Feasibility of a Music Listening Intervention for Mental Health Recovery in Chronic Stroke

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NEW YORK UNIVERSITY

Prof. Pablo Ripollés Department of Psychology
6 Washington Place, 8th Floor New York, NY 10001
P: 929 355 0074
pripolles@nyu.edu

Consent Form for Adult Participants IRB-FY2024-8826

Introduction

You have been invited to take part in a study to learn more about the effect of intentional listening on mental health and the underlying neural basis of these processes. This is a small-sample parallel group randomized controlled feasibility trial where participants are assigned to a music listening or audiobook listening group. Assignment to the groups will be made in a randomized fashion (e.g., like flipping a coin). Both groups will complete 1-hour long listening sessions daily (except for weekends) for a period of 4 weeks (a total of 20 sessions). Participants will undergo 4 evaluation sessions. A baseline assessment will be followed by a pre-intervention evaluation 4 weeks later to determine the stability of the outcome measures. After this, participants will complete the intervention for 4 weeks. This will be followed by a post-intervention assessment. A final follow- up evaluation will occur 3 months later. Baseline, pre, and post-intervention evaluations will include clinical outcomes (behavioral tests of mental health and cognitive status). Pre and post- intervention evaluations will include clinical outcomes in addition to biomarkers (MRI and physiology). The follow-up session will only include clinical outcomes.

If you experience fear of enclosed spaces (*claustrophobia*), then you likely will **not** want to participate in the research.

Participation in this study is voluntary. You may refuse to participate or withdraw at any time without penalty. Participation in this experiment does not preclude participation in normal treatment/health- promoting activities that you are already engaged in. For example, there are complementary interventions other than listening to music or audiobooks for mental-health and cognitive recovery after stroke, such as meditation or the practice of yoga. You can also participate in the study if you are currently taking medications that may affect brain function (e.g., antidepressants). The participant signing this form should continue their regular treatments (i.e., treatments or complementary interventions/therapies that the participant is already engaged in regularly). If you begin any new medications, therapies, or complementary interventions during the study, please inform the research team. Starting a new treatment during the study is allowed; we simply need to record it.

Withdrawing from the study will not prevent individuals from participating in other studies at NYU. Participants withdrawing from the experiment will have to return the iPad and will no longer have access to the music/audiobook materials. Failing more than 5 listening sessions or more than 5 daily evaluations with the mEMA app will result in the withdrawal of the participant from the experiment without their consent.

Please read the rest of this consent form for more information about the study

Procedure
This study will be conducted by **Prof. Pablo Ripollés** of the Department of Psychology at New York University.

You must be 18 years or older to participate in this study. If you are under the care of an epileptologist, you must have doctors' consent in writing in order to participate.

If you agree to be in this study, images of your brain, called scans, will be taken using a Magnetic Resonance Imaging (MRI) scanner. The MRI scanner is a machine that enables us to acquire images of the brain using the changing magnetic fields inside your body.

As part of this study, you will be randomly placed into one of two groups, like flipping a coin. This means you have an equal chance—50%—of being in either group. One group will take part in music listening sessions, where you will listen to music you choose and enjoy. The other group will take part in audiobook listening sessions, where you will listen to audiobooks that you choose and enjoy. Both groups will follow the same schedule and receive the same amount of listening time.

If you agree to be in this study, you will be asked to do the following:

