Emotion Prosthetics for Augmentation of Mindfulness: Protocol

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Contents

1. Study Description

1.1 Objective:

This protocol will examine and elucidate a mechanistic model for tuned vibroacoustic stimulation (TVS), an exteroceptive cue that has been shown to reduce subjective and physiological indicators of stress and increase behavioral performance, applied to mindfulness meditation for stress reduction and emotion regulation in healthy adults.

1.2 Specific Aims

Aim 1: Examine how TVS added to brief instructed mindfulness meditation can affect psychological state and performance. This aim is to show that TVS is particularly potent as a catalyst towards the types of experiences documented in experienced meditators.
Hypothesis 1.1: Positive affect and calmness: TVS added to mindfulness will increase subjective positive affect and calmness compared with mindfulness alone, particularly in individuals whose state is not strongly affected by mindfulness alone.
Hypothesis 1.2: Heightened states of awareness: TVS added to mindfulness will heighten state of awareness compared with mindfulness alone and particularly in individuals whose state is not strongly affected by mindfulness alone.
Hypothesis 1.3: Performance: TVS added to mindfulness will improve performance on visual attentional preference and empathy tasks and particularly in individuals whose state is not strongly affected by mindfulness alone and in individuals with increased positive affect and heightened state of awareness.

Aim 2: Examine how TVS added to brief instructed mindfulness meditation can affect physiological indicators of emotion regulation. Our overall hypothesis is that TVS, in combination with some other task, increases performance on that task by increasing emotion regulation. Mindfulness meditation is one such task that, without TVS may decrease emotion regulation in some people - TVS will counter that.
Hypothesis 2.1: TVS added to mindfulness increases physiological indicators of emotion regulation, including decreased galvanic skin response (GSR; index of sympathetic reactivity), increased heart rate variability (HRV; index of parasympathetic reactivity), and increased prefrontal gamma and theta band EEG compared with mindfulness alone during the intervention and follow-up tasks.
Hypothesis 2.2: Mindfulness alone will share attention recruitment features from visual attentional preference and empathy tasks and can decrease emotion regulation in some individuals - those individuals will yield the most decreased reactivity during TVS added to mindfulness. Mindfulness alone in these individuals will lead to increased GSR, decreased HRV, and decreases in prefrontal gamma and theta band EEG in some individuals. In these individuals, TVS added to mindfulness will lead to increased physiological reactivity, including higher levels of decreased GSR, increased HRV, and increases in prefrontal gamma and theta band EEG during the intervention and follow-up tasks.

Aim 3: Examine how TVS added to brief instructed mindfulness meditation is affected by functions of trait. This aim is to show which individuals may yield the strongest effect of TVS added to mindfulness - they are expected to be the people who get the least effect from mindfulness alone.
Hypothesis 3.1: Deficit remediation of trait mindfulness. TVS added to mindfulness changes subjective and objective markers of emotion regulation, more in participants with low trait mindfulness because it remediates a deficit in the ability to engage mindfully.

Hypothesis 3.2: Positive affect trait. TVS added to mindfulness changes subjective and objective markers of emotion regulation along with improvements in visual attentional preference and empathy tasks, which occurs more in individuals with low positive affect trait.
Hypothesis 3.3: Facilitation of heightened states of awareness: TVS added to mindfulness increases the likelihood of subjective heightened states of awareness, particularly in those who have had prior experiences with these states.

1.3 Background

For the past decade, prospective studies have shown that positive emotions have been correlated with physical health and longevity (Chida & Steptoe, 2008). Those who experience more positive emotions have fewer colds, reduced inflammation, and can recover from stress more effectively (Cohen, Alper, Doyle, Treanor, & Turner, 2006; Ong, Bergeman, Bisconti, & Wallace, 2006; Steptoe, O'Donnell, Badrick, Kumari, & Marmot, 2008). According to the Fredrickson's broaden and build theory, positive emotion such as joy, interest, love and contentment can broaden an individual's thought-action repertoire and build on that individual's personal resources, which should lead to an upward spiral of positive emotion that can counter downward spirals of negativity and stress (Fredrickson, 2004; Fredrickson & Joiner, 2002; Tugade & Fredrickson, 2004). Induction of positive emotion has been shown to broaden scope of attention using a global-local visual processing task, increase breadth of thought-action repertoire using a thought listing task, and result in faster recovery from cardiovascular sequelae of negative emotions (Fredrickson & Branigan, 2005; Fredrickson & Levenson, 1998). Perceived positive social connections increase positive emotions, an effect moderated in part by baseline vagal tone (Kok et al., 2013).

