HIC # 2000026376

COMPOUND AUTHORIZATION & CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT

200 FR. 4 (2016-2)

YALE UNIVERSITY SCHOOL OF MEDICINE
CONNECTICUT MENTAL HEALTH CENTER (CMHC)
THE BELIEF, LEARNING, & MEMORY LAB (BLAM)

Study Title: Songmaking in a Group (SING) R33

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Funding Source: National Institute of Mental Health (NIMH)

Research Study Summary:

- We are asking you to join a research study.
- The purpose of this research study is to better understand how making music with others might help people who hear voices and have challenges in their social lives.
- Study procedures will include: Interviews about your mental and physical health, computerized tests, questionnaires, attending a weekly music making group
- The study may involve up to 7 visits to the Connecticut Mental Health Center.
- Each visit will take no more than 2 hours total.
- There are some risks from participating in this study. We might ask you questions about topics that make you feel upset. You can choose not to answer those questions and take breaks at any time. There is a small risk that your confidential data will be lost or not remain confidential. However, everyone on our team will work to prevent that.
- The study may have no benefits to you. It might help your confidence in and enjoyment of social relationships, and it might change your experience of hearing voices.
- Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You can also change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.
- If you are interested in learning more about the study, please continue reading, or have someone read to you, the rest of this document. Take as much time as you need before you make your decision. Ask the study staff questions about anything you do not understand. Once you understand the study, we will ask you if you wish to participate - if so, you will have to sign this form.

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Invitation to Participate & Description of Project

You are invited to participate in this study because you are someone experiencing voices, also called auditory hallucinations. The purpose of this research study is to find out more about how people who have auditory hallucinations (voice-hearing) experience music-making in a group. This study examines how people they hear and think might change after they attend a music-making group.

The goal of this study is to better understand how problems balancing our prior beliefs and new information may result in a range of unusual experiences and beliefs. Recent research has suggested that our expectations color everything we do—how we interact, how we make decisions, and even how we see and hear things around us. This study examines how expectations influence what we see and hear using computer games that present sights and sounds and ask players to report what they see and hear.

The research will be conducted at the following location(s): Yale University, Connecticut Mental Health Center (CMHC, 34 Park Street, New Haven, 06511). You will be one of about 200 people, overall, to be asked to participate in this study.

In order to decide whether or not you wish to be a part of this research study you should know enough about its risks and benefits to make an informed decision. This consent form gives you detailed information about the study, which a member of the research team will discuss with you. This discussion should go over all aspects of this research: its purpose, the procedures that will be performed, any risks of the procedures, possible benefits and possible alternative treatments. Once you understand the study, you will be asked if you wish to participate; if so, you will be asked to sign this form.

Your participation in this study is voluntary. You do not have to take part in this research. Read this information carefully and please ask the study staff if you have any questions.

Description of Procedures

In order to determine whether your participation in this study is appropriate, you will be asked to complete a number of medical and psychological "screening" measures. We will also ask you if you have family members with a history of severe mental illness. Other measures will ask you to remember certain facts or to solve certain problems, or ask you about which hand you use most in accomplishing certain activities (in order to determine your handedness).

Once you are determined to meet study eligibility, we will ask you to play the games. We will also ask you to talk about your experiences of your life – the things that interest you and are important to you. This interview will be recorded using a digital recording device.

We will then ask you to participate in four weekly music group sessions at the CMHC.

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There are four different types of groups. You will be assigned to a group at random, based on a dice roll. The groups are as follows:

1) SING – Song Making in a Group: The facilitator provides keyboard, professional microphone, headphones, guitar, and a computer for recording. The first 10 minutes of will involve introductions to the other participants and facilitator as well as the goals of the session. Participants will be given paper and a pencil with which to brainstorm potential lyrics. The next 5 minutes will involve body and vocal warm ups, listening to self and others. For the next 90 minutes, participants will work together with the facilitator and independently to create their own original lyrics and melody. Each song will have at least one collaborative section (usually the chorus) where lyrics are written and performed together by the whole group. Participants will also have the ability to write alone and perform sections by themselves. For the last 10 minutes, the group listens back to the entire song that they created.

