Participant Information Statement

Research Study: NeuroMusic: A Randomised-Controlled Trial of a Music-Based Training Program for Memory Difficulties

Professor Sharon Naismith (Principal Investigator)
School of Psychology, Faculty of Science
Phone: +61 2 2 9351 0781 | Email: sharon.naismith@sydney.edu.au

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1. What is this study about?

We are conducting a research study to find out if a music-based training program improves cognitive performance, mood, and daytime functioning in older adults with memory difficulties. In addition, we are interested in assessing the efficacy of our music-based training program on promoting brain plasticity in this population. We also want to get some feedback regarding participant's experience with our program. This may help in further development of the program for future studies.

This 'Participant Information Statement' document tells you about the study and explains the different tests and procedures involved. It also describes how the information we collect about you will be used and with whom it will be shared. Knowing what is involved will help you decide if you want to take part in the research.

Please read this sheet carefully and feel free to ask questions about anything that you don't understand or want to know more about. Before deciding whether to take part, you may wish to discuss this with your family, friends or doctor.

Participation in this research study is voluntary. If you don't wish to participate, you don't have to. You will receive the best possible care whether or not you take part.

By giving your consent to take part in this study, you are telling us that you:

- ✓ Understand what you have read.
- ✓ Agree to take part in the research study.
- ✓ Agree to have the tests and procedures that are described.
- ✓ Agree to the use of your personal and health information as described.

2. Who is running the study?

The study is being carried out by the following researchers:

Chief Investigators

- Professor Sharon Naismith, Director of the Healthy Brain Ageing Program, Senior Clinical Neuropsychologist; Leonard P Ullman Chair in Psychology, and NHMRC Dementia Leadership Fellow at the Brain and Mind Centre

- Professor Neal Peres Da Costa, Associate Dean of Research and Professor of Historical Performance at the Sydney Conservatorium of Music;
- Professor Cindy Lin, The Kam Ling Barbara Lo Chair in Neurodegenerative Disorders at the Brain and Mind Centre
- Dr Loren Mowszowski, NHMRC-ARC Dementia Research Development Fellow, Clinical Neuropsychologist, and Deputy Director of the Healthy Brain Ageing Program at the Brain and Mind Centre
- Associate Professor Helen Mitchell, Sydney Conservatorium of Music
- Dr Joseph Toltz, Research Support Manager, Faculty of Arts and Social Sciences
- Professor Lee-Fay Low, Professor in Ageing and Health and NHMRC Boosting Dementia Research Leadership Fellow in the Faculty of Medicine and Health
- Doctor Philip Eames, Sydney Conservatorium of Music of the University of Sydney
- Dr. Marshall Dalton, School of Psychology of the University of Sydney
- Dr. Zoe Menczel Schrire, School of Psychology of the University of Sydney
- Ms Nicole Espinosa Zarlenga, School of Psychology of the University of Sydney.
- Mr Peter Walsh, Sydney Conservatorium of Music

This project is funded by Barbara Spencer philanthropic gift. As the study sponsor, the University of Sydney will provide non-financial support as it will not charge the study for this service.

