Official Title:	Optimizing music based interventions for stroke: a mechanistic crossover study of the effects of music improvisation and live accompaniment on motor, autonomic, and neural response during a music playing task among survivors of stroke and matched healthy control participants
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Research Subject Informed Consent Form

Title of Study:	Optimizing music based interventions for stroke: a mechanistic crossover study of the effects of music improvisation and live accompaniment on motor, autonomic, and neural response during a music playing task among survivors of stroke and matched healthy control participants s23-01380
Principal Investigator:	Heidi Schambra, MD Department of Neurology NYU Grossman School of Medicine Ambulatory Care Center 222 E 41st Street, 10th Floor, New York, NY 10017 929-455-5128
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1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

People who agree to take part in research studies are called “subjects” or “research subjects”. These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a copy of this form signed by you for you to keep.

2. What is the purpose of this study?

The purpose of this research study is to learn how music impacts responses to movement tasks so that we can better apply music to promote stroke rehabilitation. We would like to measure the amount and quality of movement, physiological responses, and brain activity.

We are asking you to participate in this study either because you are a healthy adult or you had a stroke that affected your ability to move your arm. If you had a stroke, we will measure movement in your affected arm.

3. How long will I be in the study? How many other people will be in the study?

Participation in this study will last 4 - 6 hours and will involve two in-person visits to New York University Department of Psychology. Each visit will be 2-3 hours long and may be scheduled up to 36 days apart. We expect up to 70 subjects will be enrolled in this study from NYU Langone Health.

4. What will I be asked to do in the study?

If you choose to take part in this study, we will ask you to sign this consent document first before any study-related procedures are performed.

For the First Visit
To see if you meet the requirements to take part in this study:

- We will review your medical history and demographic information and also test your movement ability, level of disability, cognitive function, and depression symptoms.
- We will also ask you to complete a magnetic resonance imaging (MRI) screening to ensure you are eligible to receive an MRI.
- We will also ask you to take a hearing impairment screening and test your music comprehension and responsiveness.

These tests will take about 1 hour. Based on the results of these tests, you may not be asked to continue in this study. A member of the research team will review the results. If you do not meet the requirements to take part in this study, the research team member will tell you why.

If you are eligible to participate in this study, you will be asked to provide general demographic information, as well as complete two additional measures of movement ability and a survey of musical training. The questionnaire and survey will take about one hour to complete. You are free to skip any question you do not want to answer.

For the first movement test, you will be asked to conduct a series of tasks, such as picking up objects and placing them down in a new location. This test will help us understand how well you move.

The second movement test will ask you to guess the position of your wrist, while its position is hidden by a curtain. This test will help us understand how well you understand the position of your hand and wrist in space. The survey of musical training will help us to understand how much previous experience you have with music playing.

Finally, during the first visit, we will introduce you to the music playing task, so that you are prepared for the second visit. For this task, you will be asked to tap an electronic drum along with piano accompaniment. We will give you specific instructions regarding how to tap. You will have the chance to ask questions regarding the task to make sure you understand the procedures. This task practice will take about 15 – 30 minutes.

For the Second Visit
For this visit, you will be asked to complete the music playing task while we measure your brain activity, amount and quality of movement, and physiological responses. The music playing task will include 4

different conditions which will be assigned for you to complete in a random order. We will measure your brain activity with MRI which provides information on activity in different parts of your brain based on the amount of blood flow. MRI can also create images of the structure of your brain. This study will create images based on the activity you do playing music during the MRI and does not require any other contrast agent. For this study, you will be asked to undergo 4 MRI scans to measure brain function. Each of these scans will last about 9 minutes. You will also be asked to complete one MRI scan to measure brain structure. This scan will last about 5 minutes. All the scans will take place in a single MRI session that will last about 45-55 minutes, including breaks.

The amount and quality of movement will be measured with accelerometry and electromyography (EMG) at the same time as the MRI scan. Accelerometry is a procedure for measuring how much you are moving This measurement will be taken using an MRI-compatible sensor attached to the hand with a Velcro strap. EMG is a procedure for measuring natural muscle activity. This measurement will be taken using MRI-compatible sensors placed on the arm.

Physiological responses will be measured with electrodermal activity (EDA) at the same time as the MRI scan. EDA is a procedure for measuring emotional excitement by recording the skin's natural electrical activity. The measurements will be taken using two MRI-compatible sensors attached to the palm of the hand.

