse-S™ converts EEG signals measured over the frontal and temporal cerebral cortices into measures of brain state. At the same time Muse-S™ can also guide the user through the meditation steps. Calibrated to an individual user, Muse-S™ distinguishes between active and calm brain states to provide real-time performance feedback, and helps users realize the benefits of mindfulness practice in an engaging and accessible manner. Muse-S™ also has a PPG sensor that tracks heartrate during meditation sessions as well. This has been tested in a prior study by some of the current study team (SP and ITC), with patients undergoing breast cancer surgery[11].

Study Design and Methods

Methods:

All study participants will receive the Muse S™ Headband system at study entry and will be asked to utilize it at least 4 times per week for a minimum of 10 minutes each time over a period of 3 months (12 weeks). They will be followed for a period of 6 months (3 months of treatment and 3 months post treatment) according to the schedule below.

We will assess the following:

- Type of meditation the patient has selected from the 3 available options: Mind Meditation, Guided Meditation and Go-to-sleep meditation.
- Frequency and duration of use from baseline to month 3 (end of treatment). The participants will be informed at baseline that for best results, it will be recommended that they use it a minimum of 10 minutes, at least 4 times per week for over 3 months. If they are short on time, they can break up the 10 minutes and do shorter meditations.

- Changes in QOL, stress, resilience, and sleep score from baseline through week 2, month 1, month 3 and month 6.

	Consent /screen /baseline	Treatment Phase			Follow up Phase
Visit No.	**1**	**2**	**3**	**4**	**5**
Visit Type	**face to face**	**Phone/ email**	**Phone/ email**	**face to face/phone/ email**	**face to face/phone/ email**
Visit Days	**0**	**14**	**30**	**90**	**180**
Informed Consent	X				
Inclusion/Exclusion	X				
Demographic and History Form	X				
Depression	X	X	X	X	X
Burnout	X			X	X
Resilience	X	X	X	X	X
Sleep	X	X	X	X	X
Quality of Life	X	X	X	X	X
Stress Scale	X	X	X	X	X
Satisfaction Survey					X
Adverse Events [1]		X	X	X	X
CBS Cognitive Tests	X			X	X
Concomitant Medication [2]	X	X	X	X	X
Instructions for Muse-S™	X				
End of Treatment/End of Study Forms				X	X

1 = For visit 5, only serious adverse events will be newly collected; **2** = For visit 5, only newly added concomitant medications will be collected

Study Visit Windows:
Each visit will have a window from midpoint of prior visit to midpoint of latter visit.

Data Collection:
Subjects will have the options of completing study surveys/questionnaires online via email link to REDCap prior to study visit. If not completed by the time the study visit takes place, the coordinator can provide the iPad digital version of the survey/questionnaire to the subject for the in-person visits or can interview the patient via phone for the telephone visits. Data Collection in this study will utilize REDCap[12]. All other data collection will be entered directly into this password protected system.

Assessments:
Safety:

- PRIME-MD Questionnaire[13,14]: A validated and frequently used self-report measure of depressive symptoms comprising of 2 questions, which were derived from the PHQ[15,16].

Outcomes:

