

Effects of an Active Musical Intervention on the Health of Older Adults Living With  
Dementia: the DeMúsica Study, a Cross-over Trial on a Non-pharmacological Intervention

NCT number: not assigned

Date of the document: September 24th 2025



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## Informative Sheet for caregivers of people

Date: of of 202

Project title: project:

***Active musical intervention as a non-pharmacological strategy in older adults with dementia: A Crossed Clinical Trial.***

Project registration number of the project: DI-PI-009-2025

Name of responsible researcher: Dr. Mario Ulises Pérez Zepeda Email: [mperez@inger.gob.mx](mailto:mperez@inger.gob.mx)

This document describes the aspects of the study about musical therapy for older adults with cognitive problems. You may stop and ask at any time if you have questions or refuse to participate if you so wish.

### What is this research about?

The aim of the research is to analyze the effects of implementing an intervention based on musical improvisation in people living with dementia, as well as their caregivers. The goal is to understand this practice as an innovative accompaniment strategy that complements the care of people who suffer from this disease. There are different ways to conduct these types of studies. In this case, you as a caregiver will be asked questions by trained staff about the symptoms of the person you care for. Conducting this series of questions will not take more than 20 minutes. On the other hand, the person you care for will undergo a more in-depth evaluation, for which your presence is required. It is important to mention that the staff is trained to address any problems that may arise.

### What will happen if I authorize participation?

If you agree to participate in the research, it means that our research team will be authorized to speak with you and the person you care for, who will also be explained what the study involves and their participation.

If you agree to participate, your presence will be required for the musical interventions, totaling 24 hours, divided into 8 weekly sessions of three hours each, in consecutive weeks (that is, no weeks skipped between sessions). The sessions have a predefined structure, which we describe below:

- In the first hour a general interview is planned while the participating musicians set up. participants.
- In the second hour the emblematic composition created for the group will be performed and then a welcome melody with the names of each participant as a way of integrating and recognizing the group, then you will be invited to improvise music with the professional support of the musicians.
- In the third hour you as main caregivers will be invited to a reflection session to share your opinions and plan some adjustments for the next sessions.

As part of this intervention, photographs and videos will be taken, material that may be used as a source of information for the research. In addition to the time spent in the music therapy sessions, you will be summoned on four different days to answer a questionnaire for both you and the person you care for. As previously mentioned, the person you care for will undergo a more detailed evaluation, consisting of questionnaires and physical function tests (if they want and are able to do them). The questionnaires mentioned address the state of memory and related symptoms that may affect the person you care for. On the other hand, the physical function test includes walking a normal distance at usual speed, standing up and sitting down from a chair five times, and standing with one foot in front and the other behind. You will always be attended by both research staff and by the protocols for any problem that may arise from the Institute itself. These questionnaires and physical function test will last about half an hour, up to one hour at most. The questionnaire for you aims to understand if the disease of the person you care for is affecting your well-being. It is a questionnaire with 22 questions, which takes no more than 15 minutes on average and a maximum of 20 minutes. You will be contacted by project staff to schedule these evaluations. Additionally, we remind you that at any time you can ask for a pause or cancel the interview, regardless of the reason.

In addition, if you agree to participate, transportation will be provided (at no cost to you and your relative) for transportation from the address you provide to INGER and back.

Lastly, it is important to know that you will be provided with snacks and water during the sessions, you will have access to bathrooms in our facilities, and at all times, there will be surveillance and health personnel to attend to any of your needs.

### What are the possible benefits of participating?

The person you care for may receive as a possible benefit the opportunity to actively participate in 'non-conventional'

psychosocial strategies that help complement health care. This integration may also have a beneficial effect for you by applying what you learn in the care.

Additionally, the knowledge generated by this research will help broaden the scope and benefit more people living with Alzheimer's disease, vascular or mixed dementia, or who are in mild or moderate stages. This aims to impact a wider audience, spreading the benefits of this musical intervention. Likewise, by involving other professionals outside the health field, it will positively contribute to staff training, future care, and the elimination of stigma.