Before the MRI scans, you will complete a second MRI safety screening, to ensure nothing has changed in your eligibility for this portion of the study. The MRI screening will take approximately 15 minutes. You will then be taken into a changing room and asked to remove all metal from your body and will have the option to change into a gown.

You will also have the option to self-administer a pregnancy test. The pregnancy test is offered on the day of the MRI so that you can be certain whether or not you are pregnant. You will not be allowed to continue the study if you are pregnant.

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.

Next, we will prepare you for the music playing task and ask you to make ratings of the songs used in the task. We will provide you with instructions for the music playing task, and you will have a chance to ask questions. This will take about 15 minutes.

Next, we will apply surface sensors to your skin. This will include a Velcro strap around one hand (for accelerometry), muscle activity sensors on your arm (for EMG), and sensors on your other hand (for EDA). Placing the sensors will take approximately 5 minutes. The sensors will remain on for testing and will be removed immediately after testing is complete.

Next, we will position you for testing with MRI. You will be instructed on how to lay on the MRI imaging table, and will be provided with an emergency squeeze ball which will allow you to communicate with the MRI technicians. You will also be provided with MRI compatible headphones to put in your ears. We will then place the MRI compatible MIDI drum on your abdomen and ensure that you can comfortably play

the drum while laying down. We will also test that sound levels are comfortable to you. Positioning in the scanner will take approximately 15 minutes.

Finally, we will complete testing in the MRI. During MRI testing you will be asked to complete the music playing task. If you had a stroke, you will be asked to play the drum with your affected arm.
You will have scheduled breaks after each task. In addition, you may request additional breaks or interrupt testing at any time for any reason. You will be monitored throughout the MRI procedures by a trained MRI researcher. MRI testing will require approximately 45 – 55 minutes.

Identifiers will be removed from the identifiable data collected during the first and second visit. After such removal the de-identified data may be used for future research studies or shared with other researchers and we will not request additional informed consent from you to use the data as we have noted here.

You will also have the option to give us permission to use your identifiable information along with data from this study to determine your eligibility for future studies. You will still be able to participate in the study if you do not give us this permission, and we will not use your identifiable information for future studies without your permission.

5. What are the possible risks or discomforts?

Participation in this study may involve some added risks or discomforts. The risks or discomforts include the following:

Magnetic Resonance Imaging (MRI)
MRI uses strong magnetic fields and radio waves to make images of the inside of your body. MRI does NOT involve high-energy radiation (like X-rays). For most people MRI is very safe. However, if you have anything made of metal on your skin or inside your body, MRI may not be safe for you, and you must tell study personnel before your scan. Also, if you have any electronic devices on the outside or inside of your body, you must tell study personnel about those too. Some things, like tattoos, may have metal materials in them even though you might not realize it. For this reason, study personnel will give you a checklist of things that have metal or electronic parts in them. You must read the list carefully before your scan and put a checkmark next to everything that applies to you.

The following paragraphs will describe the possible risks of MRI. To reduce many of these risks, you will be given an emergency squeeze ball to hold in your hand during the scan. If you feel any discomfort you should squeeze the ball. This sets off an alarm that the study personnel can hear. The study personnel will then talk to you, and will stop the scan if you want. There is a microphone in the scanner so that you can communicate with the study personnel. However, the scanner makes a lot of noise when it is running and the study personnel may not always hear what you say. If you need to get the study personnel's attention, you should squeeze the ball. Remember, if at any point you feel uncomfortable and want to stop the scan, just squeeze the ball and tell the study personnel.

- ***Risks from metal*:** The strong magnetic field in the scanner will pull on things that contain certain types of metal. If someone takes a metal object into the scan room, it might fly towards the scanner and hurt you. For this reason, everyone (including you) must remove everything metal from their clothes and pockets before going into the scan room. Also, the door to the scan room will be kept closed during the scan to prevent unauthorized people from walking in. If you have something metal inside your body, the scanner might pull on it and make it move. You must tell study personnel before your scan if you have anything metal inside your body. Some types of

metal might heat up when the scanner is running. If you feel any burning sensation during the scan, you should squeeze the emergency ball and the study personnel will stop the scan.

