soundBrilliance™

Consent 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
Consent Version	1.0 / 3/17/26
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

soundBrilliance™

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.

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

IRB APPROVED
AS MODIFIED
Mar 17, 2026

soundBrilliance™

Research Participant 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

This consent form is intended for (1) the adult participant or (2) the parent or guardian of a child participant. Child participants review and sign a separate assent form. Unless otherwise specified, in this consent form "you" refers to the participant.

Taking part in this research is voluntary. You may decide not to participate, or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you have any questions, concerns, or complaints or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

RESEARCH CONSENT SUMMARY

You are being asked for your consent to take part in a research study. This document provides a concise summary of this research. It describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide all relevant details.

IRB APPROVED
AS MODIFIED
Mar 17, 2026

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.

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.

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.

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), sleep disruption, injury or exertion from exercise, experiencing stress, or negative emotions that may arise from answering questions about how you feel. There is also the risk that your data, or the fact that you were in the study, will not remain confidential. You may be asked to answer questions about severe depression or self-harm; you will be notified later in this consent form if that is the case, and your responses will be reviewed by a trained clinician who will follow up with you if needed.

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.

What other choices do I have besides taking part in this research?
This is not a treatment study. Your alternative is not to participate.

What else should I know about this research?
You will receive an additional consent information sheet that will provide more information about what your specific participation may involve, including information about time involvement and compensation for your time.

IRB APPROVED
AS MODIFIED
Mar 17, 2026

This research does NOT involve the collection of identifiable private information or identifiable biospecimens.

DETAILED RESEARCH INFORMATION

Your decision whether or not to participate in this study will not affect your employment, your grade in a class, or your medical care.

Adult participants: Please read this document carefully. If you decide you would like to participate, please indicate your informed consent by signing and dating the form at the bottom. If you decide at any point that you do not wish to participate in the research, please close this form without signing it.

Parents and guardians of child participants: Please read this document carefully. If you decide your child can participate, please indicate your informed consent by signing and dating the form at the bottom. If you decide at any point that you do not want your child to participate in the research, please close this form without signing it. Your child will participate only if you sign this consent form and they sign a separate assent form indicating their willingness to participate.

If you have any questions about this form or would like to talk to a member of the study staff before deciding whether or not to sign it, please contact the research team:

- Justin Hayes, MA: justin.hayes@soundbrilliance.com or (515) 777-4591
- Rob Mele, CMPD: rob.mele@soundbrilliance.com or (763) 360-9923
- soundBrilliance Research Support: researchsupport@soundbrilliance.com

OVERVIEW

We are conducting research to better understand how music, audio guidance, and/or visuals can help people manage their physical and emotional health. As a participant you might experience audio or visuals or follow instructions to manage your mood or energy level. We may collect "subjective" measures – such as ratings or written responses – and "objective" measures – such as how you breathe or how your heart beats – in order to understand how you are feeling or responding to stimuli. As each person is unique in how we think and feel, as well as how our bodies respond to daily stress, everyday activities, and other stimulations like music or visuals, we aim to understand how these elements and reactions relate to each other. You will not receive any therapy or treatment for medical conditions by participating in this research. This research will not diagnose any conditions or provide information regarding your health; it does not replace your medical or wellness care.

Enrollment:

Enrollment for a given study will typically range from 20 to 750 participants.

ELIGIBILITY

To be eligible to take part in the research, you must 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): C-ELIG-1
☒ 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: C-ELIG-2
☐ You have more specific demographic, psychographic, and/or behavioral characteristics (e.g., university student; musical or fitness expertise or preference): C-ELIG-3
☐ You have more specific medical or clinical diagnoses, or absence thereof: C-ELIG-4

DESCRIPTION

Time involvement:

Study sessions: You will be asked to complete one or more study sessions. A given session is typically 45 minutes long but can range from 15 to 120 minutes. Some studies involve wearing equipment that measures physiological responses as you go about your day (from 1 to 24 hours). Depending on the study, you may be asked to complete only one session or as many as multiple sessions each day of the week. Studies involving more than one session typically last from 2 to 16 weeks, with an opportunity to extend up to 2 years if you desire.

The specific time involvement for your participation is indicated in the Research Participant Information Sheet.

Procedures:
The study consists of the following activities (see Figure 1 below):

