

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**

#### **Introduction**

Dear Sir/Madam,

You are asked to take part in a medical-scientific study (the MCHOPIN study). Participation is voluntary. Participation requires your written consent. You have received this letter because you have broken your hip and will undergo surgery. Before you decide whether you want 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.

#### **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

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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**

Your participation will last until 3 months after your 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 you will listen to music. Additional information about this can be found in the enclosed general brochure on medical research.

If you have drawn the music group, you will receive a headphone and listen to music before surgery during 15 minutes. If you are using a hearing aid, you will be asked to take it off and to adjust the music volume to a pleasant level. During surgery, you will listen to music until leaving the recovery room. After surgery, you will listen to music twice a day for 30 minutes during the first 5 days of your hospital stay after surgery. If you have not drawn the music group, you will wear a headphone without music 15 minutes before surgery

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until leaving the recovery room. You are not allowed to listen to music during the first 5 days of your hospital stay after surgery, if you have not drawn the music group.

**Visits and measurements**

An additional time investment from your part is required. During your hospital stay, you 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 your level of education, living situation and the role of music in your life, which takes approximately 5 minutes to complete.
- to fill in a 6-item questionnaire on anxiety once 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 you 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, you will be asked:

- to fill in once an 8-item follow-up questionnaire on whether or not you have 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 your surgical procedure, medication use, complications and hospital stay. If necessary, one of the

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investigators will contact the hospital pharmacy, to assess which medicines you received during the hospital stay. If you stay in a nursing home or care home after discharge from hospital, one of the investigators will contact it for information on the duration of your stay.

***Other than standard care***

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

**5. What is expected of you**

In order to carry out the study properly, it is important that you follow the study instructions.

The study instructions require that you:

- listen to music before, during and the first 5 days after surgery only at the aforementioned moments if you have drawn the music group.
- do not listen to music before surgery, during surgery and during the first 5 days after surgery if you have not drawn the music group.
- do not participate in another medical study.
- fill 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 you are admitted or treated in an hospital
- if you no longer want to participate in the study.
- if your contact details change.

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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 in some cases lead to bruising.

**7. Possible advantages and disadvantages**

It is important that you properly weigh up the possible benefits and disadvantages before you decide to join. Your 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 you need to follow
- not being able to listen to music during the first 5 days after your surgery
- filling in the questionnaires and pain scores
- drawing of blood

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

**8. If you do not want to participate or you want to stop participating in the study**

It is up to you to decide whether or not to participate in the study. Participation is voluntary. If you do not want to participate, you will be treated as usual for a broken hip. If you do participate in the study, you can always change your mind and decide to stop, at any time during the study. You will then be treated as usual for a broken hip. You do not have to say why you are 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 to continue your participation.

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Your participation in the study stops when:

- you have completed the outpatient visit and the measurements as described under point 4
- you choose to stop
- the investigator considers it best for you to stop
- 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.

**10. Usage and storage of your data and bodily material**

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

**Confidentiality of your data and bodily material**

To protect your privacy, your data and your bodily material will be given a code. Your name and other information that can directly identify you, will be omitted. Data can only be traced back to you with the encryption key. The investigator and investigator assistants are the only people who will know which code you have. This is necessary, as they will have to 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 your name or other data with which you can be identified. The key to the code will stay with the investigator. The data cannot be traced back to you in reports and publications about the study.

**Access to your data for verification**

Some people can access all your data at the research location. Including the data without a code. This is necessary to check whether the study is being

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conducted in a good and reliable manner. Persons who have access to your data for 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 your data confidential. We ask you to consent to this access.

**Retention period of your data and bodily material**

Your data must be kept for 15 years at the research location (Erasmus MC). Your bodily material will be destroyed immediately after use.

**Withdrawing consent**

You can withdraw your consent to the use of your personal data 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. Your bodily material 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 your rights when processing data**

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

If you have questions about your rights, please contact the person responsible for the processing of your personal data. 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 your personal data, 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.

**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](http://www.trialregister.nl)). It does not contain any information that can be traced to you. After the study, the website may display

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a summary of the results of this study. You can find this study under MCHOPIN.

**11. Study subject insurance**

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

**12. Informing GP and contact with the hospital pharmacy**

We will always send your GP a letter to let them know that you are participating in the study. This is for your own safety. If you do not agree to this, you cannot participate in this study. You cannot participate in the study if you do 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 your medication use. You cannot participate in this study if you do not want this.

**13. No Compensation for participation**

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

**14. 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.

**15. Signing the consent form**

When you have had sufficient time for reflection, you will be asked to decide on participation 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

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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.

**16. Appendices to this information**

- A. Contact details
- B. Informed Consent Form subject
- 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](http://www.erasmusmc.nl)

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## Appendix B: Subject Consent Form

### Effect of music on the clinical outcome after hip fracture operations (MCHOPIN): a multicenter randomized controlled trial

- I have read the subject information form. I was also able to ask questions. My questions have been answered to my satisfaction. I had enough time to decide whether to participate.
- I know that participation is voluntary. I know that I may decide at any time not to participate after all or to withdraw from the study. I do not need to give a reason for this.
- I give permission for my GP to be informed about my participation in this study.
- I give permission for the collection and use of my data and blood 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 my data to verify the study. These people are listed in this information sheet. I consent to the inspection by them.
- I consent to my data being stored at the research location (Erasmus MC) for another 15 years after this study.
- I want to participate in this study.

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Name of the study subject: Date: Signature:	..... __ / __ / __ .....
I hereby declare that I have fully informed this study subject about this study. If information comes to light during the course of the study that could affect the study subject'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 study subject will receive the full information sheet, together with a copy of the signed consent form