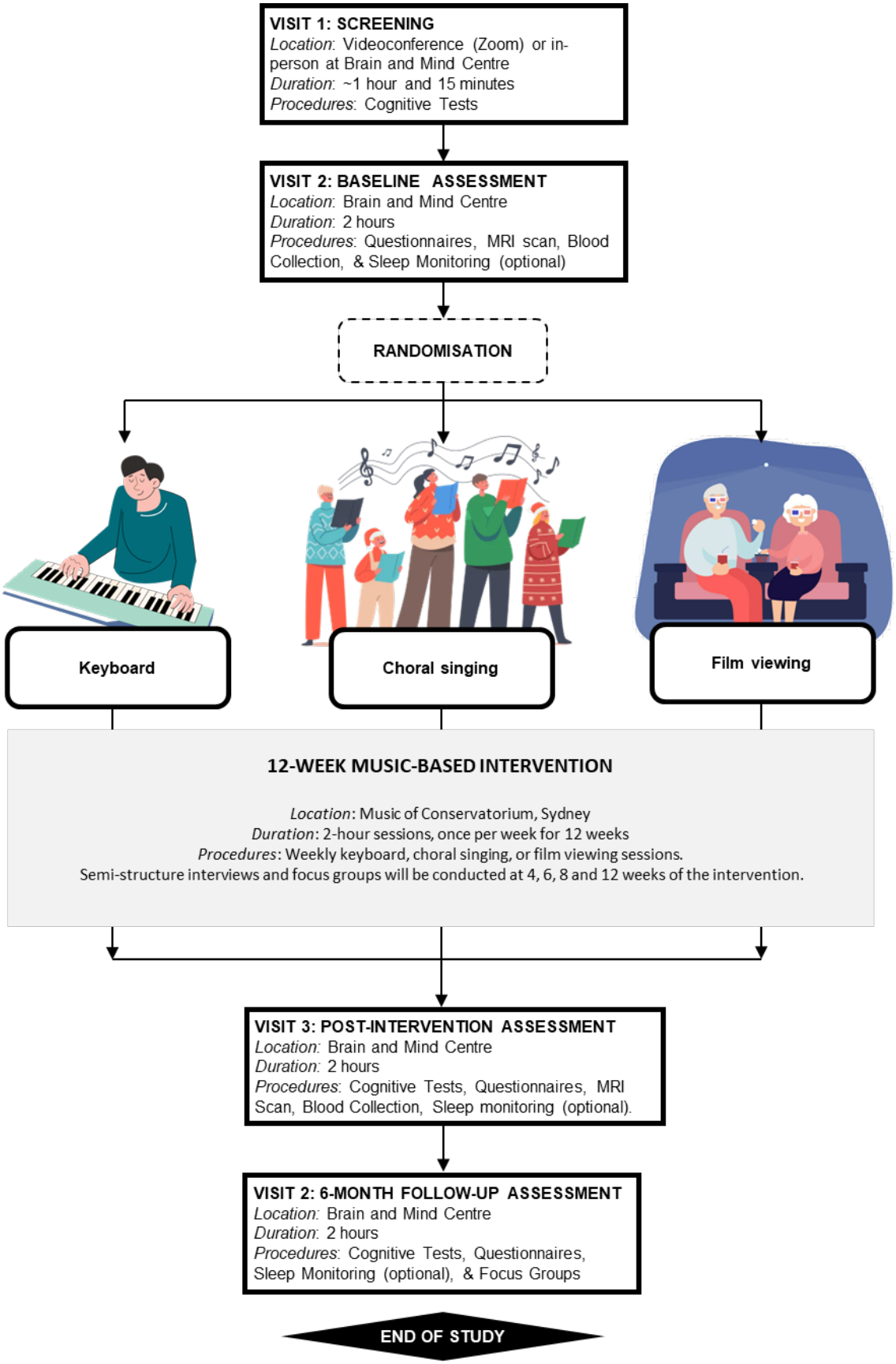
3. Who can take part in the study?

We are seeking adults **aged between 60-90 years** with **memory difficulties** and **no previous experience in instrumental playing or singing in an organised group** in the last 6 months.

You will <u>not</u> be able to participate in this study if you have:

- a history of employment as a professional musician,
- played an instrument or sang in an organised group in the last 6 months,
- had more than 3 years of formal music lessons,
- problems with your hand dexterity,
- impaired or not-corrected visual or auditory accuracy,
- other major neurological problems (e.g. stroke, epilepsy, head injury),
- an alcohol or substance use disorder,
- a severe mental health disorder (e.g. schizophrenia, bipolar disorder),
- a current diagnosis of major depression, or
- commenced with antidepressants in the last 4 weeks, or
- engaged in a music training program or cognitive training intervention in the last 4 weeks.

4. What will the study involve for me?



In total, the study will involve 3-4 in-person visits (~2 hours each) at the Brain and Mind Centre (Camperdown, Sydney) and 12 music-based training sessions (2 hours each) at the Sydney Conservatorium of Music (Sydney City).

The trial will take approximately 10 months to complete including 6 month follow-up assessment.

STUDY VISIT 1: SCREENING

First, we need to confirm that the study is suitable for you.