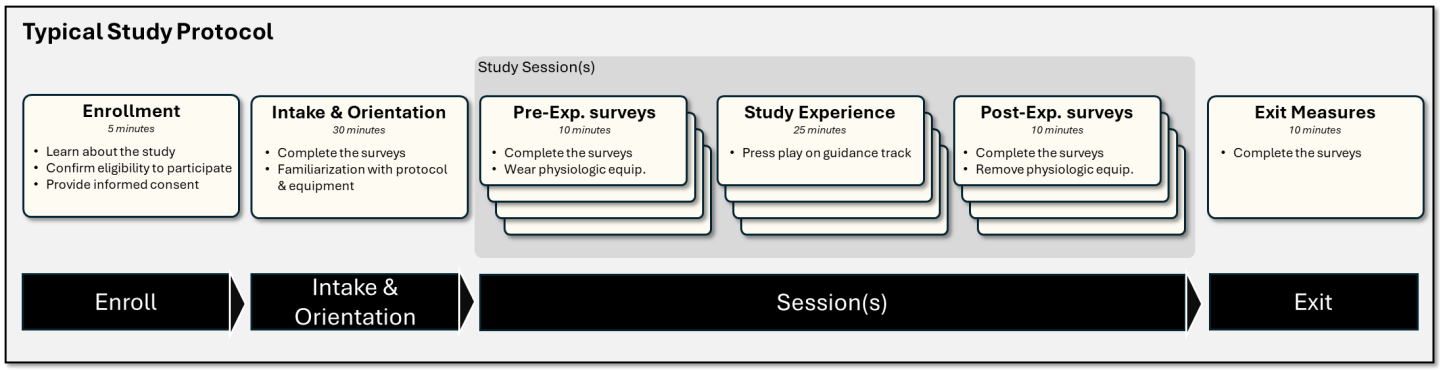


Figure 1: Study Activities

Part 1: Enrollment

1.1 Eligibility and Consent
Adult participants: If you confirm that you are eligible to participate in the study and sign this consent form and (when applicable) the HIPAA form, you will be enrolled in the study. Our research team or the research recruiting platform (e.g., Prolific, User Interviews) will email or message you a short code name, which lets us organize the responses you provide while keeping your data separate from your identity.

Parents and guardians of child participants: If (1) you confirm the child participant's eligibility and sign this consent form and (when applicable) the HIPAA form and (2) the child confirms their eligibility and signs a separate assent form, the child will be enrolled in the study. Our research team or the research recruiting platform (e.g., Prolific, User Interviews) will email or message the participant a short code name, which lets us organize the responses provided by the participant while keeping their data separate from their identity. Once the child is enrolled, they will receive all further study materials and communication directly from the study staff.

Part 2: Intake and Orientation

We'll ask you to complete some activities to get ready for the upcoming study session(s). You may be asked to complete some surveys and/or provide some physiological measures, chosen from the list in **Appendix A.** You will also be asked to make sure that the device you'll use for listening is set to a safe listening level. Finally, you'll make sure you have all of the necessary equipment. You may need to set up one or more applications with a code name we give you, and make sure that all of the pieces of equipment are working together. Equipment and software applications we may use are given in **Appendix B**.

Participants enrolling for adjunctive therapy under clinician supervision: Your clinician may have considered aspects of your condition or treatment history when referring you to this study. However, your clinician does not share your clinical treatment records with us, and we analyze only the data we collect directly through your participation in the research.

IRB APPROVED
AS MODIFIED
Mar 17, 2026

Part 3: Study Sessions

You'll be asked to complete one or more study sessions as specified in the Research Participant Information Sheet.

Confirmation of eligibility: Before beginning a session, you'll need to confirm that you meet the following eligibility criteria for the session:

- ☒ You are available for the duration of the session without interruption and can give your undivided attention to the session activities (no multi-tasking).
- ☒ Not currently under the influence of any substances that could prevent you from safely participating in today's session.
- ☒ Not consumed any alcohol, THC, Psilocybin, or other mood-altering drugs for at least the 12 hour(s) leading up to the session.
- ☐ Pregnant people are not permitted to participate. Should you become pregnant during the study, notify study staff to withdraw your participation.

Study session activities: A given study session can include any of the following activities:

- ☒ Experience stimuli: Use of earbuds, headphones, and/or external speakers as well as audio or audiovisual devices (e.g., smartphone, tablet, virtual reality headset) provided by the participant or by soundBrilliance to experience auditory and/or visual stimuli. Audio may include spoken guidance, spoken media, music, and/or ambient soundscapes and may also be enhanced soundBrilliance (dB) proprietary audio products such as binaural beats, targeted frequency enhancements, or spatialization. You may also experience visual stimuli including still images and dynamic video. The stimuli are downloaded to the device, streamed from the study website, or experienced through the soundBrilliance app. In some cases you may also be asked to experience an absence of stimuli.
- ☒ Provide subjective (self-report) responses: Report your perceived physical or emotional state; perception of or reaction to stimuli; prior night's sleep quality and quantity; current level of sleepiness; usability of the experimental apparatus and ease of following the experimental protocol; and/or other aspects of your experience of the study session. These reports may be given via survey delivered via email, website, and/or text messaging (MMS), and/or verbally to the investigator and may be requested at various points during a session. Surveys are included in the list of measures and inventories provided in Appendix B. Verbal reports could relate to the topics of enjoyment and ease of participation; experience of the audio-listening activities; experience of stimuli; and/or suggestions for process improvement.
- ☐ Provide objective (physiological) responses during study sessions: Physiological responses will be collecting during study sessions using non-invasive sensors that are worn on the surface of the body—such as a chest strap, arm strap, or smart watch, blood pressure arm cuff—or placed under a bed mattress, such as a sleep mat. The response measures that may be recorded in a given study session are listed in **Appendix B**. The list of apparatus that may be used to measure and record physiological responses is included in **Appendix C**.
- ☐ Provide objective (physiological) responses throughout the day: You may be asked to wear the physiological monitoring equipment for the whole day (from 1 to 24 hours per day) on select/several days per week (e.g. smart watch).Your HRV, HR, and autonomic nervous system functioning may be assessed throughout this entire experience by use of non-invasive technology worn on the surface of the body (e.g. Polar watch and Polar chest strap), and analyzed with software (e.g. Polar, Kubios, and other leading software) as outlined in **Appendix E**.