Mindfulness interventions also have physical and mental health benefits. Mindfulness can be defined as moment-to-moment awareness in one's present experience and adopting an attitude of openness or acceptance toward one's experience (Creswell, 2017). Standard protocol for Mindfulness-Based Stress Reduction (MBSR) consists of 8 weekly 2.5-hour group sessions and has been applied to many populations including those with depression and anxiety (Kabat-Zinn, 1982; Kabat-Zinn et al., 1992; Ludwig & Kabat-Zinn, 2008; Teasdale et al., 2000). There are also brief experimental mindful attention inductions that have been developed although these approaches appear to have small and transient effects (Schofield, Creswell, & Denson, 2015; Westbrook et al., 2013). Positive predictors of mindfulness include individuals with higher self-esteem, autonomy and competence. Negative predictors of mindfulness include individuals with higher levels of neuroticism trait, anxiety, depression, and negative affectivity (Brown & Ryan, 2003). However, studies have also shown that mindfulness is less effective when individuals behave compulsively or automatically, without awareness or attention to one's behavior (Brown & Ryan, 2003).

Prior research has shown that mindfulness do affect markers of calmness and stress, including heart rate variability (HRV), galvanic skin response (HRV), and EEG (Azam, Katz, Mohabir, & Ritvo, 2016; Lomas, Ivtzan, & Fu, 2015). Stress is characterized by hyper-reactivity in the sympathetic nervous system which is associated with increased arousal and vigilance, and compromised reactivity of the parasympathetic nervous system, which helps to regulate emotion and stress responses (Kibler, Tursich, Ma, Malcolm, & Greenbarg, 2014; Lehrer & Gevirtz, 2014). HRV is widely used as a biomarker for the coordinated activity of the sympathetic and parasympathetic nervous symptom. A calmer, less stressful state is typically marked by increased HRV, likely attributed to respiration based parasympathetic stimulation (Grossman & Taylor, 2007). GSR is also a reliable index for sweat gland activity and changes in activation level of the sympathetic nervous system, and GSR usually increases with higher levels of stress (Mohan, Sharma, &

Bijlani, 2011). EEG changes, such as elevated prefrontal gamma and theta, have also been associated with state of relaxed alertness.

Large scientific literature supports the role of vibration in regulating physiology (Takahashi, Ohashi, & Yokoyama, 2011; M. Uchikune, 2002; M. Uchikune, 2004). Based on literature, slow whole-body vibration, in the 0.01 to 0.3 Hz range, is associated with increased ratings of pleasantness and increased parasympathetic tone (M. Uchikune, 2002; M. Uchikune, 2004). Stimulation at about 100 Hz has been shown to activate the posterior insula (Coghill et al., 1994) which is associated with increased attention to interoception, as promoted in many meditative traditions. Transcutaneous targets for the vibration frequencies have also been identified, including stellate ganglion and vagus nerve (Cipriano et al., 2014; Fang et al., 2016). Currently, in Dr. Siegle's lab, TVS has been shown to reduce subjective stress, increase positive affect, along with increases in behavioral performance (Siegle). We hypothesize that TVS added to mindfulness will increase positive emotions and heighten state of awareness, leading to broadening of perspectives in individuals.

1.4 Significance

In this study, we will be testing the potential for TVS combined with mindfulness meditation to be used to increase well-being (subjective calmness, heightened states of awareness, increased preference and physiological reactivity) in a healthy population. Positive results would suggest that dynamic intervention is possible without effort, medications, or psychotherapy. This would be the first such intervention

2. Research Activities

2.1 Location

All procedures will occur at the PI's lab, 3501 Forbes Ave, Suite 420B

2.2 Assessment Days

The study takes place in one assessment day lasting up to 4 hours

2.3 Consent

Participants will have the study initially described to them by the clinician at the Oxford Building, and if the participant agrees to participate, they will sign informed consent.

2.4 Interviews

Participants will undergo several structured diagnostic interviews including a post-intervention debriefing:

1. Mini-International Neuropsychiatric Interview (MINI 7.0): The MINI 7.0 is a short, structured clinical diagnostic interview designed for DSM-V that covers all psychiatric disorders. It is widely used in epidemiological studies and multi-site clinical trials (Sheehan et al., 1998).
2. North American Adult Reading Test (Uttl, 2002)

3. Post intervention Questionnaire: Determine how individuals felt about the study overall, whether it was consistent with the individual's overall expectation of the experiment, and whether improvements could be made.

All or some of these interviews will be audio or video recorded. The videos may be reviewed by study personnel and investigators for quality assurance, training purposes, or analysis. Physical backups are kept in locked filing cabinets and are labeled with subject identification number and date only. Electronic video or audio files will be stored on a password protected server which only study personnel can access. Video and audio recordings will be kept indefinitely and may later be reviewed by other researchers. Participants may request destruction of video or audio recordings, or may also request not to be audio or video taped.