After providing written informed consent, we will confirm your eligibility to participate in the study via a screening assessment. This can be completed via videoconference (e.g., Zoom) or in-person at the Brain and Mind Centre (Camperdown, Sydney). This will take approximately 75-minutes to complete. A trained researcher will ask you to complete a series of cognitive tasks assessing your memory and thinking skills.

If you were referred to this study through the Healthy Brain Aging (HBA) clinic or other memory clinic, we will obtain your consent to access your neuropsychological assessment results from the memory clinic (to avoid repetition of tests). As such, this screening visit will only take approximately 15-minutes to complete. During this visit, we will collect some information about you and your health to assess your eligibility for the study.

You will be asked to repeat these cognitive tasks again after 16 and 36 weeks.

STUDY VISIT 2: BASELINE ASSESSMENT

During the baseline visit, you will be asked to attend the Brain and Mind Centre in Camperdown, Sydney to complete the following:

- ***Questionnaires****:* You will be asked to complete various online questionnaires regarding changes in your daytime functioning and mood. These should take approximately 45 minutes to complete. There will also be one short questionnaire that you will need to forward to someone to fill out about you, like a significant other, close friend, or family member.

  You will be asked to repeat these questionnaires again after 16 and 36 weeks.

- ***Blood Tests****:* You will be asked to provide a fasting blood sample (30mL or 2 tablespoons per visit) for standard (chemistry & haematology) tests at baseline and 16-weeks. This process will take approximately 10 minutes to complete. This sample will be assessed for blood-based biomarkers of inflammation and neurodegeneration. The samples will be collected at the Healthy Brain Ageing clinic at the Brain and Mind Centre in Camperdown. *Results of these blood tests will not be available to you.*

  You will be asked to repeat these blood tests after 16 weeks.

- **Sleep monitoring:** To measure your sleep and daytime functioning, you may be asked to keep a sleep diary and wear a wristwatch, also known as an '*Actiwatch'*, for 7 days prior to starting the intervention and in the last week of the intervention. The actiwatch measures wrist movements to determine sleep and wakefulness. Recording wrist movements during the study will help us assess your sleeping and physical activity. This will be an optional part of the study. ***MRI Scan****:* You will be invited to have an MRI brain scan as part of your study activities. The scan will be conducted at I-Med Radiology in Camperdown, Sydney. The purpose of this procedure is to take MRI images of your brain to look at associations between structural and functional brain changes and our music-based training programs. We will also look to see if there is a correlation with your memory and thinking function.

  On the day of your test a qualified technician will ask you a few questions and prepare you for the scan, then the scanning procedure takes approximately 60 minutes. An MRI scan will be performed at your baseline visit and after 16 weeks.

RANDOMISATION

You will be randomised (assigned by chance) to either a keyboard intervention, a choral singing intervention or an active control group (film-viewing). The decision about which intervention you will receive will be made by an automated computer system. Everyone gets the same chance of being assigned to either group. If you are assigned to the active control group, you will have access to one of our music-based training programs after you complete the study.

INTERVENTION (12 VISITS TOTAL)

The goal for both music interventions (keyboard and choral singing) is to complete 24 hours of group training over 12 weeks. You will be requested to attend a 2-hour training session, once a week. Lessons will be delivered by professional musicians from the Sydney Conservatorium of Music. Each training program will take place in groups of 10 to 12 for the keyboard intervention, and larger groups for the choral singing intervention.

Please note that by participating in this group activity, you will be identifiable to others in the group as having met criteria for memory difficulties.

You will be expected to achieve some repertoire each week and to work progressively on a larger repertoire. However, there will be no overall pressure on perfection, rather encouragement to attempt activities and participate. The recommendation is 30 minutes practice, 6 days a week outside of the training session If you decide to practice at home, you will be provided with weekly guidance and given access to support resources.

You will be asked to keep a reflective journal and record your practice (e.g. time spent, type of activity) in a workbook provided by the instructor. At week 12, you will be invited to be part of an optional group performance.

Keyboard intervention:

If you are randomised to the keyboard intervention, your training will consist of basic piano technique and literature, music theory and dexterity exercises. At each training session, participants are expected to perform some piano repertoire and technique (finger dexterity exercises/ scales). Each lesson will include opportunities to alternate between skill development in a group setting or individual practice. To encourage practice outside of the training session, a keyboard will be provided to each participant.