- ☐ Fitness activities: Perform exercise-related activities with varying degrees of intensity (e.g., walking, running, rowing, biking, cardiovascular, HIIT, resistance training), pre-exercise activities (e.g., instructions, guidance, visualization), and/or post-exercise recovery activities (e.g., lying supine, dynamic/static stretching). Exercise activities will involve equipment at your fitness club, such as treadmills, rowing machines, stationary bikes, elliptical machines, barbells, dumbbells, and cable machines.
- ☐ Sleep activities: Perform sleep-related activities pertaining to sleep hygiene (e.g., dimming lights, turning off electronic devices, etc.), pre-sleep activities (e.g., instructions, guidance, visualization), and/or sleep activities (e.g., listening to sleep promoting soundscapes). Sleep activities may take place in your typical environment (e.g., at home) or specific setting (e.g. hospital, hotel) and will involve personal equipment and/or equipment provided by the study sponsor.
- ☐ Experimental stressors: You may be asked to participate in activities that are psychologically or physically stressful so that we can measure your response to stress. Specifically, you may be asked to C-SSACT-1.
- ☐ Study activities scheduled in relation to real-life stressors: You may be asked to time your study sessions to everyday scenarios—that is, events encountered in everyday life, independently of your participation in the research—that you consider stressful. For example, you may complete study sessions before or after a school exam, presentation, outpatient procedure, or important meeting.
- ☒ Self-directed engagement: You may be asked to engage with the study materials according to your own pace and preference, as specified in the "Time involvement" section above.
- ☒ Multi-session studies: For multi-session studies, we may ask you to complete additional surveys or questionnaires (drawn from the list in **Appendix B**) before or after selected sessions.
- ☐ Adjunctive therapy under clinician supervision (general): Your participation in this study is considered an add-on to the treatment you are receiving from the clinician who referred you. Your clinician has helped to specify your study activities as described here, and they will have access to your results for interpretation and to inform your treatment. Your participation in this research is voluntary, and your decision of whether to participate will not impact your ability to continue treatment from your clinician. This research is not intended to replace your ongoing clinical treatment.
- ☐ Adjunctive therapy under clinician supervision (acute sessions during targeted events): You may be asked to complete shorter sessions when you experience a targeted event related to ongoing clinical treatment (e.g., a headache). When possible, if you sense that you are about to experience one of these events, you are asked to stop your current activity, perform a shorter study protocol, and complete a shorter set of post-session measures. Your participation in the research is voluntary and will not impact your ability to access ongoing treatment from your clinician. Study activities are not intended to replace your ongoing clinical treatment.

Part 4. Exit measures

After you complete your final study session, we may ask you to fill out a final set of questionnaires. We may also ask you to give final psychometric and/or physiological measures like the ones you gave during the intake stage. The surveys and measures taken here will come from the list in **Appendix B**.

Part 5. Interviews and focus groups

You may have the opportunity to participate in interviews and/or focus groups. Interviews and focus groups will be approximately 60 minutes in length and can take place in person or via video conference. Interviews and focus groups will be conducted by one or more members of the study staff. Depending on the study,

interview/focus group sessions may be required or optional, and you may be invited to complete between 0 and 8 interview/focus group sessions.

More details on your participation in interviews/focus groups are provided in the Research Participant Information Sheet.

These sessions may be recorded and transcribed for internal use, and audio or video recordings will be stored (1) within secure internal servers and/or (2) via 3rd-party cloud storage (Zoom) subject to the privacy policies of the 3rd-party platform. You may discuss one or more of the following topics in the semi-structured format of a given interview or focus group session:

- Strategies and challenges related to the topic of the study, in general or related to the study protocols. Examples:
    - In sleep studies, you may discuss sleep habits, preparation, and hygiene; next-day sleepiness; and other sleep behaviors.
    - In fitness studies, you may discuss how you prepare, perform, sustain, and recovery from exercise; and successes and challenges around sticking to an exercise or recovery routine.
    - In studies related to emotional state, you may discuss strategies for stress and/or motivation management; events or settings that you find stressful; or challenges in managing stress or mood.
    - In studies related to comfort, you may discuss strategies for pain management, and events or challenges related to quality of life.
    - You may provide feedback on study protocols and your overall experience of participating in the research.
- The role of music, sound, and visual experiences in managing emotional states, in general or related to the study protocols.
- Feedback on the user experience of the soundBrilliance application. Examples:
    - Your needs and desired features of an application to support physical or emotional health.
    - Feedback on how the soundBrilliance application supports your physical or emotional health, and how it falls short.
    - We may directly observe you using the soundBrilliance application. You might be asked to say out loud what you are thinking and feeling as you use the application, or discuss your experience with the researcher.
- Any other perspectives, feedback, or questions you wish to share.

Parents and guardians of child participants: In the signature area at the end of this form, you will specify whether you consent to your child's participation in interviews and focus groups, or whether you wish to opt them out of these specific activities.

