

NL64721.078.18 (MCHOPIN study)**Subject information for participation
in medical scientific research****Effect of music on the clinical outcome after hip fracture
operations (MCHOPIN): a multicenter randomized controlled
trial**

Dear Sir/Madam,

You are asked as legal representative to give consent on behalf of your relative/family member to take part in a medical-scientific study (the MCHOPIN study). If a patient is unable to give consent, the legal representative is asked for substitute consent. Participation is voluntary. Participation requires your written consent.

You have received this letter because your relative/family member has broken his/her hip and will undergo surgery. Before you decide whether you want your relative/family member to participate in this study, you will be given an explanation about what the study involves. Please read this information carefully and ask the investigator for an explanation if you have any questions. You can also ask the independent expert, who is mentioned at the end of this document, for additional information. You may also discuss it with your partner, friends or family. Additional information about participating in a study can be found in the enclosed general brochure on medical research.

1. General information

This study has been set up by the Erasmus MC and will be conducted by trauma surgeons in various hospitals in the Netherlands. For this study, 508 study subjects are required. The Medical Research Ethics Committee (MREC) Erasmus MC has approved this study. General information about the assessment of research can be found in the general brochure on medical research.

NL64721.078.18 (MCHOPIN study)**2. Purpose of the study**

Scientific research has shown that music during and around surgery can have a beneficial effect on pain and anxiety. The purpose of this study is to assess the effect of music during and around surgery for a broken hip. Among other things, the effect of music on delirium, pain, anxiety, medication requirement, complications after surgery, stress response of the body, length of hospital stay and / or length of nursing home stay and daily functional ability after surgery will be investigated.

3. Background of the study

It is known that 25-40% of patients with a broken hip in the Netherlands develop delirium, a sudden episode of confusion and disturbance of consciousness. This can lead to other complications after surgery, a prolonged hospitalization and a negative effect on recovery. Therefore, measures are taken to prevent delirium. For example, this is done by treating or reducing risk factors, like pain and stress. Because of the beneficial effect of music on pain and stress, we would like to assess whether music can reduce the occurrence of delirium. The benefit of music compared to other ways of treatment is that it is easy and durable, without side-effects.

4. What participation involves

If your relative/family member participates, participation will last until 3 months after his/her surgery.

Treatment

In this study, half of the subjects will listen to music before, during and after surgery during hospital stay. The other half of the subjects will not listen to music. The music consists of a preselected music list by the investigators, and subjects of the music group will be allowed to choose from this list. It will be determined by drawing lots whether or not your relative/family member will listen to music. Additional information about this can be found in the enclosed general brochure on medical research.

If your relative/family member has drawn the music group, he/she will receive a headphone and listen to music before surgery during 15 minutes. If your

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relative/family member is using a hearing aid, he/she will be asked to take it off and to adjust the music volume to a pleasant level. During surgery, your relative/family member will listen to music until leaving the recovery room. After surgery, he/she will listen to music twice a day for 30 minutes during the first 5 days of his/her hospital stay after surgery. If your relative/family member has not drawn the music group, he/she will wear a headphone without music 15 minutes before surgery until leaving the recovery room. He/she is not allowed to listen to music during the first 5 days of his/her hospital stay after surgery, if your relative/family member has not drawn the music group.

Visits and measurements

An additional time investment from the part of your relative/family member is required. During the hospital stay of your relative/family member, he/she will be asked:

- to fill in a pain score once a day, which takes less than 1 minute to complete.
- to fill in once a 6-item questionnaire on his/her level of education, living situation and the role of music in his/her life, which takes approximately 5 minutes to complete.
- to fill in once a 6-item questionnaire on anxiety before and 2 times after surgery, which takes approximately 5 minutes to complete.
- to fill in a 3-item questionnaire on cognition once before surgery. This questionnaire will be administered to your relative/family member by the attending physician or investigator.
- for 2 blood samples to measure the cortisol level, a measurement for the body's stress response. The first sample will be drawn at the start of surgery. For the second blood sample, an extra tubule of blood will be drawn for this study during a routine blood collection after surgery for a broken hip.

During the regular outpatient hospital visit 3 months after surgery, your relative/family member will be asked:

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- to fill in once an 8-item follow-up questionnaire on whether or not he/she has been readmitted to hospital, which takes approximately 5 to 10 minutes to complete.
- to fill in once a 6-item questionnaire on daily functional ability, which takes approximately 5 minutes to complete.

Furthermore, the investigator and investigator assistant will collect data from the electronic patient database to answer the research question of this study. This consists of personal data, like age and data on his/her surgical procedure, medication use, complications and hospital stay. If necessary, one of the investigators will contact the hospital pharmacy to assess which medicines your relative/family member received during his/her hospital stay. If your relative/family member stays in a nursing home or care home after discharge from hospital, one of the investigators will contact it for information on the duration of his/her stay.