Choral singing intervention:

If you are randomised to the choral singing intervention, your training will involve different strategies to learn new songs, practice listening to other participants, synchronizing personal singing parts with the rest of the choir and review of previously learned songs. The repertoire will consist of various forms of canon and rounds. The songs are selected according to different degrees of popularity and difficulty to challenge participants to adapt to their level.

The choir will be accompanied by the Conductor, but there will also be options for a cappella repertoire and backing tracks if needed. A small number of external volunteers with experience in community choral singing will supplement the singing intervention. Their inclusion will boost the numbers of the ensemble size to approximate a choral environment and provide vocal support.

Note: Sessions will be audio and video (AV) recorded and provided as participant revision/catch up materials in the event of absence, as well as to inform the researchers about the progress of the intervention. AV for catch up will focus on the facilitator and only the back of participants' heads, or faces will be blurred. The AV may be used in conferences or to promote the project. If this occurs, we will seek your permission for unblurred AV footage to be used for these purposes using a standard release form

Active control group:

If you are randomised to the active control group, you will attend weekly film-viewing events for 12-weeks at the Conservatorium of Music. After each film, you will also be invited to a 25-minutes afternoon tea and group discussion. At trial completion (week 36), you will be offered the opportunity to engage with a keyboard or choral singing interventions (subject to availability).

Semi-structured interviews and focus groups to measure participant experience:
You will be invited to share your experience of our interventions during semi-structured focus groups or interviews with a member of the research team during and at the cessation of the intervention period (i.e. weeks 4, 8, 12 and 36). **Focus groups and interviews will use the same semi-structured format but focus groups will involve multiple participants after an intervention session. Interviews will be offered to participants who cannot attend focus groups.** Each interview will last approximately 30 minutes, and focus groups will last up to 45 minutes, due to the nature of the group

interaction. Topic areas and prompt questions will address your enjoyment, challenge of the musical tasks and the broader impacts of the intervention. The interviews and focus groups will be audio-recorded and transcribed.

STUDY VISIT 3: POST-INTERVENTION ASSESSMENT

You will be asked to repeat the following tasks and procedures at the end of the intervention (Week 16) and 6 months after the end of the study (Week 36):

- Cognitive tests
- Questionnaires
- Sleep monitoring
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STUDY VISIT 4: 6-MONTH FOLLOW UP ASSESSMENT

Will I get results of my MRI brain scan?

Your brain scan is done as part of a research trial and neither the reporting radiologist or our study doctor have access to information about your health or any symptoms you may have. As such, if you do have any health concerns, please note that this scan does not take the place of speaking with your general practitioner to have these concerns addressed. However, if there is anything on your brain scan that our reporting radiologist and study doctor think may be helpful to relay to you and your general practitioner then the study team will contact you to arrange a time for our study doctor to speak with you. If you wish to receive a copy of your MRI brain result, noting the above comments on its limitations, then please contact the study coordinator at neuromusic.info@sydney.edu.au and we will be able to forward the results to your GP at the conclusion of the intervention.

5. Can I withdraw once I've started?

Being in this study is completely voluntary and you do not have to take part.

If you do take part, you may withdraw at any time without having to give a reason. Your decision will not affect your current or future relationship with the researchers or anyone else at The University of Sydney.

Further, if you experience any physical or mental health issues, you may withdraw from the study or if we are concerned about you, your participation may be terminated.

If you decide to withdraw, you should notify on the study coordinator on 02 9351 0755 or at Neuromusic.info@sydney.edu.au. Your decision to stop participating in the study will not affect your current or future medical care, or any benefits to which you may otherwise be entitled.

Any information that we have already collected however will be kept in our study records and may be included in the study results.

6. Are there any risks or costs?

There are no financial costs associated with participating in this study.

Taking part in the study is considered to be of minimal risk. However, some specific risks are worth noting:

- **Music-based training programs:** You may experience some pain, tension or discomfort in your hand muscles or tendons due to keyboard practice or get a sore throat from singing. Our professional musicians from the Sydney Conservatorium of Music are trained to manage these symptoms and will be available to help you reduce the discomfort or pain.