- Participate in a 4-week long intervention where you will use an iPad provided by the research team to complete a 1-hour listening session every day (excluding weekends) during a video call the researchers.
- Be recorded during the listening sessions.
- Complete questionnaires and measurements on an iPad app, which will be included on the iPad provided by the research team, after each of the listening sessions over the course of 4 weeks. The mEMA app will be used to collect daily measures during the 4 weeks of the pre-intervention and the 4 weeks of the intervention. You will have to agree to the app's terms of use and privacy policy. You can ask for a copy of these forms before consenting to the study.
- Participants should use the iPad only for study purposes (listening to music/audiobooks, completing the mEMA assessments, communicating with the researchers). Participants can listen to music/audiobooks outside of the programmed listening sessions if they wish to do so. The iPad must be returned to the researchers at the end of the study.
- Complete 4 evaluation sessions (4 weeks before the intervention begins, 2-3 days before the intervention begins, 2-3 days after the intervention ends, and 3 months after the intervention ends). During these evaluation sessions, you will be asked to answer questions about yourself and complete measurements to assess your cognitive functioning.
- Participate in a structural and functional MRI scan at 2 of the evaluation sessions (2-3 days before the intervention begins and 2-3 days after the intervention ends). During the MRI, you will be asked to:
    - Lie on a table that will slide into the MRI scanner so that your head and upper body are inside the magnet tube.
    - Wear earplugs to reduce the noise made by the MRI scanner (the magnets can make very loud noises).
    - Wear headphones to limit the noise from the MRI and allow you to hear audio and instructions for the tasks you are being asked to do or questions from the investigator or the MRI operator.
    - Have foam pads placed around your head to help you hold your head still during the MRI scan, so that the scans will be clear.
    - Lie still throughout your time in the MRI scanner **(**up to **1** hour**).**
    - Allow small electrodes to be placed on your hand and fingers to measure physiological responses such as skin conductance and heart rate.
    - Anatomical images (images that show us the structures in your brain) will be obtained during the first 5 to 15 minutes of the scan. After the anatomical images, functional images will be obtained for about 45 minutes. Functional images are scans that show us how the brain works

by illustrating what the brain is actively doing at a particular time. During this time, you will be asked to listen to audio, such as music or speech, see visual stimuli on a screen, and provide responses by pressing buttons. In addition, you may be asked to participate in 1 practice session outside of the scanner, where you will be asked to listen to auditory speech or music, see visual stimuli on a screen, and make a series of responses by pressing a button.

- During your MRI scanning session, occasional breaks of a few minutes will be provided. You will remain in the MRI scanner during breaks, but you may close your eyes and rest. You may rest for as long as you need to be ready to continue the session

Participation in this study will involve two MRI sessions (1 hour) and no more than 13 hours total for all four of the evaluation sessions. There are no known risks associated with your participation in this research beyond those of everyday life. Previous studies have shown that listening to music or audiobooks after stroke is an activity deemed enjoyable, relevant to the patients' situation, and that moderately contributes to post-stroke recovery. In particular, listening to music can moderately improve mental health, verbal memory and attention.

Participation in this study is voluntary. You may refuse to participate or withdraw at any time without penalty. Participation in this experiment does not preclude participation in normal treatment/health- promoting activities that you are already engaged in. For example, there are complementary interventions other than listening to music or audiobooks for mental-health and cognitive recovery after stroke, such as meditation or the practice of yoga. You can also participate in the study if you are currently taking medications that may affect brain function (e.g., antidepressants). The participant signing this form should continue their regular treatments (i.e., treatments or complementary interventions/therapies that the participant is already engaged in regularly). If you begin any new medications, therapies, or complementary interventions during the study, please inform the research team. Starting a new treatment during the study is allowed; we simply need to record it.

Eligibility
The following participants will be excluded from this study:

1. Any participant from whom informed consent cannot be obtained.
2. Any participant whose age falls outside the range of 50-90 years.
3. Any participant with significant hearing loss.
4. Any participant who indicates any risk factor on the NYU MRI screening questionnaire administered prior to participation, see details below.
5. More than Mild Cognitive impairment.
6. Specific musical anhedonia (inability to feel emotion from music).
7. Amusia (inability to perceive music).

In addition, you should not participate in this study if you have any of the following:

1. Surgical aneurysm clips
2. Cardiac pacemaker (even if removed)
3. Prosthetic heart valve
4. Neurostimulator
5. Implanted pumps
6. Cochlear implants
7. History of injury to eye involving metal

Each of these are related to potential harm during the MRI scan. Additionally, if you have any of the following, please notify the researcher:

1. History of head trauma
2. Transdermal patch (nicotine, nitroglycerin, hormone)
3. Metal rode, plates, or screws

4. Previous surgeries
5. IUD (Intrauterine device)
6. Hearing aid
7. Dentures, braces, or non-removable retainer
8. Any metal in the body (shrapnel, bullets, or buckshot)
9. Colored contact lenses
10. Facial tattoos or tattoos that cover more than 5% of your body or is larger than 8 inches
11. Worked as a welder or metal worker

This does not necessarily exclude you from the study but should be disclosed in advance as they may cause you mild discomfort or affect the MRI images.