### **What are the possible risks of participating?**

Neither you nor the person you care for will be exposed to health risks, since the sessions are designed only to include small musical activities and to answer a few simple questions. However, if you experience any discomfort or any problem of any kind, please let us know as soon as possible; immediate attention will be provided.

### **What will happen if you do not wish to continue in the research?**

Please note that neither you nor the person you care for is required to participate. You are completely free to decline to participate, or to agree and withdraw from the research at any time, without having to provide any explanation, and this will not affect the care you receive at the institution. Please feel free to make your decision.

It is important to emphasize that not participating or deciding to withdraw at any time will not mean losing INGER services (clinical or of any kind), nor will it prevent you from receiving services in the future if you are not currently receiving care at the Institute.

### **Will the information obtained during the study be confidential?**

Yes, all information collected will be strictly confidential and will be kept under the custody of the principal investigator at the National Institute of Geriatrics, who will omit personal data from all participants, including you and the person you care for. It should be noted that the information you provide will be used only for research purposes.

*(The information obtained in this study regarding the participant's identity, as well as all personal data, is confidential information and will be handled in accordance with Articles 18, 19, and 21 of the Federal Law on Transparency and Access to Public Government Information.)*

### **What will happen to the results when the research ends?**

The information you provide will allow us to document the effect of the musical intervention on people with Alzheimer's disease, vascular or mixed dementia, or those in mild or moderate stages, in order to consolidate it as a strategy.

To this end, the research group will prepare a final report for the institution, in addition to:

- Organizing dissemination and outreach of the results through an open science event at the National Institute of Geriatrics, with the participation of the entire team and students to promote the use of research data for subsequent analyses.
- Publishing an article in a Mexican open-access journal describing the main findings of the study.

Confidentiality and protection of your personal data will be maintained, and neither you nor the person you care for will be identified as participants in any of these scientific publications or academic or public presentations.

### **How will privacy and confidentiality be protected?**

All information collected will be strictly confidential and will be stored and safeguarded by the principal investigator at the National Institute of Geriatrics, who will also omit variables that could make all participants identifiable. In addition, only the members of the field research team will have access to the information; it should be noted that the information provided by your family member will be used solely for research purposes.

*(The information obtained in this study regarding the participant's identity, as well as all personal data, is confidential information and will be handled in accordance with Articles 18, 19, and 21 of the Federal Law on Transparency and Access to Public Government Information.)*

### **Do I have to participate?**

The decision to allow your family member to take part in this research is completely free and voluntary. If you decide that your family member will not participate, this will not affect your right to obtain health services or other services you receive, if any, at the National Institute of Geriatrics (any service, but particularly those of the Comprehensive Care Unit). If you decide to authorize your family member's participation but later change your mind, you may withdraw the authorization to participate in this study at

any time; we only ask that you inform the contact person listed at the end of this document.

On the other hand, if your family member or you are not a patient of the National Institute of Geriatrics, participation is also free and voluntary. Choosing not to participate will not affect the decision that you or your family member may be admitted as a patient of the Institute, and if you wish, at that time you will be given information on the requirements to receive care at the Institute by the research staff attending to you.

### **Who sponsors and organizes this research?**

This type of study would not be possible without funding from institutions such as INGER, which has some resources available (such as facilities, staff, etc.). We currently have support from the Embassy of the Netherlands, which will allow us to fund some parts of the study. For this study, funding is being sought from government agencies. Once additional funding is obtained, you will be informed of the details. The research is organized by Dr. Mario Ulises Pérez Zepeda, whose contact information can be found at the end of this document and whom you may contact whenever you consider it necessary. This sponsorship allows us to provide round-trip transportation for each of the eight music therapy sessions and additionally on the days when you must attend your evaluations.