2) Karaoke: The trained facilitator will provide a microphone and speaker, along with a karaoke playlist of music and a screen to view lyrics. In the first 10 minutes, participants will be encouraged to write down a list of songs that they would like to sing. The list can be edited at any point. For 5 minutes, they will conduct body and vocal warm ups, listening to self and others. For 90 minutes, the facilitator will invite participants to perform karaoke at 60-75 decibels. Each participant will be encouraged to participate. For the final 15 minutes, the session will be concluded, and if the final session, participants will be informed of local opportunities to engage further with music making and musical experiences.

3) Listening: The group will meet on four occasions, once a week for two hours. The trained facilitator, having procured a playlist of popular music, will spend 15 minutes introducing the session, reminding participants not to sing along and to just sit quietly listening to the music. Next, the facilitator will play music from the playlist through a high-quality speaker at 60-75 decibels for 90 minutes. In the final 15 minutes, the facilitator will summarize the session and dismiss the participants, sharing follow-up music opportunities at the end of the fourth and final session.

4) Playlists: The group will meet once a week for four weeks, for two hours at a time. The trained facilitator will provide a computer and speaker with the ability to stream songs through many media outlets (i.e., Spotify, YouTube, Google). In the first fifteen minutes, the facilitator will introduce the session, participants are reminded not to sing along and to just sit quietly listening to the music. Next the participants will choose songs that they would like to hear. The list can be edited at any point. For the next 90 mins, the playlist will be played through a high-quality speaker at 60-75 decibels. In the final 15 minutes, the group will be concluded, and the participants will be dismissed. If it is the final session, they will be offered follow-up information about the musical opportunities.

After completing 4 sessions, we will ask you to play the computer games again and talk to you about your experiences of the groups. We will ask you again about the things that are interesting and important to you. Again, this interview will be recorded using a digital recording device.

All visits will take place at the CMHC or an affiliated site.

Risks & Inconveniences

Interviews & Questionnaires. Some questionnaires may include some questions that cause you distress, for example, causing feelings about past events to resurface. You can take a break and you may refuse to answer any question if you are uncomfortable.

Confidentiality. As with any research study, there is a small potential for the loss/breach of confidentiality. The data from the study may be published. However, you will not be identified by name. Investigators on the protocol, their staff, and clinical staff will be allowed to inspect sections of your medical and research records related to this study, and researchers will make disclosures to the appropriate authorities, as necessary, to prevent serious harm to you or others. Everyone working with study information will work to keep your personal information confidential. Study data will be stored on separate systems and identified only by participant number. Any identifying information (e.g. your name) will be kept securely and separately from your health-related information.

Your participation in this study will be kept confidential as noted above. Your name, initials, or other identifying information will not be released or published without your permission.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

In addition to the risks described in this form, there may be unknown risks/discomforts involved in participating in the study. Study staff will update you in a timely way on any new information that may affect your health, welfare, or decision to stay in this study.

Benefits

This study will not benefit you directly. In terms of benefits to society, we hope that this study will increase our understanding of the neural processes that may give rise to hallucinations and delusions and how these processes may differ among different clinical and non-clinical populations.

Economic Considerations

Complying with scheduled study appointments is essential for your continued participation in the study. If you need to reschedule a study visit, please contact a member of our study team at (475) 241-4514.

You will be compensated for your time related to your participation in this study.
You will receive $100 for each of the seven study visits, for a total of up to $700.

To receive the maximum compensation of $100 per visit, please arrive on time for your scheduled study appointments. If you arrive late to any of the four music group sessions (without giving prior notice to study staff), we will compensate you for that visit at a reduced rate:

- $75 if > 30 minutes late
- $50 if > 60 minutes late
- $25 if > 120 minutes late

We can also compensate you up to $125 per visit in travel expenses. If we book an Uber or Lyft ride for you to or from a study visit, we will pay for the ride and tip the driver. You do not need to pay the driver.