- ***Risks from electronic devices*:** If you have any electronic devices on the inside or outside of your body, the scanner might make them stop working properly. For this reason, you must tell study personnel before your scan if you have anything electronic on or in your body.

- ***Burns*:** Metal is not the only thing that can cause burns in MRI. It's possible (although very rare) to get burned by touching the inside walls of the scanner or by making skin-to-skin contact. The study personnel will give you a blanket or cushions so that you don't touch the inside walls of the scanner. You should also avoid letting your hands or legs touch each other. Remember, if you feel any burning sensation during the scan, you should squeeze the emergency ball and the study personnel will stop the scan.

- ***Tinnitus (ringing in the ears) and hearing loss***: The scanner makes very loud sounds while it is running. You will be given headphones with earplugs to wear during the scan. Make sure you roll the earplugs tightly and let them expand in your ears so that they work properly. If the sound of the scanner is still so loud that it causes you discomfort, squeeze the emergency ball and tell the study personnel. This is important because very loud sounds can cause ringing in the ears or even hearing loss.

- ***Feeling warm or hot*:** The radio waves used in MRI are like those your cellphone uses, but much stronger. Sometimes they are strong enough to make you feel warm (just like standing in bright sunshine makes you feel warm). MRI scanners are designed to try to avoid you getting too hot. However, if you start to feel uncomfortable, squeeze the emergency ball and tell the study personnel.

- ***Peripheral nerve stimulation (tingling or twitching)*:** The magnetic field inside the scanner changes very quickly while the scanner is running. If it changes too quickly, it can give you tingling sensations or make you twitch. MRI scanners are designed to try to avoid this. However, if you experience tingling or twitching, squeeze the emergency ball and tell the study personnel.

- ***Claustrophobia (discomfort in enclosed spaces):*** Some people get panic attacks inside enclosed spaces. This is called 'claustrophobia', which means 'fear of confined spaces'. If you know that you are claustrophobic, tell study personnel before your scan. Some people only find out they are claustrophobic when they have an MRI for the first time. If you feel anxious or panicky inside the scanner, squeeze the emergency ball and the study personnel will get you out.

- ***Quench*:** In very rare circumstances, the scanner can lose its magnetic field. This happens very suddenly and is known as a 'quench'. The helium that helps keep the magnetic field strong will then escape from the scanner. The scanner is connected to a vent so that the helium will go outside the building. However, if for some reason the vent doesn't work properly, helium might fill the scan room, making it difficult to breathe. In the very unlikely event of a quench, the study personnel will get you out of the scanner immediately.

Electrodermal Activity (EDA)
EDA measures the skin's natural electrical activity with sensors on the surface of the skin. EDA recording has been used safely for many years, including during MRI, and carries no significant risks. However,

wires placed on the body during an MRI scan can result in warming and in some cases the potential for burns. The operator is trained to inspect and arrange wires to minimize the risk for burns. Remember, if you feel any burning sensation during the scan, you should squeeze the emergency ball and the study personnel will stop the scan.

Accelerometry
Accelerometry measures the velocity of physical movement with sensors on the surface of the skin. Accelerometry has been used safely for many years, including during MRI, and carries no significant risks. However, wires placed on the body during an MRI scan can result in warming and in some cases the potential for burns. The operator is trained to inspect and arrange wires to minimize the risk for burns. Remember, if you feel any burning sensation during the scan, you should squeeze the emergency ball and the study personnel will stop the scan.

Electromyography (EMG)
EMG measures natural muscle activity using sensors on the surface of the skin. EMG has been used safely for many years, including during MRI, and carries no significant risks. However, wires placed on the body during a scan can result in warming and in some cases the potential for burns. The operator is trained to inspect and arrange wires to minimize the risk for burns. Remember, if you feel any burning sensation during the scan, you should squeeze the emergency ball and the study personnel will stop the scan.

Risks associated with motor function testing
The risk of motor function testing is potential discomfort from making movements for periods of a few minutes at a time.

Risks associated with cognitive testing and screening for depression symptoms
For some individuals, questions related to cognitive function and depression symptoms may trigger confusion and/or emotional distress. You will have the option to stop testing at any time.

Risks associated with music screening
Music screening will involve answering questions related to your experience and enjoyment related to music, as well as completing a music comprehension task that requires listening to tones and recording your response. Some people may find the music comprehension task challenging or experience confusion.