Other than standard care

If your relative/family member has drawn the music group, he/she will listen to music during and around surgery, both groups will fill in the afore mentioned questionnaires and pain scores and blood will be drawn twice. If your relative/family member has drawn the control group, he/she is not allowed to listen to music during and around his/her surgery and the first five days after his/her surgery, even though he/she might have done this normally. The daily care during hospital stay remains unchanged. This study will end after the regular outpatient hospital visit, 3 months after hospital discharge. No additional study-related visits are required. If no outpatient visit is planned at that time after the operation, one of the investigators will contact you and your relative/family member.

5. What is expected of your relative/family member

In order to carry out the study properly, it is important that your relative/family member follows the study instructions.

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The study instructions require that he/she:

- listens to music before, during and the first 5 days after surgery only at the aforementioned moments if he/she has drawn the music group.
- does not listen to music before surgery, during surgery and during the first 5 days after surgery if he/she has not drawn the music group.
- does not participate in another medical study.
- fills in the afore mentioned questionnaires and pain scores, and that twice a tubule of blood will be drawn.

It is important that you contact the investigator:

- if your relative/family member is admitted or treated in an hospital
- if you want your relative/family member to stop participating in this study
- if your contact details or the contact details of your relative/family member change.

6. Possible side effects, complications and discomforts

The music intervention is safe and has no known side effects or complications. To prevent hearing loss, a maximum sound level has been set. Drawing blood can hurt and can lead to bruising in some cases.

7. Possible advantages and disadvantages

It is important that you properly weigh up the possible benefits and disadvantages before you decide for your relative/family member to join. His/her participation can contribute to more knowledge on delirium and the use of music in health care.

Music could potentially have a beneficial effect on delirium, pain and anxiety after surgery, but this is not certain. Disadvantages of participating in this study can be:

- the extra time it will require
- the instructions your relative/family member needs to follow
- that he/she will not be able to listen to music during the first 5 days after surgery
- filling in the questionnaires and pain scores

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- drawing of blood

All these aspects have been described above under points 4, 5 and 6.

8. If you do not want your relative/family member to participate or want to stop participation in the study

It is up to you to decide whether or not your relative/family member participates in the study. Participation is voluntary. If you do not want your relative/family member to participate, he/she will be treated as usual for a broken hip. If your relative/family member does participate in the study, you can always change your mind and decide to stop, at any time during the study. He/she will then be treated as usual for a broken hip. You do not have to say why your relative/family member is stopping, but you do need to tell the investigator immediately. The data collected until that time will still be used for the study.

If there is any new information about the study that is important for you, the investigator will let you know. You will then be asked whether you still want your relative/family member to continue participating in this study.

9. Resistance of the person you represent

The person you represent may resist (refuse to cooperate) during the study. The investigator will then have to stop the study immediately. It is difficult to describe what exactly resistance is. Before the start of the study you will be given an explanation of what is considered resistance. The investigator will follow the Code of Conduct on resistance of mentally incompetent and geriatric patients.

10. End of the study

The participation of your relative/family member in the study stops when:

- he/she has completed the outpatient visit and the measurements as described under point 4
- you choose to stop
- the investigator considers it best for your relative/family member to stop

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- the sponsor (Erasmus MC), the government or Medical Research Ethics Committee, decides to stop the study.

The study is concluded once all the participants have completed the study.

11. Usage and storage of data and bodily material of your relative/family member

The personal data and bodily material of your relative/family member will be collected, used and stored for this study. This concerns data such as name, address, date of birth and data about health. Also, blood is required for this study. The collection, use and storage of the data and bodily material of your relative/family member are required to answer the questions asked in this study and to publish the results. We ask your permission for the use of the data and bodily material of your relative/family member.

Confidentiality of the data and bodily material of your relative/family member

To protect the privacy of your relative/family member, his/her data and bodily material will be given a code. His/her name and other information that can directly identify your relative/family member will be omitted. Data can only be traced back to your relative/family member with the encryption key. The investigator and investigator assistants are the only people who will know which code your relative/family member has. This is necessary, as they will collect information from the electronic patient database, questionnaires and bodily material. The data and bodily material that is sent to the sponsor will only contain the code, not his/her name or other data with which your relative/family member can be identified. The key to the code will stay with the investigator. The data cannot be traced back to your relative/family member in reports and publications about the study.

Access to the data of your relative/family member for verification

Some people can access all the data of your relative/family member at the research location. Including the data without a code. This is necessary to check whether the study is being conducted in a good and reliable manner. Persons who have access to the data of your relative/family member for

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review are members of the research team, a monitor working for the sponsor of the study, and national supervisory authorities, for example, the Healthcare and Youth Inspectorate. They will keep the data of your relative/family member confidential. We ask you to consent to this access.

Retention period of the data and bodily material of your relative/family member

The data of your relative/family member must be kept for 15 years at the research location (Erasmus MC). His/her bodily material will be destroyed immediately after use.

Withdrawing consent

You can withdraw your consent to the use of the personal data of your relative/family member at any time. This applies to this study. The study data collected until the moment you withdraw your consent will still be used in the study. The bodily material of your relative/family member will be destroyed after your consent has been withdrawn. If measurements have already been made with that bodily material, then this data will still be used.

More information about the rights when processing data

For general information about the rights when processing the personal data of your relative/family member, you can consult the website of the Dutch Data Protection Authority.