Risks
There are no known significant risks or side effects associated with behavioral, physiological testing or MRI scans. The magnetic fields, at the strengths used, fall within the Food and Drug Administration [FDA] guidelines for radiofrequency electromagnetic field exposure created by the MRI.

There is a risk if metal objects are near the MRI because they can be drawn into the MRI scanner and that could hurt someone in or near the machine. Metal objects might be in a body if a person has electrically, magnetically, or mechanically activated implants (such as cardiac pacemakers), or clips on blood vessels in their brain, or metallic fragments in the eye. To protect against this risk, you will be carefully screened for previous exposure to metallic fragments or to implanted devices. You will also be asked to place all metallic and magnetic objects in your possession (e.g., keys, jewelry, credit cards) in a locker outside the MRI room.

The Center for Brain Imaging uses software that is not regulated by the FDA because it is intended for research purposes and not for diagnostic purposes.

Although there are no known risks of an MRI scan to the unborn fetus, we will not let you take part in the study if you are or might be pregnant. We will have you take a urine pregnancy test right before the scan to find out if you are pregnant. If the test shows that you are pregnant, we will cancel the scan. Results will only be reported to you as this is considered private health information.

If you would like to decline this pregnancy test, please initial here:

_____My initials indicate that *I choose not* to take a urine pregnancy test and will still be scanned.

Some people have reported mild discomfort during MRI scans, such as:

- Claustrophobia (fear of enclosed spaces). You will be asked to lie on a table that slides into a horizontal cylinder only slightly wider than your body in all directions and your head will be secured to help you stay still. If you are likely to be uncomfortable or afraid in enclosed spaces, you will not be allowed to participate.
- Mild back discomfort. If you have ever had back surgery or have a history of chronic backache, please notify the researcher in charge of the scan so that the padding on the MRI table can be enhanced.
- Reaction to noise levels. The MRI scanner makes loud knocking or beeping sounds during scans; earplugs and/or headphones will be provided to help reduce this noise.
- Peripheral nerve stimulation. Because the magnet turns on and off during the scan, the possibility exists for peripheral nerve stimulation. If this happens, you may feel creeping or tingling sensations, typically along your arms or lower back.
- Dizziness and nausea that may occur while you are in the MRI.
- Drying of eye contact lenses. This rarely occurs, but you should notify the investigator that you have contact

lenses in your eyes, and you should either moisten your eyes before entering the scanner or remove your contacts. MRI safe glasses are available for use if needed, with lenses that accommodate the most common prescriptions.

- Feeling some warmth from the radio frequency coils can occur. The MRI scanner is set so that this warmth will be not heat the body to more than one degree of normal body temperature.

During the MRI we will monitor your skin reactivity (also called electrodermal activity and skin conductance) and heart rate using electrodes. You may experience mild irritation/discomfort from the used to attach the electrodes.

When completing some of the questionnaires, you may experience some emotional distress or feel uncomfortable answering some of the questions.

You may notify the research staff at any time if you feel uncomfortable, no matter what the reason. Between each scan, you will be in contact with the research staff through a microphone mounted in the MRI scanner. However, while the scanner is on, the speaker will be turned off and the research staff will not be able to hear you. Nonetheless, in the case of an emergency, you will have a handheld squeeze ball device to let the operator know if you wish to immediately stop scanning and be removed from the magnet. The MRI scan can be stopped at any time at your request; when you squeeze the squeeze ball, the research staff will be notified and stop the scan. If you think that you have experienced a research- related injury call Pablo Ripollés at 929-355-0074 or email at pripolles@nyu.edu. Please be aware that emergency medical services are not available onsite.

