soundBrilliance™

Assent Form

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
Assent Version	1.0 / 2/23/26
Sponsor	soundBrilliance, LLC
Principal Investigator	Jason S. Doescher, M.D.

Principal Investigator:	Jason Doescher, MD
Protocol Director:	Blair Kaneshiro, PhD
Administrative Contacts:	Rob Mele, CMPD & Justin Hayes, MA

IRB APPROVED
Feb 23, 2026

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Research Participant Information Sheet – Addendum to the Main Consent Form

TITLE: Impacts of music, audio enhancements, audio guidance, and visuals on physical and emotional well-being

PROTOCOL NO.: dB Intervention 1.0
WCG IRB Protocol #20260183

SPONSOR: soundBrilliance, LLC

INVESTIGATOR: Jason Stuart Doescher, MD
Suite 401, 3701 Wayzata Blvd
Minneapolis, Minnesota 55416
United States

STUDY-RELATED PHONE NUMBER(S):
Justin Hayes, MA
(515) 777-4591 (24 hours)

Rob Mele, CMPD
(763) 360-9923 (24 hours)

Jason Doescher, MD
jason.doescher@soundbrilliance.com

soundBrilliance Research Support
researchsupport@soundbrilliance.com

Time involvement
Summary: We expect that your taking part in this research will entail; a minimum of **4** session(s) per week over **12** week(s), for a total of **48** sessions. You will typically spend **8 to 15** minutes in a study session, but a session can range from **12** minutes to **20** minutes. For multi-session studies, there may be an opportunity to extend up to 2 years if you desire. Additionally, you may complete orientation, intake, and exit activities and participate in 60-minute interviews or focus groups. Your total duration of participation will be based on the number of sessions that are completed.

Specific time involvement: The specific time involvement for your participation is indicated in the following list:

- ☒ Intake activities: Complete intake forms, questionnaires, and measures; approximately **30-45** minutes.
- ☒ Orientation session: Learn how to complete study session activities; approximately **10-15** minutes.
- ☒ Study sessions (single session): Each study session will last approximately **8-15** minutes.

☐ Sessions during acute clinical events: Abbreviated sessions (each lasting approximately ___ minutes) timed to acute clinical events, when feasible and safe to participate.
☒ Interviews and focus groups: You may have the opportunity to provide direct feedback to study sponsors in the form of one or more interviews or focus groups lasting approximately 60 minutes.
☒ Exit activities: Complete exit forms, questionnaires, and measures; approximately **10** minutes.

Payments
Payment rate: You will be paid for your participation as follows:

☐ No payment.
☐ Intake/exit measures and orientation (flat rate): ___
☒ Study-related activities: ___
- For each week you participate, you will receive 2 weeks' free access (credits) to use the soundBrilliance app upon completion of the study. So, at the end of the 12-week study, you'll have up to 24 weeks (or 6 months) credit.
- You will receive a text every 2 weeks over the 12-week study period (6 texts in total) with a link to our survey platform Upon timely completion of the surveys each 2 weeks, you will be compensated $10. **Over the 12-week period, you could earn as much as $60**.

☐ Interviews and focus groups: ___
☐ Additional incentive for completing multi-session study in full: ___

Payment schedule: Dollar-based payment will be given in the form of a non-cash incentive (gift card) according to the following schedule:

☐ Not applicable – no payment.
☐ At the end of each study session intake/exit measure session, or orientation session.
☐ Within two weeks of each study session intake/exit measure session, or orientation session.
☒ Within two weeks of the conclusion of all study-related activities.

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1. **Why is this research being done?**
   We conduct research to test new ideas and learn new things. The purpose of this research is to learn more about the ways in which music, other audio, spoken guidance, and visuals can help people manage their physical and emotional well-being.

2. **Am I eligible to be in this study?**
   You are eligible to be in this study if you meet ALL of the following requirements:

   - You are 13 years of age or older
   - You can read, write, and speak English at a 5th-grade level or higher
   - You are legally capable of providing informed consent (adult participants) or capable of providing assent (child participants)
   - To the best of your knowledge, you are willing and able to commit to the session(s) and activities of this study

- You are willing and able to use the sound-delivery and data-collection apparatus of this study

☐ You are in a more specific age range (13 years or older): ____
☒ You are willing to use your own personal equipment. Depending on the study, you may need to have your own ear buds/headphones and/or a "smart" device with internet and/or Bluetooth access (e.g., smartphone, iPad)
☒ You have normal hearing in both ears
☒ You never experience ringing noises or buzzing sensations in your ears (tinnitus)
☒ You do not use a heart/cardiac pacemaker and do not have any history of cardiac rhythm disturbances, such as cardiac conduction delays or blocks
☒ You have no known history of fainting, fainting, spells or seizures, spinning sensations, or trouble with balance (medical terms include epilepsy, seizures, syncope, vertigo, nystagmus)
☒ You do not use of any of the following medications: Beta blockers, steroids, ephedrine, acute anti-anxiety medication (e.g., benzodiazepines such as diazepam/Valium, lorazepam/Ativan or clonazepam/Klonopin), or acute or chronic pain medications (including narcotics and codeine)
☐ You are not pregnant. If you are pregnant or become pregnant during the study, you will not be eligible to participate or continue participation and will be removed from the study.
☒ For any study session, you will not be under the influence of any substances that could prevent safe participation and will not have consumed e.g., alcohol, THC, Psilocybin, or other mood-altering drugs in the 12 hours preceding the session
☐ You are willing and able to perform specified physical exercise in the range of mild to moderate cardiovascular exercise: _____
☐ You have more specific demographic, psychographic, and/or behavioral characteristics (e.g., university student; musical or fitness expertise or preference): _____
☐ You have more specific medical or clinical diagnoses, or absence thereof: _____

3. How long will I be in this research?

Taking part in this research can range from one session up to multiple sessions per day for 16 weeks with an option to complete additional sessions for up to 2 years. A given session is typically 45 minutes but can range from 15 minutes to 2 hours. In some cases, sessions can last up to 24 hours as participants record responses throughout the day.

