soundBrilliance™

Study Protocol

Impacts of Music, Audio Enhancements, Audio Guidance, and Visuals on Physical and Emotional Well-being. (Emotional Health - Longitudinal 1 Randomized, Controlled Multi-center Study)

A 12-Week Parallel-Group Randomized Controlled Multi-center Trial

Field	Details
NCT Number	[Not yet assigned]
Unique Protocol ID	SB EMH L 001
Protocol Version	1.0 / 4/22/26
Sponsor	soundBrilliance, LLC
Principal Investigator	Jason S. Doescher, M.D.

Study design

The objective of this study is to identify factors predicting beneficial impact on emotional health from the soundBrilliance (dB) digital tool when utilized in a self-directed manner. The study will utilize a treatment (Tx) and control (treatment as usual) group for comparison of outcome measures and additionally compare pre-session to post-session changes within the treatment intervention group. Emotional health will be measured across several subjective and objective metrics. The study is IRB-approved and will target various cohort subgroups such as college students and working professionals from different sectors, geographic regions, and clinical programing.

Methodology

Participants

Current recruitment will target n=200 healthy individuals aged 13 years and above. Recruitment will be accomplished via collaboration with a number of research sites using common outreach and information dissemination methods. A consistent informational webpage will provide inclusion criteria as well as relevant updates based on targeted cohort or protocol features such as the inclusion of clinical metrics or physiologic measurements. Prior to enrollment, adult participants will provide written informed consent, while for child participants, a parent or guardian will provide written informed consent and the child will provide written assent. Contact information of the research team will be provided during the consent/assent process so that any questions from prospective participants can be addressed.

Experimental treatment conditions

Each participant will be assigned to either the Tx or control arm. Participants in Tx will be instructed to engage with preferred content on the dB app at least 4 times per week. Control participants will be asked to continue day-to-day life as usual (i.e., no active control). This study is self-directed: Participants in Tx will choose, on a per-session basis, which of four experience Categories to engage with. Experiences range in length from approximately 8 to 40 minutes depending on experience Category and number of songs in the playlist.

<u>Category 1: Enhanced music only</u>

Experience Category 1 comprises audio-only experiences in which curated and participant-selected commercial music arrangements have been engineered with proprietary audio enhancements. Audio enhancements include targeted binaural beats, frequency enhancements, and audio spatialization patterns.

Category 2: Enhanced music + natural visuals

In experience Category 2, the curated and enhanced commercial music selections described in Category 1 (see above) are presented along with natural visual stimuli. These visuals include video photography of natural landscapes, microscopic photography of physical science, and other imagery curated to complement the music and overall experience.

Category 3: Enhanced music + expert guidance

Experience Category 3 is also an expansion of Category 1, now adding therapeutically informed verbal guidance to the enhanced commercial music selections. The verbal guidance is scripted by a licensed clinical psychologist and is intended to support participants in improving their goal-directed experience towards a calm or motivated state of mind.

Category 4: Enhanced music + natural visuals + verbal guidance

Finally, experience Category 4 combines the proprietary audio enhancements of curated commercial music selections, natural visual stimuli, and wellness-directed verbal guidance into the stimulus experience.

Procedure

Onboarding and pre-measures

Upon completing the consent and/or assent process, a participant is considered enrolled. At this time, they will be randomly assigned to the treatment or control arm and assigned a de-identified code name used to label data files. Next, via the soundBrilliance website, all participants will complete a digital onboarding program designed to inform them of the study requirements. During the onboarding phase of the study, all participants will also complete the following pre-measure instruments:

- Demographics survey
- Multidimensional Assessment of Interoceptive Awareness (MAIA; Mehling et al., 2018)
- Mindful Attention Awareness Scale – Trait (MAAS; Brown & Ryan, 2003)
- Perceived Stress Scale (PSS; Cohen et al., 1983)
- Stress management inventory
- Cantril's Ladder (Cantril, 1965)
- Big Five Inventory (BFI; Goldberg, 1990)
- Positive and Negative Affect Schedule (PANAS; Watson et al., 1988)
- State-Trait Anxiety Inventory – State & Trait portions (STAI; Spielberger, 1983)
- Patient Health Questionnaire (PHQ-8; Kroenke et al., 2009)

Adult participants who enroll under clinician supervision only will also complete the following intake measure:

- Beck Depression Inventory (BDI-II; Beck et al., 1996)

Finally, participants in Tx only will receive instructions to download and log into the dB app. Participants who are also recording electrocardiogram (ECG) activity will receive training on usage of the physiological response apparatus at this time (see "Physiological response measurement", below).