### **Who has reviewed this study?**

It was reviewed and approved by the Research Ethics Committee of the National Institute of Geriatrics, file number: DI-PI-009/2025

### **What do I do now?**

We appreciate you taking the time to consider participation. Please read this information sheet as many times as necessary and ask any questions you consider important to clarify your doubts.

If you decide to participate, you will then be provided with a copy of this information sheet and a form (informed consent) to be completed and signed by you.

We thank you for your interest in our study.

### **Who should I contact to obtain information, suggestions, or if any problem arises?**

If you have any questions, comments, or concerns regarding the project, please contact the principal investigator of the project:

Name of the investigator: Dr. Mario Ulises Pérez Zepeda Mobile: 55 3270 0669

Available from 8:00 AM to 6:00 PM or by email: [mperez@inger.gob.mx](mailto:mperez@inger.gob.mx)

If you have general questions related to your rights as a participant in this research, you can contact the Research Ethics Committee of the National Institute of Geriatrics, with Dr. Mariana López Ortega, by telephone +52 55 4794 1442 from 9:00 AM to 3:00 PM, email address: [mlopez@inger.gob.mx](mailto:mlopez@inger.gob.mx)



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### Informed consent formulary for the caregiver

**Date:**

Project title: project:

**Active musical intervention as a non-pharmacological strategy in older adults with dementia: A Crossed Clinical Trial.**

Project registration number of the project: DI-PI-009-2025

Name of responsible researcher: Dr. Mario Ulises Pérez Zepeda Email: [mperez@inger.gob.mx](mailto:mperez@inger.gob.mx)

1. I confirm that I have read and understood the information sheet, dated in Mexico City on \_\_\_\_\_ of \_\_\_\_\_ 202\_. for the project titled: Active Musical Intervention as a Non-Pharmacological Strategy in Older Adults with Dementia: A Crossover Clinical Trial
2. I have had the opportunity to consider the information, ask questions, and have those questions answered satisfactorily.
3. I give my consent to participate in this study, accompanying the person I care for, supporting them in the activities, and participating in interviews as a means of reflecting upon my experience, perceptions, and opinions regarding the musical intervention.
4. My participation and that of the person I care for are voluntary. If my family member or the person I care for decides not to participate at any time during the project, this decision will not in any way affect the care they receive at the institution, or if they are not currently receiving care, non-participation will not be an impediment to receiving care at the INGER in the future.
5. I authorize that any opinions expressed by my family member be recorded anonymously and used in subsequent reports and analyses.
6. I understand that the research team, regulatory authorities, and/or the National Institute of Geriatrics may review any of the data collected during the study, provided that my family member's participation is relevant. I authorize these persons to have access to my data.

_____ Name of the participant	_____ Signature	_____ Date
_____ Witness name 1	_____ Witness signature 1	_____ Date
_____ Witness name 2	_____ Witness signature 1	_____ Date
_____ Name of the Researcher	_____ Signature of the Researcher	_____ Date



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### Consent to video and audio record

**Date:**

Project title: project:

**Active musical intervention as a non-pharmacological strategy in older adults with dementia: A Crossed Clinical Trial.**

Project registration number of the project: DI-PI-009-2025

Name of responsible researcher: Dr. Mario Ulises Pérez Zepeda Email: [mperez@inger.gob.mx](mailto:mperez@inger.gob.mx)

By signing this document, I freely, voluntarily, and with informed consent authorize the capture of my image and/or voice through photographs and video recordings during our participation in the project *Effects of an Active Musical Intervention on the Health of Older Adults Living with Dementia: DeMúsica Study, a Clinical Trial on a Non-Pharmacological Intervention*, at the National Institute of Geriatrics.