- **Cognitive and Memory tests**: This can sometimes cause mild anxiety. However, this usually lessens when testing begins. Our research staff are trained to manage these symptoms and are available to help you work through them, should they arise.

- **MRI scan:** MRI is considered to be safe when performed at a centre with appropriate procedures. There are no proven long-term risks related to MRI scans as used in this study. This technique involves the use of very powerful magnets and sophisticated computer programs to provide images of your brain without the use of ionising radiation. The scan uses techniques that are not the same as ionising radiation used in CT scans. The magnetic attraction for some metal objects can pose a safety risk, so you will be screened for the presence of a pacemaker, metal pins after an injury, or other metal implants.

- The MRI scanner itself is a long tube that is open at both ends and contains a table that is able to move in and out of the tube. For some people, lying in the scanner can cause anxiety and feelings of panic. You may experience risks such as a fear of small-enclosed spaces (claustrophobia), discomfort due to lying still for a prolonged period of time, and other factors which will discussed with you prior to entering the scanner. There are procedures in place to help reduce and/or manage these feelings if they occur. The scanner also makes loud noises during this procedure, but you will be given earplugs to minimize disturbance. You will be able to speak to the operators through an intercom and if needed, you will be removed from the scanner.

All of your MRI scans will be examined by a trained radiologist. If an incidental finding occurs, the study doctor will inform you and contact your general practitioner and treating clinician for further investigation if required.

- **Blood test:** You will be asked to provide a blood sample which may cause mild discomfort, bruising, minor infection, or bleeding. If this happens, it can be easily treated. The sample will be taken by trained staff who will provide support and/or discontinue blood collection if appropriate.

7. What if injury or complications happen?

If you suffer any injuries or complications as a result of this study, please contact the research team as soon as possible who will then assist you in arranging appropriate medical treatment. In addition, you may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study.

In the event of loss or injury, the parties involved in this study agree to be bound by the Medicines Australia Guidelines for Compensation for Injury Resulting from Participation in an Industry-Sponsored Clinical Trial. A copy of these guidelines is available from the Executive Officer of the Ethics Review Committee or electronically at https://medicinesaustralia.com.au/policy/clinical-trials/indemity-and- compensation-guidelines/.

It is the recommendation of the independent ethics committee responsible for the review of this study/investigation that you seek independent legal advice.

8. What happens when the study ends?

At trial completion (week 36), active control participants will be offered the opportunity to participate in our music-based training program.

If you had access to our music-based training program, and after the 36 weeks you still feel that you need help with your memory difficulties, the team will assist you to find your closest memory clinic where you can receive an assessment. You are also welcome to attend the Healthy Brain Ageing Clinic to have a formal assessment and will receive a report and recommendations from a geriatrician and neuropsychologist. We will also recommend that you seek guidance from your GP.

In case of any questions, please contact the study coordinator on 02 9351 0755 or at neuromusic.info@sydney.edu.au.

9. Are there any benefits?

We cannot guarantee that you will receive any immediate benefits from this study. The study offers comprehensive neuropsychological assessment free of charge, and you will learn how to play the keyboard or sing in a choir which some people may consider

beneficial. However, this study may help us to understand better the effects of music training on memory difficulties. The information from this research might benefit others in the future.

10. Reimbursement

You will be offered a $50 gift card at completion of the study at week 36.

11. What will happen to information that is collected?

By indicating your consent, you agree to the NeuroMusic research team collecting and using personal information for the research study. Any information obtained in connection with this research study is coded and confidential. Data from individuals who have completed the initial screening questionnaires but were ineligible will be deleted.

All data collected will be anonymised using a code number when you consent to participate in the study. The key linking your identity to your participant code will be stored online in a password protected manner on a secure server. This ensures your data will remain anonymous. Access to your data will only be granted to the research personnel and data will be held for a minimum of 15 years, as per policy. Data will not be shared without permission of Principal Investigators of the current project. All data available for sharing will be stored on a web-based database located in Australia. Your data may be published in an open access data repository or also be made available to a third party in the future in which case further ethical approval would be sought from the Ethics Review Committee.