Federal regulations require that all subjects be informed of the availability of medical treatment or financial compensation in the event of physical injury resulting from participation in the research. New York University cannot provide either medical treatment or financial compensation for any physical injury resulting from your participation in this project. You do not give up any legal rights to seek payment for personal injury by consenting to this research. Inquiries regarding this policy may be made to the Principal Investigator Pablo Ripollés at 929-355-0074 or email at pripolles@nyu.edu**.** or, alternatively, the NYU IRB at (212) 998-4808.

Benefits

Previous studies have shown that listening to music or audiobooks after stroke is an activity deemed enjoyable, relevant to the patients' situation, and that moderately contributes to post-stroke recovery. In particular, listening to music can moderately improve mental health, verbal memory and attention. Previous feasibility studies using listening to music and/or audiobooks after stroke have found the intervention feasible and acceptable for stroke patients, carrying no greater risk than everyday life activities.

Incidental Findings

During the course of this study, we may find more information that could be important to you. This includes information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

Incidental Findings from Screener Procedures

During the screening process we collect information that might be of interest to you regarding your cognitive state and your hearing.

Incidental Findings from Radiology Procedures

The scans performed in this study are for specific research purposes and are not being done to find medical abnormalities. The researchers on this research study may not be trained to perform medical diagnosis. The researchers and NYU are not responsible for failure to find existing abnormalities with these MRI scans. However, on occasion, the researcher may notice a finding on an MRI scan that seems abnormal. If you agree below and should this occur within twelve months of the scan a neuroradiologist would be consulted and the MRI scan will be sent to the NYU Medical Center. This MRI scan along with the consulting neuroradiologist's report will be part of your permanent medical record. When this occurs, there will be no cost to you, and the neuroradiologist

report will be paid for by the study. The neuroradiologist will report whether the findings need further investigation, in which case the researcher will contact you, inform you of the finding, and offer to relay the finding to your physician at your discretion. The decision as to whether to proceed with further examination or treatment lies solely between you and your physician. The researchers, the consulting physician, and NYU are not responsible for any examination or treatment that you undertake based on these findings. Because the images collected in this study may not comprise a proper clinical MRI scan, these images will not be made available for diagnostic purposes.

Please initial below to indicate your decision:

____ Yes, I consent to my MRI scan being shared with a neuroradiologist if the investigator notices a finding on the MRI scan that seems abnormal. I understand that the MRI scan along with the consulting neuroradiologist's report will be part of my permanent medical record.

____ No, I do not consent to my MRI scan being shared with a neuroradiologist and I understand that I will *not* be notified if the investigator notices a finding on the MRI scan that seems abnormal.

When you complete the questionnaires at evaluation sessions and during the 1-hour listening sessions, if the investigators find alarming signs of mental health distress, we will immediately report these results to you and provide you with a document that includes a list of wellness resources, including self-care apps, mental health practices, and New York City clinics that accept many insurance plans and provide psychological treatment.

Access to Your Study Information
Your results on some of the assessments we will use, such as cognitive assessments, may be relevant to you. The investigators for this project are not trained to perform diagnoses relating to cognitive function, and the cognitive assessments used are not meant to be used for diagnostic purposes. You may request the results of these screening procedures from the investigators in order to pursue examination or treatment as a result of these incidental findings. Because the evaluations collected in this procedure do not comprise a proper clinical assessment, their results will not be made available for diagnostic purposes.

Cost and Compensation
You will be paid **$50** for completing the baseline (behavior-only) session, **$100** each for the pre- and post-intervention sessions (which include behavioral tasks and MRI), and **$100** for the follow-up session (**$350 total**). In the event you are asked to complete a screening session or a practice session, you will be paid **$30** for each of these sessions. Should you withdraw before the end of the study, partial payment will be given for each of the evaluation sessions that you completed. There will be no cost to you associated with participation in this study. Transportation costs will also be covered.

If you earn (or if you are compensated) in excess of $600 from New York University, within any calendar year, for participation as a research subject, you will need to report the earnings/payments as income on your taxes, as NYU will be required to report the payments to the IRS as other income and will issue you a 1099 form. We will ask you to complete an IRS W-9 form, which will include your social security number or taxpayer identification number, so that NYU can track if you receive an excess of $600.