1. I understand that these images will be used exclusively for analysis, informational, or scientific dissemination purposes, and never for commercial purposes.
2. I have been informed that the right to privacy and dignity of the person(s) I care for will be respected, and that, should it be necessary, the images may be anonymized or blurred to protect their identity.
3. I have been informed that my right to privacy and dignity will be respected, and that, should it be necessary, the images may be anonymized or blurred to protect my identity.

_____ Name of the participant	_____ Signature	_____ Date
_____ Witness name 1	_____ Witness signature 1	_____ Date
_____ Witness name 2	_____ Witness signature 1	_____ Date
_____ Name of the Researcher	_____ Signature of the Researcher	_____ Date

Project title: project:

***Active musical intervention as a non-pharmacological strategy in older adults with dementia: A Crossed Clinical Trial.***

Project registration number of the project: DI-PI-009-2025

Name of responsible researcher: Dr. Mario Ulises Pérez Zepeda Email: [mperez@inger.gob.mx](mailto:mperez@inger.gob.mx)

Your family member has been selected to be invited to participate in a research project coordinated by the National Institute of Geriatrics. The aim of this project is to closely analyze the effect that improvisation-based music intervention has on health. This is intended to better understand this practice in order to restructure support strategies throughout their health, care, and treatment process. Before you decide whether to authorize your family member's participation, it is necessary that you carefully read (or listen to) the following information.

**What happens if you authorize your family member's participation?**

If you agree for your family member to take part in the research, this means that our research team will be authorized to speak with you and with the person you care for, who will also be explained what this study involves and what their participation consists of.

If you agree, it is estimated that your presence will be required for the music interventions for a total of 24 hours, divided into 8 weekly sessions of three hours each, held in consecutive weeks (that is, no weeks will be skipped between sessions). The sessions have a structure that is already defined, and we describe it below:

- During the first hour, a general interview is planned while the participating musicians are setting up.
- During the second hour, the emblematic composition created for the group will be performed, followed by a welcome melody with each participant's name as a way of fostering integration and recognizing the group. After that, they will be invited to improvise music with the professional accompaniment of the musicians.
- During the third hour, your family member will be in the waiting room, where someone will always be attentive, and they may have a snack or drink water if they wish.

As part of this intervention, photographs and video recordings will be taken, and this material may be used as a source of information for the research.

In addition to the time devoted to the music therapy sessions, you will be asked to come on four different days to answer questionnaires, both for the person you care for and for yourself. As mentioned previously, the person you care for will undergo a more in-depth evaluation, which consists of questionnaires and physical function tests, if they are willing and able to do them. The questionnaires address memory status and related symptoms that may affect the person you care for. The physical function test includes walking along a path at a normal speed, standing up from and sitting down on a chair five times, and standing with one foot in front of the other. It should be noted that the person will always be cared for by both research staff and the Institute's protocols for responding to any issue that may arise. These questionnaires and the physical function test will take approximately half an hour and at most one hour.

The questionnaire that will be administered to you aims to understand whether the illness affecting the person you care for is having any impact on your well-being. It consists of 22 questions, and takes no more

than 15 minutes on average and no more than 20 minutes at most. You will be contacted by project staff to schedule these assessments. Additionally, please remember that at any time you may request that the interview be paused or canceled, regardless of the reason.

Also, by agreeing to participate, transportation will be provided at no cost to you and your family member for travel from the address you provide to INGER and back.

Finally, it is important for you to know that snacks and water will be provided during the sessions; you will have access to the restrooms in our facilities; and at all times there will be both security and health personnel available to attend to any of your needs.

### **Who will be with your family member?**

They will not be alone. During the sessions, your family member will be with their primary caregiver, who will also participate in the music intervention sessions. INGER staff trained to address any problem that may arise or to answer any questions you may have will also be present.

### **Are there any risks if your family member participates in the study?**

If you agree for your family member to participate, there will be no health risks, since during the intervention sessions they will only take part in small musical activities and the questions asked will be simple. However, if your family member experiences any discomfort or any problem of any kind, immediate attention will be provided.