- Demographics Form: This form collected demographic and other lifestyle history of the research subject.
- Burnout: We will measure burnout using 2 single-item measures adapted from the full Maslach Burnout Inventory (MBI)[17]. These 2 items have been demonstrated to correlate strongly with the emotional exhaustion and depersonalization domains of burnout measured by the full MBI in a sample of over 10,000 individuals with an area under the ROC curve of 0.94 and 0.93 for emotional exhaustion and depersonalization, respectively, for these single items relative to the full MBI[18,19].
- Quality of Life: Will be measured using the *Linear Analogue Self-Assessment (LASA)*[20-22]. This measure is a six-item measure of quality of life (QOL), in which QOL is conceptualized as a multidimensional construct with five domains (physical, functional, emotional, spiritual, and social). This data will be collected at screen (prior to any treatment), day 14, day 30, day 60, end of treatment day 90, and at end of study day 180 (3months post last treatment).
- Stress: Will be evaluated through the *Perceived Stress Scale (PSS)*[23,24]. The PSS is a 10-item Likert scale that measures global life stress by assessing the degree to which experiences are appraised as uncontrollable or unpredictable. Scores can range from 0 to 40, with higher scores indicating greater perceived stress. Reliability is reported as 0.85, with Cronbach alphas ranging from 0.75-0.86.
- Resilience: Will be evaluated through the *Connor-Davison Resilience Scale 10 (CD-RS10)*[25]. This is a 10-item, likert scale, validated, scoring system. The CD-RS10 is a reliable means of assessing resilience and most often used in medical and/or disaster studies[26].
- Sleep Quality: *The Pittsburgh Sleep Quality Index (PSQI)*[27-29] is an effective instrument used to measure the quality and patterns of sleep in adults. This is a 9-item, likert scale, validated, scoring system. It differentiates "poor" from "good" sleep quality by measuring seven areas (components): subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medications, and daytime dysfunction over the last month.
- Cognitive Testing: *The Cambridge Brain Science* (CBS) web-based tests were developed in the laboratory of Dr. Adrian Owen, Canada Excellence Research Chair in Cognitive Neuroscience and Imaging (owenlab.org), over the course of his 25-year career. The tests are self-administered, do not require supervision, and effectively assess aspects of cognition including reasoning, memory, attention and verbal ability. Over 300 scientific studies have been run to date using the CBS tests, yielding numerous publications in leading academic journals[30-33]. The tests have been validated in studies of patients, brain imaging studies of healthy volunteers and in several large-scale public studies involving tens of thousands of volunteers. They have proven to be efficient and sensitive measures of cognitive performance and can be used to consistently monitor participants and patients due to the unlimited versions of problem sets within each task. The 12 tasks (*see CBS Task Overview.pdf) can be customized to use specific tasks if a shortened assessment is required for research. A custom 3-task assessment would take approximately 10 minutes and for the purposes of this study, we would recommend the use of the following tasks:
  1) **Double Trouble –** 90 seconds (*measure of Response Inhibition*) - Version of the Stroop task. It is a "double" version in which there can be up to two incongruities (the top word and the bottom words), so is a little more difficult than other versions and has been sensitive to a range of interventions known to improve attention, response inhibition, or cognition in general. Response times and accuracy can be separately calculated for each difficulty level (congruent /incongruent / double incongruent), in addition to an overall score.

2) **Feature Match –** 90 seconds (*measure of Attention*) - Version of a "spot the difference" game. It uses areas of the brain involved in tuning attention and requires both fast response time and accuracy to get a good score.
3) **Grammatical Reasoning –** 90 seconds (*measure of Verbal Reasoning*) - Based on Alan Baddeley's grammatical reasoning test (Baddeley, 1968). Short sentences describing the relationship of two shapes along with an image of the shapes are displayed on the screen. Participants must indicate whether the sentence correctly describes the pair of objects displayed on the screen.

- Satisfaction with the program: This questionnaire is adapted from *Was it Worth it Questionnaire (WIWI)*[34] to measure study and Muse-S™ satisfaction. It will be administered to the participants after completing the intervention at the end of the study, probing their satisfaction with the research study. These data could be used to assess the feasibility of the intervention by asking the patient if the entire research experience was worth it for them.

Adherence to Intervention:

- Adherence to the Muse-S™ will be assessed by de-identified data available within the cloud, provided by InteraXon. InteraXon only has information per subject through subject ID only (as was provided by Mayo Clinic site), so when the cloud data is provided to Mayo, it will be linked to each subject through their study ID.

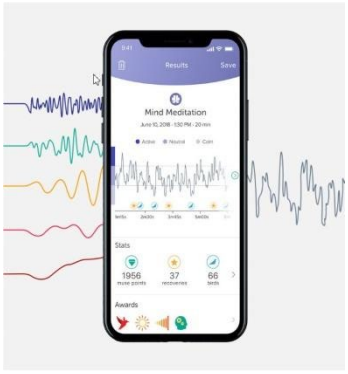
Intervention:

- The Muse-S™ Headband system: The Muse-S™ Headband system is a brain sensing headband that measures brain activity by detecting electrical impulses created by the brain. The Muse-S™ Headband system uses a series of focus attention training methods to train the brain. Each focus attention session can vary in length, with the ideal being a minimum of 10 minutes, and has been shown to reduce stress, anxiety, and improve focus and productivity. The Muse-S™ Headband system has seven sensors with four channels of EEG data for an accurate, high-quality experience. The battery life is approximately five hours and uses an industry-standard micro-USB charger. Twenty Muse-S™ Headband systems will be provided by the manufacturer at no cost in support of this study.