Risks associated with hearing impairment screening
The hearing impairment screening will involve answering questions about your hearing ability, and there are no known risks. However, you may become aware of hearing impairment for the first time after the screening and not be eligible for the study. If this occurs you will be provided a referral to an appropriate clinician.

Risks associated with music playing
The risk of music playing is potential discomfort from making movements for a few minutes at a time. Additionally, sound levels during music playing may cause discomfort if levels are set too high. For this reason, volume levels of music will be adjusted to a comfortable level for each subject, and you will have the option to adjust volume levels at any time.

Risks associated with loss of confidentiality
Although we will protect your confidentiality by storing identifiable data in secure locations and only sharing identifiable data with authorized individuals, there is a possibility of loss of confidentiality that includes having your personal information shared with someone who is not on the study team.

Risks associated with pregnancy
Although there is no known risk of MRI to a fetus, you will not be allowed to participate if you are pregnant. We will ask you to take a urine pregnancy test right before the MRI 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.

Unforeseeable Risks
The research may involve risks that are currently unforeseeable.

6. What if new information becomes available?

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 for 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 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 the MRI scan will be sent to a neuroradiologist at NYU Langone Health. 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 the Institution 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.

Below we are asking you to indicate whether or not you would like to know about any incidental findings as described above. Please initial one of the options below to confirm whether you would like to be informed of any incidental findings:

____ Yes ____ No

7. What are the possible benefits of the study?

You are not expected to get any benefit from being in this research study. However, information to be gained from this study might change how we treat patients who suffer from stroke in the future.

8. What other choices do I have if I do not participate?

This is not a treatment study. The only alternative to participating in the study is to not participate. If you decide not to participate, your decision will not interfere with your future care, payment for your health care or your eligibility for health care benefits.

9. Will I be paid for being in this study?

You will be paid for taking part in this study. You will receive $40 for each study visit. You will receive the full $40 for the first visit, even if you are found not to be eligible to take part in this study. If you complete both study visits, you will receive a total of $80.

We will also pay you for travel costs to and from the study visits. You will receive $15 for travel costs after each study visit, regardless of whether you complete all assessments.

All payments will be provided in the form of a pre-paid Visa Debit Card immediately following each study visit.

As is required by the laws that apply to NYU Washington Square, in order for you to receive a payment, you need to give the study staff either your Social Security number or your Alien Registration number and will be asked to complete a W-9 form issued by the Internal Revenue Service (IRS). If you do not have either of these numbers or are not willing to complete the W-9, you may be in the study but will not receive any payment.

You are required to track all payments made to you by NYU Washington Square for your participation in any research for this calendar year. You must let us know immediately if/when the total research payments presently equal or is likely to exceed $600.00 total (not including travel reimbursements) for this calendar year. If your total payments (for one or more studies) reach $600.00, please advise Dr. Heidi Schambra at Heidi.Schambra@nyulangone.org.

10. Will I have to pay for anything?

There are no costs to you for taking part in this study. The costs of the study procedures will be covered by the study funding.

11. What happens if I am injured from being in the study?

For medical emergencies contact 911. If you think you have been injured as a result of taking part in this research study, tell the principal investigator as soon as possible. The principal investigator's name and phone number are listed at the top of page 1 of this consent form.

There are no plans for NYU Langone Health or NYU Grossman School of Medicine to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

12. When is the study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped or your participation ended at any time without your consent because:

- The principal investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The principal investigator or other body responsible for monitoring the study has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Leaving the study will not interfere with your future care, payment for your health care or your eligibility for health care benefits.

13. How will you protect my confidentiality?

Your medical information is protected health information, or “PHI”, and is protected by federal and state laws, such as the Health Insurance Portability and Accountability Act, or HIPAA. This includes information in your research record as well as information in your medical record at NYU Langone Health. In compliance with NYU Langone Health policies and procedures and with HIPAA, only those individuals with a job purpose can access this information.

Medical information created by this research study may become part of your medical record. We may include your research information in your medical record for several reasons, including for the billing of services provided in connection with the study, to securely document any medical services you receive, and so that other members of the NYU Langone Health community who may treat you have access to important information about your health.