Your family member will also undergo several assessments throughout the study, four in total, in which they will be asked some questions and given other tests to evaluate their physical health.

### **Are there any benefits?**

The main benefit of participating is being actively involved in “non-conventional” psychosocial strategies that help complement health care, considering that this integration may also have a beneficial effect for your family member and the primary caregiver by applying what is learned in the care provided to you.

### **What will happen to the results when the research ends?**

The information obtained will allow us to document the effect that the music intervention has on people with Alzheimer’s disease, vascular or mixed dementia, or those in mild or moderate stages, in order to consolidate it as a strategy.

To this end, the research group will prepare a final report for the institution, in addition to:

- National and international dissemination of the results and discussion with expert groups.
- Publication of an article in a Mexican open-access journal describing the study’s main findings.

At all times and in all documents, the confidentiality and protection of your family member’s personal data will be maintained; neither your family member nor the person who cares for them will be identifiable as participants in any of these scientific publications or academic or public presentations.

### **How will privacy and confidentiality be protected?**

All information collected will be strictly confidential and will be stored and safeguarded by the principal investigator at the National Institute of Geriatrics, who will also omit variables that could identify all

participants. In addition, only the members of the field research team will have access to the information; it should be noted that the information provided by your family member will be used solely for research purposes.

*(The information obtained in this study regarding the participant's identity, as well as all personal data, is confidential information and will be handled in accordance with Articles 18, 19, and 21 of the Federal Law on Transparency and Access to Public Government Information.)*

### **Do I have to participate?**

The decision to allow your family member to participate in this research is completely free and voluntary. If you decide that your family member will not participate, this will not affect their right to obtain health services or other services they receive, if any, at the National Institute of Geriatrics (any service, but especially those of the Comprehensive Care Unit). If you decide to authorize your family member's participation but later change your mind, you may withdraw authorization to participate in this study at any time; we only ask that you inform the contact person listed at the end of this document.

On the other hand, if your family member or you are not a patient of the National Institute of Geriatrics, participation is also free and voluntary. Choosing not to participate will not affect the decision for you or your family member to be admitted as a patient of the Institute, and if you wish, at that time you will be given information on the requirements for receiving care at the Institute by the research staff attending you.

### **Who sponsors and organizes this research?**

This type of study would not be possible without funding from institutions such as INGER, which has some resources available (such as facilities, staff, etc.). We currently have support from the Embassy of the Netherlands, which will allow us to fund some parts of the study. For this study, funding is being sought from government agencies. Once additional funding is obtained, you will be informed of the details. The research is organized by Dr. Mario Ulises Pérez Zepeda, whose contact information can be found at the end of this document and whom you may contact whenever you consider it necessary. This funding will partially cover your transportation from your home to the INGER facilities for the eight music sessions and the four scheduled interviews.

### **Who has reviewed this study?**

It was reviewed and approved by the Research Ethics Committee of the National Institute of Geriatrics, file number: DI-PI-009-2025

### **What do I do now?**

We thank you for taking the time to consider your family member's participation. Please read this information sheet as many times as necessary and ask any questions you consider important to clarify your doubts. If you decide to authorize your family member's participation, you will then be provided with a copy of this information sheet and a form (informed consent) to be completed and signed by you.

We thank you for your interest in our study.

### **Who can I contact for information, suggestions, or if a problem arises?**

If you have any questions, comments, or concerns regarding the project, please contact the principal investigator:

**Investigator's name:** Dr. Mario Ulises Pérez Zepeda

**Cell phone:** 55 3270 0669

**Hours:** 8:00 a.m. to 6:00 p.m.

**Email:** [mperez@inger.gob.mx](mailto:mperez@inger.gob.mx)

If you have general questions related to your rights as a participant in this research, you may contact the Research Ethics Committee of the National Institute of Geriatrics, with Dr. Mariana López Ortega, by phone at +52 55 4794 1442 from 9:00 a.m. to 3:00 p.m., or by email at [mlopez@inger.gob.mx](mailto:mlopez@inger.gob.mx).