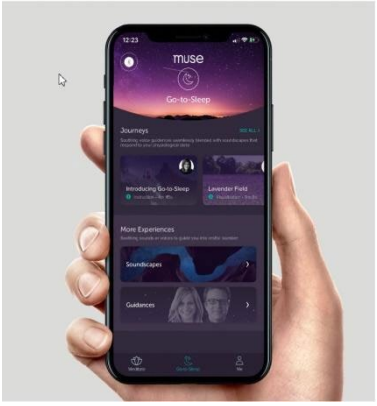
  Use of Muse-S™ Headband systems will be demonstrated to each participant prior to their first mindfulness practice session, which will be completed during the baseline visit with the study coordinator. The study coordinator will present the participant with detailed instructions on how to begin each session. The frequency of the sessions thereafter will be at the participant's discretion according to the study's requirements (daily practice). Mindfulness training will follow the protocol in the Muse-S™ APP, which follows a standard breathing exercise with EEG brain state feedback through the mobile device, as designed by a panel of experienced mindfulness practitioners. In short, the Muse-S™ is a *FitBit* like device for the brain.

  The study participants can access 3 different types of meditation while using the Muse-S™ Headband system. They are as follows:

- **Mind Meditation** uses the Muse-S™ headband to track the user's brain activity during meditation and translates the brain's activity into guiding sounds. Users get real time feedback to know when their mind is focused and when it's distracted, and are cued to return to a state of focused attention (meditation state). Users also see data from their brain after the meditation. Real time feedback during Mind Meditation is the Muse-S™ signature meditation and teaches the fundamentals of a meditation practice- remaining in a calm focused attention state and being able to move your mind away from distracting thoughts.



- **Guided Meditations from Healthcare Burnout Collection.** Guided meditations are narrated meditations on a range of subjects like stress, focus, breath and body practices. We will put together a collection of meditations specifically for HCP. Guided meditations can be done with or without the Muse-S™ headband. When they are done with the headband, there is no real-time feedback, but you see data from your brain, heart and movement after the session. You are welcome to do guided sessions without the headband.
- **Go-to-sleep Meditations** use the headband and are guided meditations that can be combined with an audio sound scape generated from your biosignals (heart rate, brain and movement). Sleep Journeys are designed to help you fall asleep faster. They are intended to be used in bed while you fall asleep to help calm your body and mind and entrain you into sleep. If you fall asleep with the headband on you can wear it through the night if you wish. Some people find Go-to-sleep journeys deeply relaxing and use them during the day as a relaxation tool as well.



All study participants will have access to The Muse-S™ Headband system's customer service team based in Toronto, Canada, by telephone and email for assistance should they experience technical problems with the device.

- Server Data: As the subject completes any Muse-S™ sessions, the information from these sessions will be uploaded to the Muse-S™ ICloud servers hosted by Google. Each subject will be able to see their own data at the end of each session, and data from the previous session stored in the "me" tab in the app. Subject to the study organizers ensuring that the subjects have signed the appropriate consents, study organizers will have access to each subject's data to monitor compliance, performance and outcomes, but will not get access to Journal entry information (if subject chooses to write a Journal entry). These data that the study organizers will have access to can include the study-specific identification number, gender, and age of the subject, the session type, the time and duration of each session, EEG data, heart rate (PPG) data, and the performance per session. Interaxon's privacy policy, which can be found at www.choosemuse.com/privacy will apply to Interaxon's use of the subjects' data. In order to maximize protection of the individual's privacy, the study organizers will ensure that the subjects

are assigned anonymized email address and names for use in the Muse -S™ application and when contacting the Muse-S™ customer support. To ensure that no health data is shared with Interaxon, the study organizers have agreed to ensure that no health data will be shared with Interaxon. At the end of the study, the data collected in Google ICloud Server associated with study email addresses will be deleted.