Per-session activities (Tx group)

Once a participant in Tx has completed onboarding and downloaded the app, they will be encouraged to complete daily sessions, with a minimum target of 4 sessions per week. Participants are encouraged to select either 2- or 4-song playlists from the four experience Conditions described above, where experiences are designed to provide either a calming or motivating experience. Participants will also have the option to build their own playlists from the available content catalog in 2-, 4-, or 8-song playlists. Each 2- or 4-song session will last approximately 8 (2 songs), 20 (4 songs), or 40 minutes (8 songs) depending on the selected Condition and content.

Each session will include the following optional surveys pre- and post-stimuli:

- State Anxiety Inventory – 6 item short form (SF-SAI; Spielberger, 1983);
- Positive and Negative Affect Schedule (PANAS; Watson et al., 1988);

Each session will additionally include a two-dimensional (valence, arousal) charting tool based on Russell's two-factor model of core affect (Russell, 2002) pre- and post-stimuli. Finally, each session will provide a post-stimuli satisfaction and tolerability survey.

Physiological response measurement (subset of Tx group)

A subset of participants assigned to Tx may be provided commercial grade, non-invasive heart rate monitoring equipment in order to utilize app-integrated technology for continuous recording of ECG during each session. These participants will be asked to follow instructions for equipment and positioning when completing in-app sessions.

Treatment as usual (control group)

Participants assigned to the control group do not complete any sessions on the dB app. Instead, they manage day-to-day life as usual.

Biweekly instruments (all participants)

Starting at baseline (week 0), all participants will complete a series of instruments at two-week intervals. Participants will be contacted via SMS and follow a link provided in the text message to complete the following instruments:

- PANAS-20
- SAI-20 – State
- PHQ-8
- Satisfaction & Tolerability
- (Clinical cohorts only) BDI-II

Beck Depression Inventory (BDI-II)

A subset of participants in clinical cohorts who enroll under clinician supervision will be asked to complete the Beck Depression Inventory (BDI-II). This instrument will be administered at 2-week intervals beginning in week 0 and included with the other biweekly instruments. In accordance with our approved IRB materials, because this inventory includes questions relating to severe depression and suicide, it will only be administered to participants who enroll through a site with a collaborating clinician; responses to this questionnaire will be scored promptly, and a clinician will follow up with the participant within 24 hours if they have indicated thoughts or intentions related to suicide or self-harm.

Outcome measures and questionnaires

Primary dependent variables measured in two-week intervals starting at week 0 and ending following week 12 are as follows:

- State anxiety (SAI-20)
- Depression (PHQ-8)
- Affect (PANAS)

Secondary dependent variables measured at week 0 and following week 12 are as follows:

- Perceived stress (PSS)
- Quality of Life (Cantril's Ladder)

Secondary dependent variables derived from ECG data include the following:

- Root mean square of successive differences (RMSSD)
- Parasympathetic nervous system (PNS) activation
- Sympathetic nervous system (SNS) activation
- Stress index (SI; Tarvainen et al., 2014)

Hypotheses

Previous pilot data shows that dB novel music stimuli reduce both psychological and physiological measures of stress and anxiety. We aim to replicate and extend these findings. Thus, we hypothesize that compared to a treatment-as-usual control group, participants receiving 12 weeks of treatment via the dB app will see significant reductions in state anxiety (SAI-20) and perceived stress (PSS).

Additionally, we expect that through the repetition of self-directed experiences within the dB app, significant reductions in depression (PHQ-8) as well as lower ratings of negative affect and higher ratings of positive affect (PANAS) will be observed. We hypothesize that the Tx group will have an improvement, and larger mean change on quality-of-life metric (Cantril's Ladder) compared to the control group.

For Tx participants measuring ECG throughout the study, we expect to see significant increases in RMSSD and PNS, as well as reductions in SNS and stress index, over time.

Finally, we expect effect sizes to differ for participants based on a number of demographic and psychological factors including age, sex, trait anxiety (STAI-T), interoceptive awareness (MAIA), and trait mindfulness (MAAS).

References

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