Informed Consent Formulary for authorization by caregivers of older adults who are unable to make decisions

Project title: project:

***Active musical intervention as a non-pharmacological strategy in older adults with dementia: A Crossed Clinical Trial.***

Project registration number of the project: DI-PI-009-2025

Name of responsible researcher: Dr. Mario Ulises Pérez Zepeda Email: [mperez@inger.gob.mx](mailto:mperez@inger.gob.mx)

Thank you for your interest in having your family member participate in this study. If you have any doubts or questions, please speak with the investigator before deciding whether you want to participate. We will give you a copy of this form so you can keep it. This way you can read it whenever you want.

Do you agree?	Yes	No
I confirm that I have read, or that it has been read to me, and that I have understood the information sheet of the study: <i>Active musical intervention as a non-pharmacological strategy in older adults with dementia: A Crossed Clinical Trial.</i>		
I confirm that I have had the opportunity to consider the information. I was able to ask questions and receive clear answers.		
I understand that my family member's participation is voluntary and that they may withdraw at any time without giving any reason.		
I understand that the information collected will be kept confidential. The name of your relative will not appear in any report or written document from the study. No one will be able to know that it refers to your family member.		
I accept that participation in the eight sessions of the musical intervention, I understand that the weekly sessions have a total duration of 3 hours, and that my family member will participate actively during one hour.		
I confirm that I agree that tests are run (4) with a duration of four hours, that will include questions and one physical performance test.		
I understand that if the physical performance test cannot be done or my family is tired from the assessments and/or sessions can leave them at any point without further consequences.		
I have been explained about the total time my familiar will participate in this project: 28 hourse along three months.		
I accept that the personal data of my family member will be stored for this study. Also, I understand that the personal data of my family member will be kept safe at the National Institute of Geriatrics and the only person who will know them will be the researcher in charge.		
I do understand that the results obtained from each assessment, will only have research goals.		
I do understand that if I wish to withdraw the personal information at any time I just need to ask for it and will be done without further questions.		

_____ Name of the participant	_____ Signature	_____ Date
_____ Witness name 1	_____ Witness signature 1	_____ Date
_____ Witness name 2	_____ Witness signature 1	_____ Date
_____ Name of the Researcher	_____ Signature of the Researcher	_____ Da

## Informative sheet for older adults

**Date:**

Project title: project:

***Active musical intervention as a non-pharmacological strategy in older adults with dementia: A Crossed Clinical Trial.***

Project registration number of the project: DI-PI-009-2025

Name of responsible researcher: Dr. Mario Ulises Pérez Zepeda Email: [mperez@inger.gob.mx](mailto:mperez@inger.gob.mx)

You have been selected to be invited to participate in a research project coordinated by the National Institute of Geriatrics. The aim of this project is to examine in depth the effect that improvisation-based music intervention has on your health. This is intended to help us better understand this practice so that we may redesign support strategies throughout your health care, caregiving, and treatment process. Before you decide whether you wish to participate, it is important that you carefully read (or listen to) the following information.

### What happens if you participate?

If you agree to take part in the research, this means that our research team will be authorized to speak with you and with the person who cares for you, who will also be informed about what this study involves and what their participation will entail.

If you agree to participate, it is estimated that your presence will be required for the music interventions for a total of 24 hours, divided into 8 weekly sessions of three hours each, held in consecutive weeks, meaning that no weeks will be skipped between sessions. The sessions follow a pre-established structure, described below:

- During the first hour, participants will settle in and be organized while the participating musicians set up.
- During the second hour, the group's signature composition will be performed, followed by a welcome melody using each participant's name as a way of fostering integration and recognizing the group. After that, you will be invited to improvise music with the professional accompaniment of the musicians.
- During the third hour, you will remain in the waiting room, where someone will always be attentive to you, and you may have a snack or drink water if you wish.