You have a right to access information in your medical record. In some cases, when necessary to protect the integrity of the research, you will not be allowed to see or copy certain information relating to the study while the study is in progress, but you will have the right to see and copy the information once the study is over in accordance with NYU Langone Health policies and applicable law.

Certificate of Confidentiality
To help us further protect your confidentiality, this research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). The NIH has issued a Certificate of Confidentiality for this research. This adds special protection for the research information (data, documents, or biospecimens) that may identify you.

Research information protected by this Certificate of Confidentiality cannot be disclosed to anyone else who is not connected with the research, without your consent. With this Certificate of Confidentiality, the researchers may not disclose or use research information 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, without your consent. However, disclosure, without your consent, is still necessary if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases).

The Certificate of Confidentiality cannot be used to refuse a request for information from appropriate government agencies responsible for project oversight.

The Certificate of Confidentiality does not prevent you from releasing information about yourself and your involvement in this research, including for your medical treatment. Federal regulations may also allow for the use or sharing of information for other scientific research.

By agreeing to be in this research and signing below, you are giving your consent to share research information with others at NYU Langone Health. This means that your research information, including MRIs, may be included in your NYU Langone Health electronic medical record.

14. HIPAA Authorization

As noted in the Confidentiality section above, federal law requires us, and our affiliated researchers to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions. We are asking for your permission (authorization) to use and share your health information with others in connection with this study- in other words, for purposes of this research, including conducting and overseeing the study.

Your treatment outside of this study, payment for your health care, and your health care benefits will not be affected even if you do not authorize the use and disclosure of your information for this study.

What information may be used or shared with others in connection with this study?
All information in your research record for this study may be used and shared with those individuals listed in this section. Additionally, information in your medical record that the research team believes may be important to the study may be accessed by those listed here. This includes, for example, results from your physical examinations, procedures, questionnaires, and MRIs.

Who may use and share information in connection with this study?
The following individuals may use, share, or receive your information for this research study:

- The research team, including the Principal Investigator, study coordinators, and personnel responsible for the support or oversight of the study
- The study sponsor: National Institutes of Health
- Governmental agencies responsible for research oversight (e.g., the U.S. Food and Drug Administration or FDA).
- Health care providers, including your doctors and others who provide services to you in connection with this study, and laboratories or other individuals who analyze your health information in connection with this study.
- Fully de-identified data, that does not include any personally identifiable information, may also be shared in open-access online data repositories. These data repositories promote advancement of scientific knowledge by allowing open access to scientific findings.

Your information may be re-disclosed or used for other purposes if the person who receives your information is not required by law to protect the privacy of the information.

What if I do not want to give permission to use and share my information for this study?
Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this study.

Can I change my mind and withdraw permission to use or share my information?
Yes, you may withdraw or take back your permission to use and share your health information at any time for this research study. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

How long may my information be used or shared?
Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

15. Optional permission to be contacted about future research

We would like your permission to contact you in the future about future research studies. If you agree to be contacted, we will use a secure database to store your contact information, limited health information, and other data from this research study needed to determine eligibility for future studies.

To give this additional permission, check the box below and write your initials where indicated. You may still participate in this study even if you do not give us this additional permission.

Please check one box below to indicate whether you give permission for future use of your health information as described above:

☐ Checking this box indicates I **give my permission** to store, use, and share my contact information, limited health information, and other data from this research study needed to determine eligibility for future research to be conducted by NYU Langone Health, NYU Department of Psychology, or its research partners.

☐ Checking this box indicates I **do not give my permission** to store, use, and share my contact information, limited health information, and other data from this research study needed to determine eligibility for future research conducted by NYU Langone Health, NYU Department of Psychology, or its research partners.

_____
Subject Initials

16. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU Langone Health IRB Office number is 212-263-4110. The NYU Langone Health IRB is made up of doctors, nurses, non-scientists, and people from the Community.

17. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal

Investigator listed on top of the page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the NYU Langone Health IRB at (212) 263-4110.

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

NYU Langone Health is committed to providing a safe, productive, and welcoming environment for participants and researchers in all research studies and interactions. All participants will be treated with respect and consideration, and in turn, we ask that you please treat fellow participants and research staff with respect.

Please refer to the NYU Langone's Statement on the Conduct of Participants in Research Studies for further information.

When you sign this form, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

Name of Subject (Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date