If you have questions about these rights, please contact the person responsible for the processing of the personal data of your relative/family member. For this study, that is: Erasmus MC. See Appendix A for contact details and website.

If you have questions or complaints about the processing of the personal data of your relative/family member, we advise you to first contact the research location. You can also contact the Data Protection Officer of the Erasmus MC (See Appendix A. Contact details) or the Dutch Data Protection Authority.

NL64721.078.18 (MCHOPIN study)**Registration of the study**

Information about this study is included in a list of medical-scientific studies namely the Dutch trial registry (www.trialregister.nl). It does not contain any information that can be traced to your relative/family member. After the study, the website may display a summary of the results of this study. You can find this study under MCHOPIN.

12. Study subject insurance

This study is not associated with any additional risks for your relative/family member. The MREC Erasmus MC has therefore decided that the sponsor does not need to take out additional insurance.

13. Informing GP and contact with the hospital pharmacy

We will always send the GP of your relative/family member a letter to let them know that he/she is participating in the study. This is for the safety of your relative/family member. If you do not agree to this, your relative/family member cannot participate in this study. Your relative/family member cannot participate in the study if he/she does not have a GP.

During this study, the effect of music on medication use will be assessed. Therefore, the investigators will contact the hospital pharmacy to ask about medication usage. Your relative/family member cannot participate in this study if you do not want this.

14. No Compensation for participation

Participation in this study and use of the sound equipment is free of charge for you and your relative/family member. You and your relative/family member will not be paid for the participation in this study.

15. Any questions?

If you have any questions, please contact the study team. If you would like any independent advice about participation in this study, you may contact the independent doctor. He knows about the study but is not involved in it. If you have any complaints, you may contact the complaint officer at your hospital. All the relevant details can be found in Appendix A: Contact details.

NL64721.078.18 (MCHOPIN study)**16. Signing the consent form**

When you have had sufficient time for reflection, you will be asked to decide on participation of your relative/family member in this study. If you give permission, we will ask you to confirm this in writing on the appended consent form. By your written permission you indicate that you have understood the information and consent to participation of your relative/family member in the study. The signature sheet is kept by the investigator. You will get a copy or a second copy of this consent form.

Thank you for your attention.

17. Appendices to this information

- A. Contact details
- B. Representative Informed Consent Form
- C. Medical Scientific Research Brochure. General Information for Study Subjects (version 01-03-2017)

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**Appendix A: contact details for Erasmus MC****Principle investigator:**

Prof. dr. M.H.J. Verhofstad, trauma surgeon Tel. no.: 010-7031050

Available during office hours. You can contact the general number of the hospital (tel. no. 010-7040704) outside of office hours and ask for the attending of the (trauma)surgery department.

Coordinating investigator:

Mr. V.X. Fu, research physician Erasmus MC Tel. no.: 06-21128074

Available during and outside of office hours.

Independent doctor:

Prof. dr. H.J.M. Verhagen, surgeon Erasmus MC Tel. no.: 010-7040112

Available during office hours.

Complaints:

Secretariaat Klachtenopvang Erasmus MC Tel. no.: 010-7033198

Available during office hours.

P.O. Box: Erasmus MC, attn. secretariaat Klachtenopvang

Antwoordnummer 55, 3000 WB Rotterdam

E-mail: klachtenopvang@erasmusmc.nl

Data Protection Officer of Erasmus MC:

Data Protection Officer Erasmus MC Tel. no.: 010-7034986

Secretariat Department of Legal Affairs

Available during office hours.

For more information about your rights: www.erasmusmc.nl

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**Appendix B: Representative Informed Consent Form****Effect of music on the clinical outcome after hip fracture operations (MCHOPIN): a multicenter randomized controlled trial**

I have been asked to consent to the following person participating in this medical-scientific study:

Name of the study subject:
Date of birth:	__ / __ / __

- I have read the information sheet for the study subject. I was also able to ask questions. My questions have been answered to my satisfaction. I have had enough time to decide whether this person will participate.
- I know that participation is voluntary. I also know that I can decide at any time that this person will not participate after all. I do not need to give a reason for this decision.
- I give permission for this person's GP to be informed about this person's participation in this study.
- I give permission for the collection and use of data and blood of this person to answer the research question in this study.
- I give permission for information to be requested from the nursing home or care home in the way and for the purpose stated in the information sheet.
- I give permission for information to be requested from the hospital pharmacy in the way and for the purpose stated in the information sheet.
- I know that some people may have access to all the data of this person to verify the study. These people are listed in this information sheet. I consent to the inspection by them.
- I consent to the data being stored at the research location (Erasmus MC) for another 15 years after this study.
- I agree to this person's participation in this study.

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Name of legal representative: Relationship with the study subject: Date: Signature: __ / __ / __
I hereby declare that I have fully informed this/these person(s) about this study. If information comes to light during the course of the study that could affect the legal representative's consent, I will inform him/her of this in a timely fashion.	
Name of investigator (or his/her representative): Date: Signature: __ / __ / __
Additional information was given by	
Name: Job Title: Date: Signature: __ / __ / __

The representative will receive the full information sheet, together with a copy of the signed consent form