Please note that this payment will be considered earned income and will be reported to the IRS as required by law. You will receive a 1099 Form (tax form). If you do not know what this form is, please ask one of the staff at the clinical research center. Additional costs to you such as cost of childcare fees, time off from work, compensation for lost wages, etc. that may result from participation in this research study are not reimbursable.

Alternatives

This is not a treatment study. Your alternative is to not take part. If you choose not to take part, your healthcare at the CMHC will not be affected.

Confidentiality & Privacy

During the course of the study, the study staff will collect health information about you (when you do the assessment, task, and debriefing). This will include information that identifies you. You must give your authorization (permission) before the study staff can use or share your health information with others. This section will describe how your health information will be

collected, used, and disclosed and describes your rights, including the right to see your health information.

We understand that information about you obtained in connection with your health is personal, and we are committed to protecting the privacy of that information. If you decide to be in this study, the researcher will get information that identifies you and your personal health information. This may include information that might directly identify you, such as your name, date of birth, telephone number, email address, home address, social security number.

The information we collect about you will be de-identified at the earliest reasonable time after we receive it, meaning we will replace your identifying information with a code that does not directly identify you. The principal investigator will keep a link that identifies you to your coded information, and this link will be kept secure and available only to the PI or selected members of the research team. Any information that can identify you will remain confidential. Data and research materials will be stored in locked cabinets and in password-protected files on a computer. The research team will only give this coded information to others to carry out this research study, or if you agree, to invite you to participate in related studies conducted by members of our research team (if you agree by signing below). The link to your personal information will be kept for 10 years, after which time the link will be destroyed and the data will become anonymous. The data will be kept in this anonymous form indefinitely.

The information we are asking to use and share is called “Protected Health Information.” It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission. If you want, we can give you more information about the Privacy Rule. Also, if you have any questions about the Privacy Rule and your rights, you can speak to Yale Privacy Officer at 203-432-5919.

The information about your health that will be collected in this study includes:

- Research study records
- Medical and laboratory records of only those services provided in connection with this study
- Records about phone calls made as part of this research
- Records about your study visit
- The diagnosis and treatment of a mental health condition
- Use of illegal drugs or the study of illegal behavior

Information about you and your health which might identify you may be used by or given to:

- The U.S. Department of Health and Human Services (DHHS) agencies
- Representatives from Yale University and the Human Investigation Committee (the committee that reviews, approves, and monitors research on human subjects), who are responsible for insuring research compliance. These individuals are required to keep all information confidential.

- Those individuals at Yale who are responsible for the financial oversight of research including billings and payments
- The Principal Investigator, Dr. Philip Corlett
- Health care providers who provide services to you in connection with this study.
- Laboratories and other individuals and organizations that analyze your health information in connection with this study, according to the study plan.
- Co-Investigators and other investigators
- Study Coordinator and Members of the Research Team

How will you keep my data safe and private?

We will keep information we collect about you confidential. We will share it with others if you agree to it or when we have to do it because U.S. or State law requires it. For example, we will tell somebody if you we learn that you are hurting a child or an older person.

Information that contains your identity will be stored in a locked file on a locked unit or be password-protected on a computer. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity unless your specific consent for this activity is obtained.

When we publish the results of the research or talk about it in conferences, we will not use your name. If we want to use your name, we would ask you for your permission.

We will also share information about you with other researchers for future research but we will not use your name or other identifiers. We will not ask you for any additional permission.

By signing this form, you authorize the use and/or disclosure of the information described above for this research study. The purpose for the uses and disclosures you are authorizing is to ensure that the information relating to this research is available to all parties who may need it for research purposes.