Communication: We may communicate with you in any of the ways listed below. Unless otherwise specified, the study staff will only communicate directly with the participant, even when the participant is a child aged 13 years or older.

- Email: Members of the study staff may initiate correspondence; you can also elect to email the research team.
    - Participants 13-15 years of age: The parent/guardian signing this consent form will be cc-d on emails sent by the research team to your child.

- Dedicated webpages: Webpages contain study information, instructions, and links to access surveys and stimuli.
- Online study platform: When studies are conducted via a third-party online platform (e.g., User Interviews, Prolific), you may receive announcements, reminders, or other communication from the online platform.
- In-person: Members of the study staff may seek informal feedback from you (see Procedures, above) and may be approached by you. Collaborators from research partners may implement or support protocol delivery as necessary.
- Phone: You can call dedicated contact personnel in the study staff with any questions, concerns, or complaints about the research. Members of the study staff will generally not initiate contact with you by phone but will return your calls as requested.
- Text messaging: You may be contacted during the day at one or more time points and be asked to respond to one or more survey questions. In this case, participant information given to the text service provider is limited to your phone number and survey responses, typically limited to questions on sleep quality for the previous night and their current level of alertness, mood, or comfort. Text messages may also be sent to invite you to continue participation in the research. You will be able to control whether text messages will be received.
    - Participants 13-15 years of age: The parent/guardian signing this consent form will be notified via email whenever a text is sent by the research team to your child.
- Mobile application: You may receive notifications including prompts to complete activities related to the protocol in a timely manner. You will be able to control notifications including whether, when, and where they will be displayed, in the same manner as is standard with all approved smart phone applications.

Data collection, storage, and use:

- Code names: If you choose to participate, you will be given a code name to use in your study sessions. This is to ensure that your data files are labeled in a way that does not reveal your identity. Only select members of our research team will know the mapping between your identity and your code name. The mapping between your code name and your identity will be stored securely on a password-protected, encrypted computer.
- Survey and physiological data: All survey and physiological data collected in this research will be linked to your code name, ensuring that your identity is not directly mapped to your data. Data files are uploaded to a secure server before being combined and analyzed to determine the results of the study. The research team may access the data and use other software packages to analyze it.
- User data from the soundBrilliance application. When research activities are carried out using the soundBrilliance application, we may analyze corresponding user data, including but not limited to when and how long you use the application as well as what content you interact with. When we analyze your user data for research, your data will be stored on secure servers and password-protected, encrypted computers and labeled with the your code name, ensuring that your identity is not directly mapped to your data.
- Verbal responses: Any verbal responses given during a study session will be stored digitally or in written form by a member of the research team. These reports will be labeled with your code name and not directly linked to your identity.
- Retrospective data use: Previously provided data that is compliant with this consent form, collected as part of a pilot study or in preparation for this study, may be used in data analysis.

- Interview and focus group data: All interviews and focus groups will be conducted by members of our research team, either in person or over secure videoconferencing software (Zoom). These sessions may be audio or video recorded and transcribed for internal use. Any audio or video recordings will be stored in our secure internal servers, or in Zoom's cloud storage. The research team will have access to the transcripts, but only select members of the research team will have access to the audio or video recordings. Recordings stored in Zoom are subject to Zoom's privacy policy (link: https://explore.zoom.us/en/privacy/).
- Closing of the study: Unpublished data will be deleted at the end of the research, once all analyses have been completed and reported.

The data and results of this research study may be quoted, paraphrased, and/or summarized to be presented at scientific or professional meetings or published in scientific journals or data repositories. Your individual privacy will be maintained in all published and written data resulting from the study. As is common in a scientific study, the data from this research may be used or shared with other researchers for future research (after removing personally identifying information) without additional consent from you.

Protected Health Information (PHI): Some studies are conducted in collaboration with your/your child's clinician and involve Protected Health Information (PHI). In these cases, we may share and discuss your research data, mapped to your/your child's identity, with the clinician. This will help the clinician interpret findings from the research in relation to your/your child's ongoing clinical treatment.

The following points apply for studies involving PHI:

- You will be asked to sign an "Authorization To Use Your Health Information For Research Purposes" form to approve sharing of your/your child's PHI with the partnering clinician.
- Sharing of data is only from soundBrilliance to the clinician; the clinician will not share treatment records with us.
- Any external reporting of your/your child's data and results will not disclose your/your child's identity.

RISKS AND BENEFITS

Risks

Risks of disturbances or injury resulting from study session activities:

- ☐ Sleep disturbances: There are no known risks to listening to music during sleep. However, while no systemic adverse outcomes have been reported in scientific or general publications, impacts of music on sleep are by nature personal and vary from person to person. Negative impacts of listening to music during sleep are unlikely but could happen. If you experience any negative effects on your sleep from the research activities – including sleep disruptions – let the research team know. Please exercise personal judgment and responsibility regarding your behavior, safety, and daily function related to your sleep quality and quantity.
- ☐ Injury or exertion resulting from exercise: Exercise activities performed in fitness studies should be part of your currently tolerated and medically approved routine. Please consult your medical team for any screening or precautions related to the exercise activities of this research (e.g., moderate to vigorous cardiovascular exercise) and manage your tolerance of exercise and determine capacity to participate safely. Despite all precautions, you might experience adverse events such as injury during the exercise portion of the sessions. If you sustain any injury or illness that is directly caused by participation in the exercise, you will be responsible for any associated expenses, co-payments, or deductibles as required by insurance. Additionally, soundBrilliance is not responsible for research and medical care by other

institutions or personnel participating in this study. Exercise personal judgement and responsibility regarding your behavior, safety, and daily function.