As part of this intervention, photographs and video recordings will be taken, and these materials may be used as a source of information for the research.

In addition to the time devoted to the music therapy sessions, you will be scheduled to complete four questionnaires about your mood, behavioral symptoms, memory status, and illnesses, for descriptive purposes. These sessions will consist of questions with a maximum duration of one hour and an average duration of half an hour. You will be asked to attend accompanied by your caregiver or family member. This will take place on four different days in order to learn how you have been during the course of the study. Project staff will contact you and your caregiver to schedule these interviews at a time that is most convenient for you. You will be comfortably seated in the facilities of our research unit, and at any time you may request a pause or cancel the questionnaire.

In addition, by agreeing to participate, transportation will be provided at no cost to you and your family

member for travel from the address you provide to INGER and back.

Finally, it is important for you to know that snacks and water will be provided during the sessions; you will have access to the restrooms in our facilities; and at all times there will be both security and health personnel available to attend to any of your needs.

### **Who will be with you?**

You will not be alone. During the sessions, your primary caregiver will be with you and will also participate in the music intervention sessions. INGER staff trained to address any problem that may arise or answer any questions you may have will also be present.

### **Are there any risks if you participate in the study?**

If you agree to participate, there will be no risk to your health, since during the intervention sessions you will only take part in small musical activities and the questions asked will be simple. However, if you experience any discomfort or any problem of any kind, please let us know as soon as possible; immediate attention will be provided.

As mentioned previously, you will be scheduled to come on four occasions to complete some tests about your emotional state and memory. These will be carried out by trained staff and in INGER facilities, where protocols are in place to assist you in the event of any health issue. You are reminded that at any time you may ask for a pause or even cancel the interview.

### **Are there any benefits?**

The main benefit of participating is to actively take part in “non-conventional” psychosocial strategies that help complement health care, considering that this integration may also have a beneficial effect for your primary caregiver by applying what they learn in the care they provide to you.

### **What will happen to the results when the research ends?**

The information you provide will allow us to document the effect that the music intervention has on people with Alzheimer’s disease, vascular or mixed dementia, or those in mild or moderate stages, in order to consolidate it as a strategy.

To this end, the research group will prepare a final report for the institution, in addition to:

- National and international dissemination of the results and discussion with expert groups.
- Publication of an article in a Mexican open-access journal describing the study’s main findings.

At all times and in all documents, the confidentiality and protection of your personal data will be maintained. Neither you nor the person who cares for you will be identifiable as participants in any of these scientific publications or academic or public presentations.

### **How will your privacy and confidentiality be protected?**

All information collected will be strictly confidential and will be stored and safeguarded by the principal investigator at the National Institute of Geriatrics, who will also omit variables that could make all participants identifiable. In addition, only members of the field research team will have access to the information. It should be noted that the information you provide will be used solely for research purposes.

*(The information obtained in this study regarding the participant's identity, as well as all personal data, is confidential information and will be handled in accordance with Articles 18, 19, and 21 of the Federal Law on Transparency and Access to Public Government Information.)*

### **Do I have to participate?**

If you are a patient of the National Institute of Geriatrics, your participation in this research is completely free and voluntary. If you decide not to participate, this will not affect your right to receive health services or other services you obtain, if any, at the National Institute of Geriatrics (any service, but especially those of the Comprehensive Care Unit). If you decide to participate but later change your mind, you may withdraw from this study at any time; we only ask that you inform the contact person listed at the end of this document.

On the other hand, if you are not a patient of the National Institute of Geriatrics, your participation is also free and voluntary. Choosing not to participate will not affect the decision for you to be admitted as a patient of the Institute, and if you wish, at that time you will be given information about the requirements for receiving care at the Institute by the research staff attending you.