Details about your expected time commitment are provided in the Research Participant Information Sheet.

4. What will happen to me if I agree to take part in this research?

If you decide to take part in this research study, the general procedures include completing surveys and questionnaires, experiencing audio and/or visual stimuli, and providing physiological data using software applications. You may be asked to do these things on their own or in an exercise session, as you go to sleep, as you go about your day, or while you experience stress. You may need to use your own personal equipment such as an in-ear or over-ear headphones or personal listening device to listen to audio and experience visual stimuli including still images and dynamic video. You may have the opportunity to provide direct feedback to study sponsors in the form of interviews or focus groups.

5. Could being in this research hurt me?

The most important risks or discomforts that you may expect from taking part in this research include adverse reactions related to audio listening, such as hearing damage or discomfort. There is also the risk that your data, or the fact that you were in the study, will not remain confidential.

Additional risks or discomforts you may experience:

- ☐ Sleep disruption.
- ☐ Injury or exertion related to exercise.
- ☒ Answering questions about mental health, such as your feelings, motivation, and/or mindset.
- ☐ Answering questions about severe depression or self-harm. Your responses will be scored by a trained clinician who will follow up with you within 24 hours if your score indicates a need for follow-up if you have indicated thoughts or intentions related to suicide or self-harm.
- ☒ Completing activities that may cause psychological or physical stress

There are no anticipated risks to participating in this research while pregnant. The protocol for pregnant participants is as follows:

- ☐ While there being no anticipated risks to participating in this research while pregnant, if you are pregnant or become pregnant during the study, **you will be withdrawn from continued participation**. Please let the research team know if you are pregnant or become pregnant during the study.
- ☒ While there being no anticipated risks to participating in this research while pregnant, if you are pregnant or become pregnant during the study, **you may withdraw from the research if you wish**. Please let the research team know if you are pregnant or become pregnant during the study and wish to stop participating.

6. Will being in this research benefit me?

We cannot promise any benefits to you or others from your taking part in this research. Possible benefits to you may include improvements in the way that you manage your physical and emotional health in everyday life and stressful situations, however this cannot be guaranteed. Our findings from this research may eventually inform the development of products or health interventions that can help others manage their physical and emotional health.

7. Will I be paid for being in the research?

Information on whether you will be paid is provided in the Research Participant Information Sheet.

8. What other choices do I have besides taking part in this research?

This is not a treatment study. Your alternative is to not participate.

9. Will anyone know I am in the study?

If you agree to be in the study, some information about you will be given to the researchers. They need this information to keep track of your responses and answer questions if you need help. We will keep this information as securely as possible. Your responses may end up in science papers, datasets, or presentations, but these will not say that you were in the study, or which responses were given by you. For your safety and the safety of others, we may need to share your identity with appropriate third parties if we learn of imminent risk of harm to self or others; abuse of a child or vulnerable adult; or sex-based harassment or violence.

10. What happens if I get hurt while doing the study?

If any of the study activities hurt or injure you, be sure to tell your parent or guardian. They have information on what to do if you are hurt or injured during the study.

11. Who can I talk to about the study?

If you have any questions about the study or any problems with the study, you can contact the Protocol Director, Jason Doescher. You can email him at jason.doescher@soundbrilliance.com. You can also email soundBrilliance Research support at researchsupport@soundbrilliance.com or call the phone numbers listed at the top of this form.

If you have questions about the study but want to talk to someone else who is not part of the study, you can contact WCG IRB. An IRB is a group of people who perform independent review of research studies. You may contact them at (855) 818-2289 or clientcare@wcgclinical.com.

12. How do I join the study?

If you confirm you are eligible to be in the study and want to participate, sign this form. Your parent or guardian will also need to agree that you can be in the study and sign a separate form. Once you sign this form and your parent or guardian signs their form, you will be enrolled in the study. Then, our research team will email you a code name, which lets us organize your responses while keeping your identity a secret. You will use this code name when you participate in the study to let us know it's you.

13. What if I do not want to do this?

If you do not want to be in this study, you do not have to be in it. It is up to you to decide, and no one will be upset if you don't want to do it. Even if you agree to be in the study, you can stop at any time, and it will be okay if you want to stop.

Principal Investigator:	Jason Doescher, MD
Protocol Director:	Blair Kaneshiro, PhD
Administrative Contact:	Justin Hayes, MA

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SIGNATURE

If you agree to be in this study, please sign here:

_____ _____
Signature of child Date

_____
Printed name of child

_____
Email of child (for study correspondence)

_____
Cell phone number of child
(for text-based surveys and correspondence)

_____
Cell service provider (e.g. AT&T)