☒ There are no known physical risks of disturbances or injury associated with your participation in the research.

Risk of psychological distress:

☒ Answering questions about mental health: You may be asked about emotional health (e.g. anxiety, depression, stress management), motivation, and/or mindset. The soundBrilliance research team does not provide mental-health services and generally will not follow up with you about your data, such as your depression or anxiety scores. However, if you are seeking mental-health resources, a list is provided in **Appendix D** of this consent form.

☐ High-risk questionnaires administered in person: You may be asked to complete questionnaires that ask **questions related to severe depression and/or suicide**, as noted in **Appendix B**. These questionnaires are used only when necessary to address the research question at hand, and a collaborating clinician will always be part of the study staff. The clinician will administer these questionnaires in person and follow up with you immediately if your score indicates a need for follow-up or if you have indicated thoughts or intentions related to suicide or self-harm.

☐ High-risk questionnaires administered online: You may be asked to complete questionnaires that ask **questions related to severe depression and/or suicide**, as noted in **Appendix B**. These questionnaires are used only when necessary to address the research question at hand, and a collaborating clinician will always be part of the study staff. Your responses to these questionnaires will be scored promptly, and the clinician will follow up with you within 24 hours of your response if your score indicates a need for follow-up or if you have indicated thoughts or intentions related to suicide or self-harm.

☐ Stressful activities: You may experience **psychological or physical stress** while completing some study activities. These stressful activities are included only when necessary to address the research question at hand. It is your right to stop participating in study activities at any time; should you wish to stop participating at any point during a study session, let the experimenter know.

If a member of the research team learns that you have indicated intent to harm yourself or others, you will be contacted by a member of the study team or a partnering clinician and be provided with resources for the crisis intervention line or emergency services.

Adverse reaction related to audio listening, such as hearing damage or discomfort:

Excessively loud music has the potential to injure hearing or provoke discomfort. To reduce this risk, onboarding activities include steps for you to determine appropriate sound levels for music/audio listening in the study. There is a slight risk that music stimuli may cause discomfort or unforeseen adverse events in some listeners, including uncomfortable physical or emotional reactions. If this occurs at any point during the study, stop listening to the stimuli immediately and contact a member of the study staff (see Contact Information below).

Privacy and data breach risks

Email communication. As noted in the previous section, study data will be stored securely, minimizing the risk of a data breach. We request your email address to send your code name, communicate updates about the study, and answer any email correspondence that you initiate. Email is generally not a secure way to

communicate as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact a member of the study staff (see Contact Information below).

Data collection in a group or open setting. We ask that you keep all activities, and the identities of others in your environment, private. Although the research team will strive to maintain your privacy, privacy cannot be guaranteed in a group or open setting. Your identity and any verbal responses you give in a group or open setting will be known to others in your environment, and the researchers cannot guarantee that others in your environment will respect your privacy.

Situations in which privacy may not be maintained

- If a member of the research team or coordinating partner learns of imminent risk of harm to self or harm to others, or if responses to a screening questionnaire exceed a determined threshold related to depression or suicidal ideation, you will be contacted by a member of the study team (either from soundBrilliance or a partnering clinician) and be provided with resources for the crisis intervention line or emergency services.
- If a member of the research team learns of abuse of a child or vulnerable adult, mandated reporting law requires appropriate authorities to be notified.
- For studies conducted in partnership with academic institutions in the United States that receive federal financial assistance: Under Title IX, institutions are required to report any discrimination on the basis of sex that relates to their education programs, including but not limited to sex-based harassment and violence (see https://www.ed.gov/laws-and-policy/civil-rights-laws/title-ix-and-sex-discrimination for current policies). All study staff have received Title IX training and will report any relevant incidents to the soundBrilliance Principal Investigator and an Investigator at the institution; the local Investigator will then report the incident to the institution's Title IX office when necessary.

In general, there is a potential risk of loss of confidentiality associated with research participation. In some cases, such as those described above, privacy may also be broken in the interest of protecting your safety and/or the safety of others.

Risk of participation while pregnant

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.

Other risks

There may be risks or side effects which are unknown at this time.

You are encouraged to withdraw if you feel that your health, behavior, or sense of well-being is negatively impacted at any time during study participation. You do not waive any liability rights for personal injury by signing this consent form.

Benefits
We cannot promise any benefits to the participant or others from taking part in this research. Studies covered by this protocol are not treatment studies. Even if you have enrolled through clinician referral, your participation in this research is an add-on to your treatment as usual and does not replace it. This research does not provide therapy or treatment for a medical condition or replace standard medical care. Depending on the study, possible benefits to you may include the following:

- Improvements in preparing for, participating in, and recovering from exercise activities.
- Improvements in sleep hygiene and quality.
- Improvements in the way that you manage your own emotional state in everyday life and stressful situations.
- Improvements in discomfort and/or pain management, motivation, health, and quality of life.