2.5 Self-report Measures

--Pre-task
1) Demographic and screening questionnaire
2) Mindfulness attention awareness scale (Carlson & Brown, 2005)
3) Patient Health Questionnaire (Kroenke, Spitzer, & Williams, 2001)
4) Meditation experience questionnaire
5) Drug history questionnaire (Ventegodt & Merrick, 2003)
6) modified Differential Emotion Scale (Fredrickson, Tugade, Waugh, & Larkin, 2003)

--During tasks
1) Positive and Negative Affect Schedule (Watson, Clark, & Tellegen, 1988) will be given initially, and then after each intervention (meditation vs. meditation + TVS). This will also be given after the completion of each task (Mind in the Eyes, Global Local Task)

--Post-tasks
1) 5-Dimensional Altered State of Consciousness rating scale(Dittrich, 1998)

2.6 Tasks

OUTLINE of procedures during the tasks
--Calibration (EEG, Pupil/Eye tracking, baseline GSR/EKG, vibration)
--Intervention 1: Meditation*
--Tasks 1: Global-Local Test, Mind in the Eyes
--Intervention 2: Meditation and TVS*
--Tasks 2: Global-Local Test, Mind in the Eyes
*Participant will be randomized whether they get meditation first or meditation and TVS first

All of tasks will be video recorded (calibration, intervention, tasks). The videos may be reviewed by study personnel and investigators for quality assurance, training purposes, or analysis. Physical backups are kept in locked filing cabinets and are labeled with subject identification number and date only. Electronic video or audio files will be stored on a password protected server which only study personnel

can access. Video and audio recordings will be kept indefinitely and may later be reviewed by other researchers. Participants may request destruction of video or audio recordings, or may also request not to be audio or video taped.

Physiological measurements during tasks include galvanic skin response (GSR) measured using electrodes placed on the index and middle finger, pupillary dilation indices, EKG (electrocardiography) which will be measured using three electrodes (left clavicle, right clavicle, and under the right rib), respiration (using a respiration belt), and EEG (mobile EEG monitor on head) will be collected during: 1) calibrations, 2) interventions and 3) cognitive and affective tasks. All of the stated physiological measurements will be collected except pupillary dilation indices will not be collected during interventions (meditation, meditation + TVS) because participants are encouraged to relax and are given the opportunity to close their eyes during those times.

A) Calibrations:

Calibration tasks will initially be completed for physiology collection including a vibration calibration that allows assessment of individualized vibration frequency preferences, a GSR/EKG calibration at baseline, EEG calibration at baseline and pupillary dilation calibration. During the EEG calibration, there are some images that may evoke negative emotions, which is in the introduction, and participants are encouraged to stop the calibration at any time if they feel uncomfortable with the images.

B) Interventions:

Participants will undergo 2 blocks (randomized for order). 1) guided mindfulness meditation and 2) guided mindfulness meditation with TVS (0.1 Hz to 100 Hz) using SubPac, which is a marketed, wearable vibration technology that can deliver TVS, worn like a backpack. Participants will be wearing the SubPac (vest with vibration) the whole time but only during mindfulness with meditation, will the vest vibrate at various frequencies. The intensity of stimuli can vary from barely detectable through somewhat uncomfortable, but will not be painful. Similar vibratory stimuli have been standardly used in Siegle's lab. The intensity of the vibration will be adjusted to the subjects' comfort. Each of the interventions will be have a 12 minuted guided mindfulness meditation, with or without vibration coming out of the vest. They are given the choice to either sit in a desk chair or in a lounge chair, both in the same room. We advise them to concentrate to the meditation and the feelings in their body.

C) Cognitive and affective tasks:

These tasks are standard for our emotion/cognitive research lab.

1. Global-local visual processing task (Fredrickson & Branigan, 2005)

-- In general, images contain both local and global features. This task determines which attention is first directed, either at the local features (details, parts) or global features (the whole)

-- There will be a letter "T" made up of 4 smaller letter "T's". The smaller T's and the large "T" are incongruent in its orientation. The global feature of the letter "T" (the whole) will be of a particular orientation (up, down, left, right) and the local features (details, parts, in this case the 4 smaller letter "T's") will be of a different orientation (up, down, left, right). Participants will have to choose an answer by looking at the letter "T". There is no right answer, and the participant has the choose between 1) a letter "T" with congruent 4 smaller "T's" in the orientation of the global features (the whole) or 2) A letter "T" with congruent 4 smaller "T's" in the orientation of the local features (details, parts).

2. Reading the Mind in the Eyes test (Baron-Cohen, Wheelwright, Hill, Raste, & Plumb, 2001)

Participants will see a picture of a person only with the eyes present. There will be four words that describes the possible mood of the participant. The participant will be asked to choose the adjective that fits best with eye mood conveyed by picture of the person when only the eyes can be observed.

2.7 REGARDING INCOMPLETE DATA COLLECTION

On any given assessment day, data may be incomplete for any number of reasons such as time constraints or equipment malfunctions. In such cases, not all participants will receive all tasks, measures, or procedures for this study. This information will be noted on checklists associated with each task and procedure and stored in the participant's file but will not constitute grounds for a separate note to file as it is an expected outcome and not a protocol violation.

3. PERSONNEL

Because the intervention is automated, clinical training should not be required for staff. A primary value of procedures such as these is that they may someday have translational potential in that they can be accomplished by non -clinically trained personnel. Thus, assessment and intervention personnel will include research assistants or students working in the lab who have been highly trained for the protocol and who have agreed to the lab's research associate integrity agreement (http://www.pitt.edu/~gsiegle/RA integrity -agreement.docx)