All health care providers subject to HIPAA (Health Insurance Portability and Accountability Act) are required to protect the privacy of your information. The research staff at the Yale School of Medicine and Yale New Haven Hospital are required to comply with HIPAA and to ensure the confidentiality of your information. Some of the individuals or agencies listed above may not be subject to HIPAA and therefore may not be required to provide the same type of confidentiality protection. They could use or disclose your information in ways not mentioned in this form. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

Your Right to See and/or Copy Your Study-Related Health Information

You may see and copy your study-related health information as long as the study doctor keeps this information. You may also, under data protection laws, have the right to ask that any mistakes in your study-related health information be corrected.

This authorization to use and disclose your health information collected during your participation in this study will never expire.

Voluntary Participation and Withdrawal

Participating in this study is voluntary. You are free to choose not to take part in this study. Refusing to participate will involve no penalty or loss of benefits to which you are otherwise entitled (such as your health care outside the study, the payment for your health care, and your health care benefits). However, you will not be able to enroll in this research study and will not receive study procedures as a study participant if you do not allow use of your information as part of this study. You do not give up any of your legal rights by signing this form.

Withdrawing from the Study

If you do become a subject, you are free to stop and withdraw from this study at any time during its course.

To withdraw from the study, you can call a member of the research team at any time and tell them that you no longer want to take part. This will cancel any future appointments.
The researchers may withdraw you from participating in the research if necessary, for example if you find it hard to comply with the study requirements.

Withdrawing from the study will involve no penalty or loss of benefits to which you are otherwise entitled. It will not harm your relationship with your own doctors or with the Connecticut Mental Health Center.

Withdrawing Your Authorization to Use and Disclose Your Health Information

You may withdraw or take away your permission to use and disclose your health information at any time. You may withdraw your permission by telling the study staff or by writing to:

Philip Corlett
CMHC
34 Park Street
New Haven, CT 06511.

If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others

until the end of the research study, as necessary to ensure the integrity of the study and/or study oversight.

Questions

We have used some technical terms in this form. Please feel free to ask about anything you don't understand and to consider this research and the consent form carefully – as long as you feel is necessary – before you make a decision.

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Authorization & Permission

I have read (or someone has read to me) this form and have decided to participate in the project described above. Its general purposes, the particulars of my involvement, and possible hazards and inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this consent form.

By signing this form, I give permission to the researchers to use [and give out] information about me for the purposes described in this form. By refusing to give permission, I understand that I will not be able to be in this research.

Participant - Printed Name	Participant - Signature	Date
Person Obtaining Consent - Printed Name	Person Obtaining Consent - Signature	Date

If person is conserved:

Conservator - Printed Name	Conservator - Signature	Date

If after you have signed this form you have any questions about your privacy rights, please contact:

Yale Privacy Officer
(203)432-5919
hipaa@yale.edu

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator:

Philip Corlett, PhD
Yale University Department of Psychiatry
Connecticut Mental Health Center
34 Park Street
New Haven, CT 06519
(203)974-7866
philip.corlett@yale.edu

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If you would like to talk with someone other than the researchers to discuss problems, concerns, and questions you may have concerning this research, or to discuss your rights as a research participant, you may contact:

Yale Human Investigation Committee
(203)785-4688
HRPP@yale.edu

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Future Research (Optional)

The researchers at Connecticut Mental Health Center (CMHC) and the Belief, Learning, & Memory (BLAM) Lab will continue to do research designed to lead to a better understanding of people who hear voices and new treatments for them. If you wish to participate in any upcoming studies, these researchers can contact you in the future. By signing this form, you will allow researchers to contact you in the future to ask if you want to participate in any studies. You have no obligation to actually participate in any study. You do not have to agree to future contact to participate in the current study.

Can researchers contact you in the future about new study opportunities? ☐ YES ☐ NO

_____ _____ _____

Participant - Printed Name Participant - Signature Date

Contact Information:

Email: _____

Mobile Phone: _____ Mobile Carrier: _____

Can we leave a voicemail? ☐ YES ☐ NO

Can we send a text? ☐ YES ☐ NO

Home Phone: _____

Can we leave a voicemail? ☐ YES ☐ NO

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