However, nothing can be guaranteed. Our findings from this research may eventually inform the development of products or health interventions that can help others manage their physical, cognitive, or emotional states.

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

COSTS AND PAYMENTS
Costs
There is no cost to participate in this research. However, if using your own smart device to stream stimuli from webpages and/or access webpages to fill out surveys, you may incur cellular or WiFi costs related to these activities. Please feel free to ask any further questions you might have about this matter.

Payments
Payments for most study-related activities range from $0-$20 per hour with any one activity typically not lasting more than 2 hours. Payment amounts are calculated based on completion of specific activities (flat rate) or on time spent participating (duration-based). Additional incentives valued at less than $500 may also be offered for completion of study activity milestones.

Specific payment information for your participation in this study is provided in the Research Participant Information Sheet.

The results from this study may lead to new commercial products or tests. If this happens you will not receive any additional compensation.

Financial Disclosure:
Dr. Jason Doescher owns private equity in the Sponsor company for this research and holds a Corporate Officer/Board of Director role in Sponsor company for this research. In addition, some sub-investigators are paid consultants for the Sponsor company of this research.

Please feel free to ask any further questions you might have about this matter.

IRB APPROVED
AS MODIFIED
Mar 17, 2026

PARTICIPANT'S RIGHTS: If you have read this form and have decided to participate in this study, please understand your participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. The alternative is not to participate. You have the right to refuse to answer particular questions.

Participants at partnering academic institutions: If you are a student or faculty/staff member of a sub-investigator's academic institution (see contact information at the beginning of this document), your decision about whether to participate in this study will not affect your grades, academic status, or job status at that institution. You will not be offered or receive any special consideration if you take part in this research study.

If you take part in this research, you will be responsible to do the following during the study:

- Manage your tolerance of the study session activities and determine capacity to participate safely.
- Maintain your eligibility to participate or notify the study staff if your eligibility changes.
- Notify the study staff if you start or stop any medications that may impact your eligibility.
- Notify the study staff if you become pregnant and stop participating in the study.
- Notify the study staff if you experience any injury or adverse reaction from participating in the study.
- soundBrilliance does not provide clinical care. You are responsible for utilizing existing clinicians or community resources in case of psychological distress or injury. Mental-health resources will be provided to all participants in the consent form (and assent form, when applicable). See **Appendix D** for a list of national resources.

The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

- Your eligibility to participate changes.
- You start or stop a medication over the study duration.
- You have a side effect that requires stopping the research.
- You are unable to complete the requested number of study sessions.
- You cannot or do not follow the instructions of the study protocol.
- The study design has changed.
- You are or become pregnant.

We will contact you with any new information we receive that may affect your health, welfare, or participation pertaining to this research.

CONFIDENTIALITY:
Information from this study will be given to the sponsor. "Sponsor" includes any persons or companies that are contracted by the sponsor to have access to the research information during and after the study.

The information will also be given to the Department of Health and Human Services (DHHS) agencies (such as the Food and Drug Administration (FDA)). It may be given to governmental agencies in other countries where the study device(s) may be considered for approval. Medical records which identify you and the consent form signed by you will be looked at and/or copied for research or regulatory purposes by:

- the sponsor,

and may be looked at and/or copied for research or regulatory purposes by:

- Department of Health and Human Services (DHHS) agencies,
- governmental agencies in other countries, and
- WCG Institutional Review Board

Absolute confidentiality cannot be guaranteed because of the need to give information to these parties. The results of this research study may be presented at meetings or in publications. Your identity will not be disclosed in those presentations.

☒ A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

CONTACT INFORMATION

Questions: If you have any questions, concerns or complaints about this research, its procedures, risks and benefits, contact the Principal Investigator, Jason Doescher, MD jason.doescher@soundbrilliance.com, soundBrilliance Research Support researchsupport@soundbrilliance.com, or the phone numbers listed at the top of this form.

Independent Contact: This research is being overseen by 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 if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

ASSENT INSTRUCTIONS

All children are required to assent.

If assent is obtained, have the child sign the assent form.

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

IRB APPROVED
AS MODIFIED
Mar 17, 2026

STATEMENT OF CONSENT
If you agree to participate in this research, please provide your full name and email below. We will use the email address you provide to send you a code name to use in the study. We will also email you a copy of this consent form for you to keep.

Your signature documents your consent to take part in this research.