- The Muse-S™ steps include: 1) Open the Muse-S™ App on your phone. 2) select meditation type 3) if meditating with the headband, turn on the Muse-S™ headband. It will pair via bluetooth to the app 4) put on headband (if doing a meditation with headband) 5) meditate 6) add any journal or mood entry if desired 7) review results
- Cleaning the Muse-S™: Each patient will be given a brand new, out-of-the-box Muse-S™ Headband system. If cleaning must occur, the entire Muse-S™ including the head set can be wiped down with a standard disinfectant wipe. The band can also be hand-washed gently with soap and water. The module on the band is not waterproof but can be wiped with disinfectant.

Subject Retention:
Participants will not be remunerated for participating in this study, but they will be allowed to keep the Muse-S™ Headbands.

Resources:
- The data entry screens used will be developed via REDCap for the online forms.
- Clinician investigators will provide medical oversight.
- The Muse-S™ Headband systems are provided at no cost through the manufacturer (InteraXon) for use during study participation.

Check all that apply. If none apply, leave blank:
☒ The research involves contact or interaction with subjects, for example, surveys, questionnaires, observation, blood draw.

Study Design:
We will use standardized procedures to ensure uniform instructions and support for all subjects for the recruitment, screening, and study entry.

Recruitment:
HCP participants will be recruited from the Mayo Clinic Practice. The study staff will inform participants of the study during practice meetings, and if the participants indicate interest they will connect with research staff and arrange a time to meet to begin the consent process.

Participants will not be reimbursed for their time spent in the study, but all participants will be given the option of keeping the Muse-S™ Headband system for continued use post study participation.

Consent and Screen:
Study coordinator will meet with the potential participant who has expressed an interest in participating in the study. The study coordinator will begin by introducing the study details, and after determining that the subject has continued interest in study participation, will move on to the study consent. If the subject

chooses to consent, the study coordinator will screen the participant for study entry inclusion/exclusion criteria. If the study entry criteria are met, the subject will begin their study participation. They will be asked to complete the study surveys/questionnaires.

Please note: Participants must have access to an iOS or Android capable device to take part in this study in order to interact with the Muse-S™ Headband system.

Treatment phase:
During the first three months of study, participants will be asked to complete the online study intervention using the Muse-S™ headband. Participants will be contacted via telephone and online (REDCap) for study visits at day 14 and 30. At day 90, they will be asked to return to the clinic for an in-person visit (telephone and online will be alternatives).

Study Follow-Up Visits:
The study will consist of a 6-month visit post baseline (3-month post end of intervention). Participants will be asked to complete an in-person visit, if possible (telephone and online will be the alternative).

Subject Information

Target accrual: We plan to recruit 40 Mayo Clinic Practicing HCP.

Subject population: A total of 40 practicing HCP at Mayo Clinic who meet the following study criteria:

Inclusion Criteria:
1. 18 years of age or older at time of consent
2. Practicing HCP at Mayo Clinic
3. Not pregnant by subject self-report at time of consent
4. Have the ability to provide informed consent
5. Have the ability to complete all aspects of this trial
6. Have access to an iPhone, iPad, or Android device
7. Have no contraindicating comorbid health condition which would interfere with the proper use of the Muse-S™ system, as determined by the clinical investigators

Exclusion Criteria:
1. Used an investigational drug within the past 30 days
2. Anyone that is not on a stable dose of medication for anxiety, depression or sleep
3. Currently (within the past 3 weeks) been practicing mindfulness training on a weekly/regular basis
4. Currently (within 3 weeks) has been enrolled in another clinical or research program which intervenes on the patients' QOL, or stress
5. An unstable medical or mental health condition as determined by the physician investigator

Review of medical records, images, specimens

☒The study involves data that exist at the time of IRB submission **and** data that will be generated after IRB submission. Include this activity in the Methods section.

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