Any intended future use of data will be limited to the aims of this project and that ethical approval will be sought if intended use is outside the scope of the current project.

12. How will the results of the study be shared?

The results will be published in academic journals and presented at conferences. Any data published in scientific journals will not be able to identify you.

13. Will I be told the results of the study?

You have a right to receive feedback about the overall results of this study. You can tell us that you wish to receive feedback by ticking the relevant box on the consent form. This feedback will be in the form of a one-page summary of the trial's key findings. You will receive this feedback after the study is finished. You will not receive individualised feedback about your performance on the online assessments.

14. What if I would like further information?

When you have read this information, the Study Coordinator will be available to discuss it with you further and answer any questions you may have:

- Zoe Menczel Schrire (Telephone: 02 9351 0755/ Email: neuromusic.study@sydney.edu.au)

15. What if I have a complaint or any concerns?

The ethical aspects of this study have been approved by the Human Research Ethics Committee (HREC) of The University of Sydney 2023/026 according to the *National Statement on Ethical Conduct in Human Research (2007).*

If you are concerned about the way this study is being conducted or you wish to make a complaint to someone independent from the study, please contact the University:

Human Ethics Manager
human.ethics@sydney.edu.au
+61 2 8627 8176

Participant Consent Form

Research Study: NeuroMusic: A Randomised-Controlled Trial of a Music-Based Training Program for Memory Difficulties

Professor Sharon Naismith (Responsible Researcher)
School of Psychology, Faculty of Science
Phone: +61 2 2 9351 0781 | Email: sharon.naismith@sydney.edu.au

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Participant Name _____

I agree to take part in this research study. In giving my consent, I confirm that that:

- I am between 60-90 years old.
- The details of my involvement have been explained to me and I understand that if I have any questions or require further information, I can contact the research team.
- I understand the purpose of the study is to investigate if a music-based training program can improve cognitive performance, mood, and daytime functioning, as well as promote brain plasticity in older adults with memory difficulties.
- If applicable, I consent to the NeuroMusic study team accessing information about my health from the Healthy Brain Ageing Clinic or other memory clinic medical record.
- I acknowledge that the risks and benefits of participating in this study have been explained to me to my satisfaction.
- I understand that in this study I will be required to complete questionnaires and cognitive tests at the beginning of the study and after 16 and 36 weeks and MRI scan and blood collection at baseline and 16 weeks. Further, if I am randomised to the intervention group, I will have access to either keyboard training or choral singing intervention for 12-weeks.
- I understand that there is a one in three chance of being randomised to the keyboard, choir or film intervention and am happy to participate in all three.
- I give permission to the NeuroMusic study team to record the keyboard and singing choral sessions. I understand that this will be provided as participant revision/catch up materials in the event of absence. I understand that these recordings could be also used to inform the researchers about the progress of the intervention, as well as for conferences. I understand that the NeuroMusic study team will seek standard release forms if I am happy for unblurred AV footage to be used for these purposes.

- I understand that being in this study is completely voluntary and I can withdraw from the study at any stage without penalty by advising the research team. If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw will be stored and analysed.

- I am assured that my decision to participate will not have any impact on my relationship with the research team or the University of Sydney.

- I have been informed that the confidentiality of the information I provide will be protected and will only be used for purposes that I have agreed to. I understand that information about me will only be told to others with my permission, except as required by law.

- I understand that my involvement in this study may not be of any direct benefit to me.

- I understand how my data will be stored, who will have access to it and what will happen to the data after the end of the study.

- I understand that the results of this study may be published, and that publications will not contain my name or any identifiable information about me.

- I understand that my deidentified data may be used in collaborations with other research programs, subject to approval by the relevant Human Research Ethics Committee

I understand that after I sign and return this consent form it will be retained by the researcher, and that I may request a copy at any time.

• I would like to receive feedback about the overall results and key findings of the study.

YES ☐ NO ☐

If you answered YES, please indicate your preferred form of feedback and provide address:

☐ Postal: _____

_____

☐ Email: _____

By clicking on the 'I consent' button below, you are providing your consent to participate in this research study as outlined in this consent form and the Participant Information Statement.

I consent