_____
Printed name of adult or child participant

_____
Email of adult or child participant (for study correspondence)

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

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

Child participant may take part in interview/focus group sessions if they wish

☐ Yes ☐ No ☐ Not applicable – participant is an adult

_____ _____
Signature of participant (adult participant) **or** Date
Signature of parent/guardian, **if participant is a child**

_____
Printed name of parent/guardian, **if participant is a child**
(enter NA if not applicable)

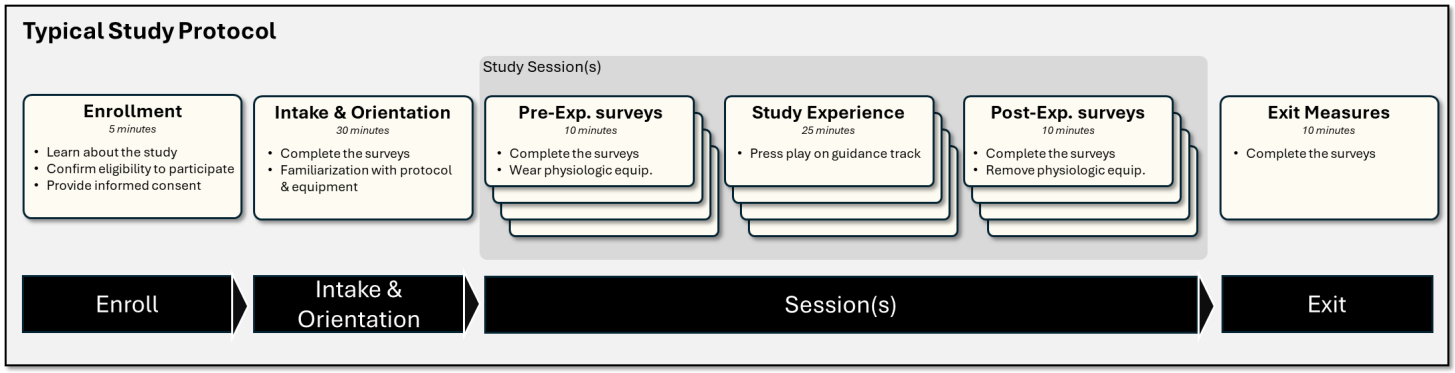
_____
Email of parent/guardian, **if participant is a child** (for study correspondence)
(enter NA if not applicable)

_____
Relationship to participant, **if participant is a child**
(enter NA if not applicable)

_____ _____
Signature of person obtaining consent Date

APPENDICES

Appendix A: Study session flowcharts



Appendix B: Questionnaires, inventories, and physiological measurements used

Questionnaires and inventories

Demographics/General

- Demographics - soundBrilliance (full version)
- Demographics - soundBrilliance (short version)
- General - soundBrilliance General Satisfaction and Tolerance

Depression

- CES-D Center for Epidemiologic Studies Depression Scale
- CES-DC Center for Epidemiologic Studies Depression Scale for Children
- DASS Depression Anxiety Stress Scales (long and short versions)
- HADS Hospital Anxiety and Depression Scale
- PHQ-8 Patient Health Questionnaire
- PROMIS Emotional Distress—Depression

Exercise

- BREQ-3 Behavioral Regulation in Exercise Questionnaire
- EFI Exercise-induced Feeling Inventory
- EMI-2 + EMGI Exercise Motivation Inventory + Exercise Motives and Gains Inventory
- Feeling scale (maybe exercise)
- PAES Physical Activity Enjoyment Scale
- Per-session eligibility questionnaire
- PMA Primary Mode of Activity
- Pre-workout satisfaction
- PRS Perceived Recovery Status
- RPE Rating of Perceived Exertion

Mindfulness/Interoception

- CAMS-R Cognitive and Affective Mindfulness Scale-Revised
- FFMQ Five Facet Mindfulness Questionnaire
- FMI Freiburg Mindfulness Inventory
- KIMS Kentucky Inventory of Mindfulness Skills
- MAAS Mindful Attention Awareness Scale
- MAIA Multidimensional Assessment of Interoceptive Awareness
- PHQ 15 Patient Health Questionnaire 15-item Somatic Symptom Severity Scale
- SSS-8 Somatic Symptom Disorder Scale

Mood

- BRUMS Brunel University Mood Scale
- Modified Russell Circumplex (chart)
- Modified Russell Circumplex (Likert only)
- PANAS Positive and Negative Affect Schedule
- SAM Self-Assessment Manikin
- WHO-5 World Health Organization-Five Well-Being Index

Music

- AIMS Absorption in Music Scale
- BRMI-2 Brunel Music Rating Inventory 2
- eBMRQ Extended Barcelona Music Reward Questionnaire
- GOLD-MSI Musical Training
- Healthy-Unhealthy Music Scale

Pain

- BPI Brief Pain Inventory (Short Form)
- McGill Pain Questionnaire
- Numeric Rating Scale for Pain
- PSEQ Pain Self-Efficacy Questionnaire
- PSQ Pain Sensitivity Questionnaire
- VAS Visual Analog Scale for Pain
- WHYMPI West Haven-Yale Multidimensional Pain Inventory

Personality

- BFI Big Five Inventory
- HSP Highly Sensitive Person Scale
- IRI Interpersonal Reactivity Index - Empathy
- MSPSS Multidimensional Scale of Perceived Social Support

Quality of life

- Cantril's Ladder
- SWLS Satisfaction with Life Scale

Sleep

- Berlin Questionnaire (sleep evaluation)
- HD-16 Insomnia Quality of Life
- KSS Karolinska Sleepiness Scale
- MOBE Sleep Quality Scale
- PSQI Pittsburgh Sleep Quality Index
- SHI Sleep Hygiene Index