Rights
Participation in this study is voluntary. You may refuse to participate or withdraw at any time without penalty. If the researchers learn of any new information that may affect your decision to participate in this study, then they will share this information with you and you will have the option to withdrawal from the study at that time.

Many forms of research involve some risk of injury. In addition, there may be risks associated with this study that we do not know about. Despite all the care and precautions taken by the investigators, you might develop medical complications from participating in this study. If you should sustain any injury during the course of the

research or experience any side effect from a study procedure, please contact the Principal Investigator **Pablo Ripollés** at the following telephone number **929-355-0074**. If such complications arise, the researchers will assist you by referring you to appropriate medical practitioners, but this study does not provide financial assistance for additional medical or other costs. Also, NYU is not responsible for research and medical care either by NYU practitioners or those at other institutions. You do not give up any rights to seek payment for personal injury by signing this form.

If there is anything about the study or your participation that is unclear or that you do not understand, or if you have questions or wish to report a research-related problem, you may contact Pablo Ripollés at 929-355-0074, pripolles@nyu.edu, 6 Washington Place, 8th Floor, New York, NY 10001.

For questions about your rights as a research participant, you may contact the University Committee on Activities Involving Human Subjects (UCAIHS), 665 Broadway, Suite 804, New York University, (212) 998-4808 or ask.humansubjects@nyu.edu. Please reference the study number IRB-FY2024-8826 when contacting the UCAIHS.

Confidentiality

Confidentiality of your research records will be strictly maintained. Information will be stored in the investigator's file and will be identified by a code number. The code key connecting your name to specific information about you will be kept in a separate, secure location. Information not containing identifiers may be used in future research or shared with other researchers without your additional consent.

The results of this study may be published in a book, journal, or used for teaching purposes. However, your name or other identifiers that could identify you will not be used in any publication or teaching materials without your specific permission, which will be requested in writing. The MRI images, physiological data, and the results of the questionnaires and behavioral tests completed may be shared anonymously (that is, without any way of identifying who of the data came from) for teaching purposes, research (such as in open-source academic databases), or displayed at scientific conferences or in publications.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. Researchers with this Certificate will not disclose or use information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, even if there is a court subpoena.

Exceptions include:

- A federal, state, or local law requires disclosure.
- Your explicit approval for the researchers to release your name and/or personally identifiable information.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This website may include a summary of the results but will never include information that can identify you. You can search this website at any time.

Future Research

I authorize the principal investigator, Pablo Ripollés, and his co-investigators to contact me about future research. If I agree, then a researcher affiliated with the NYU Department of Psychology and/or the Center for Brain Imaging might contact me in the future and they will tell me about a research study. At that time, I can decide whether or not I am interested in participating in a particular study. I will then have the opportunity to contact the researcher to schedule an appointment to be fully informed about the research project.

☐ I agree to be contacted by a researcher affiliated with the NYU Center for Brain Imaging and/or the Department of Psychology about research studies conducted

OR

☐ I do not want to be contacted by a researcher affiliated with the NYU Center for Brain Imaging and/or the Department of Psychology.

_____

Signature of participant or legal representative Date

Your permission to allow us to contact you about future research would be greatly appreciated, but it is completely voluntary. If you choose not to allow us to contact you, it will not affect your participation in this study. Please understand that giving your permission to do this is only for the purpose of helping us identify subjects who may qualify for another research study. It does not mean that you must join in any additional study.

Agreement to Participate

YOUR SIGNATURE INDICATES THAT YOU HAVE READ THE ABOVE INFORMATION, THAT YOU HAVE DISCUSSED THIS STUDY WITH THE PERSON OBTAINING CONSENT, THAT YOU HAVE DECIDED TO PARTICIPATE BASED ON THE INFORMATION PROVIDED, THAT YOU ARE 18 YEARS OF AGE OR OLDER, AND THAT A COPY OF THIS CONSENT DOCUMENT HAS BEEN GIVEN TO YOU TO KEEP.

_____ _____

Participant's Signature Date

_____

Participant's Printed Name

I certify that I have presented the above information to the subject and secured his/her/their consent.

_____ _____

Experimenter's Signature Date