### **Who sponsors and organizes this research?**

This type of study would not be possible without funding from institutions such as INGER, which has some resources available, such as facilities, staff, and so on. We currently have support from the Embassy of the Netherlands, which will allow us to fund some parts of the study. For this study, funding is being sought from government agencies. Once additional funding becomes available, you will be informed of the details. The research is organized by Dr. Mario Ulises Pérez Zepeda, whose contact information can be found at the end of this document, and whom you may contact whenever you consider it necessary.

### **Who has reviewed this study?**

It was reviewed and approved by the Research Ethics Committee of the National Institute of Geriatrics, file number: DI-PI-009-2025.

### **What do I do now?**

We appreciate you taking the time to consider participating. Please read this information sheet as many times as necessary and ask any questions you feel are important to clarify your doubts. If you decide to participate, you will then be provided with a copy of this information sheet and a form (informed consent) to be completed and signed by you.

We thank you for your interest in our study.

### **Who should I contact for information, suggestions, or if a problem arises?**

If you have any questions, comments, or concerns regarding the project, please contact the person responsible for the project:

**Investigator's name:** Dr. Mario Ulises Pérez Zepeda

**Cell phone:** 55 3270 0669

**Hours:** 8:00 a.m. to 6:00 p.m.

**Email:** [mperez@inger.gob.mx](mailto:mperez@inger.gob.mx)

If you have general questions related to your rights as a participant in this research, you may contact the Research Ethics Committee of the National Institute of Geriatrics, with Dr. Mariana López Ortega, by phone at +52 55 4794 1442 from 9:00 a.m. to 3:00 p.m., or by email at [mlopez@inger.gob.mx](mailto:mlopez@inger.gob.mx).

Informed Consent Formulary for authorization by caregivers of older adults who are unable to make decisions

Project title: project:

***Active musical intervention as a non-pharmacological strategy in older adults with dementia: A Crossed Clinical Trial.***

Project registration number of the project: DI-PI-009-2025

Name of responsible researcher: Dr. Mario Ulises Pérez Zepeda Email: [mperez@inger.gob.mx](mailto:mperez@inger.gob.mx)

Thank you for your interest in participating in this study. If you have any questions or doubts, please speak with the investigator before deciding whether you wish to participate. We will give you a copy of this form to keep. That way you can read it whenever you want.

Do you agree?	Yes	No
I confirm that I have read, or that someone has read to me, and that I have understood the information sheet for the study: Active Musical Intervention as a Non-Pharmacological Strategy in Older Adults with Dementia: A Crossover Clinical Trial.		
I confirm that I have had the opportunity to consider the information. And I was able to ask questions and receive clear answers.		
I understand that my participation is voluntary and that I can withdraw at any time without giving any reason.		
I know that my information will be private. My name will not appear in any report or written document of the study. No one will be able to know that it concerns me.		
I accept participation in the eight sessions of the musical intervention; I have been explained that the weekly sessions have a total duration of 3 hours, but that my active participation will be only one hour.		
I confirm that I agree to undergo the four evaluations with an approximate duration of one hour each, which will include questions and a physical test.		
I understand that if I am unable to perform the physical test or have become tired, I can suspend the evaluations at any time.		
I have been explained that the total time I will have to invest in this project is 28 hours over the course of three months.		
I accept that my personal data will be stored for this study. Since I understand that my personal data will be safeguarded at the National Institute of Geriatrics and that the only person who will have knowledge of it will be the investigator in charge.		
I understand that the results obtained from each cycle will be used solely for academic and research purposes.		
I understand that if I wish to withdraw my personal information, I will have to contact the investigator and request it directly.		

_____ Name of the participant	_____ Signature	_____ Date
_____ Witness name 1	_____ Witness signature 1	_____ Date
_____ Witness name 2	_____ Witness signature 1	_____ Date
_____ Name of the Researcher	_____ Signature of the Researcher	_____ Date