Stress

- CRSQ Clinical Rotation Stress Questionnaire
- K10 Kessler's Psychological Distress Scale
- PSS Perceived Stress Scale
- SMI Stress Management Inventory - Dan Bowling
- SMI Stress Management Inventory - soundBrilliance
- soundBrilliance Stress Slider
- STAI State-Trait Anxiety Inventory (state portion)
- STAI State-Trait Anxiety Inventory (trait portion)
- STAI-6 short-form state scale (state portion)
- STAI-6 short-form state scale (trait portion)
- SUDS Subjective Units of Distress

Inventories flagged for high-risk questionnaires

- BDI-II Beck Depression Inventory (adults)
- CDI Children's Depression Inventory
- CDRS-R Children's Depression Rating Scale-Revised
- HAMD/HDRS Hamilton Depression Rating Scale
- HSCL-25 Hopkins Symptom Checklist
- KADS Kutcher Adolescent Depression Scale
- MADRS Montgomery-Åsberg Depression Rating Scale
- Pain Catastrophizing Scale
- PHQ-9 Patient Health Questionnaire-9 (adults)
- PHQ-A Patient Health Questionnaire-9 for Adolescents
- SDS Zung Self-Rating Depression Scale

<u>Physiological response measures</u>

General

- Heart rate (HR): Min, max, average, % of max, time spent in zones, resting, reserve
- Heart rate variability (HRV): Stress index, PNS index, SNS index, SDNN, SDRR, SDANN, pNN50, HRmax minus HRmin, HRV triangular index, TINN, non-exercise related (e.g., morning, snapshot), mean RR (ms), RMSSD (ms), SD1 (%), mean HR, SD2 (%), HF power (normalized), LF power (normalized), LF/HF ratio (by FTT calc method).
- Distance metrics, pace metrics, sleep metrics

- Weight, height, KCal expended, % body fat, lean muscle mass
- Estimated VO2, training load, training impulse (TRIMP), average training intensity (TRIMP/min), power (Watt), cadence (steps/min), RPE (rate of perceived exertion)
- Respiratory rate, respiratory amplitude.
- Blood pressure measurements (systolic, diastolic, mean arterial pressure)
- Body temperature
- Galvanic skin response

Sleep architecture variables

- Total Time in Bed (min)
- Total Sleep Time (min)
- Sleep Efficiency (%) – calculation of time in bed / total sleep time
- Sleep Latency (min) — also known as Sleep Onset Latency; important, some also argue this is a sleep fragmentation variable
- REM Latency from Sleep Onset (min)
- Wake Time (min)
- Stage N1 Time (mins)
- Stage N2 Time (mins)
- Stage N3 Time (mins)
- REM Time (mins)
- Stage N1 % Sleep Time
- Stage N2 % Sleep Time
- Stage N3 % Sleep Time
- Stage REM % Sleep Time
- Wake % of Time in Bed
- NREM1 % of Time in Bed
- NREM2 % of Time in Bed
- NREM3 % of Time in Bed
- REM % of Time in Bed

Sleep fragmentation variables

- WASO (wake after sleep onset–total number of minutes that a person is awake after having initially fallen asleep, this is a good indication of sleep fragmentation, or measure of continuity of sleep)
- Total Arousals Index (includes spontaneous arousals and respiratory arousals)

Appendix C: Experimental equipment, apparatus, and software

Delivery of stimuli

- Ear buds or over-ear headphones, provided by participant or research team.
- External speaker, provided by the research team.
- Smart device: Provided by participant or research team to access instructions, stimuli, and survey links via soundBrilliance research webpages. Access is either login-agnostic or linked via participant's anonymized code name.
- Virtual Reality (VR) system.

- Screen size and type consistency: When observing visual stimuli, participants are advised to be consistent with selection of screen type and size throughout the study by using the same device (e.g. laptop, smart phone, VR system). Selection of a large screen is preferred.

Collection of survey responses

- Zoho survey platform
- Secured text messaging (MMS) service
- soundBrilliance extract-transform-load (ETL) to secure internal database
- Written and collected prior to digital entry

Physiological responses: Data-collection apparatus

- Polar: Watch (Pacer version), Arm Strap (Polar Verity Sense), and/or Chest Strap (H10 version), provided by study sponsor
- Withings: Watches, scales, and/or monitors, provided by study sponsor
- Blood pressure measurement cuff and monitor
- Apple Watch

Physiological responses: Software applications and user interfaces

- Apple Health, Elite HRV, Kubios HRV Scientific software, Polar Flow App, soundBrilliance app and/or Withings:
    - Participant may download application(s) and use study-provided anonymized code name and/or email address for login, to review biometrics, and track activities.
    - Researchers may use for acquisition and/or analysis of physiological data; participants identified via anonymized code name only.
- soundBrilliance extract-transform-load (ETL) to secure internal database

Appendix D: Mental-health resources

National

US Centers for Disease Control and Prevention (CDC): https://www.cdc.gov/mental-health/caring/index.html

National Institutes of Mental Health (NIMH): https://www.nimh.nih.gov/health/find-help

National Alliance on Mental Illness (NAMI): https://www.nami.org/

988 suicide & crisis lifeline: https://988lifeline.org/

- Call or text 988
- Chat online at http://www.988lifeline.org/

Local

No additional resources listed