

# Effect van muziek op de klinische uitkomst na heupfractuur operaties (MCHOPIN): een multicenter gerandomiseerde studie

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Proximal femur fractures are the most common fractures in the elderly. These elderly patients, often with significant comorbidity and polypharmacy, are at high risk for delirium, which increases the risk of other postoperative complications, a...

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|-----------------------------|--------------------------|
| <b>Ethische beoordeling</b> | Positief advies          |
| <b>Status</b>               | Werving nog niet gestart |
| <b>Type aandoening</b>      | -                        |
| <b>Onderzoekstype</b>       | Interventie onderzoek    |

## Samenvatting

### ID

NL-OMON25655

### Bron

NTR

### Verkorte titel

MCHOPIN

### Aandoening

Proximal femur fracture

Delirium

### Ondersteuning

**Primaire sponsor:** Erasmus MC, University Medical Center  
Rotterdam

Department of Surgery

P.O. Box 2040, 3000 CA Rotterdam, The Netherlands

**Overige ondersteuning:** None

# Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

Delirium (DOS scale and clinical diagnosis by geriatrician)

## Toelichting onderzoek

### Achtergrond van het onderzoek

Proximal femur fractures are the most common fractures in the elderly. These elderly patients, often with significant comorbidity and polypharmacy, are at high risk for delirium, which increases the risk of other postoperative complications, a longer hospital stay and a reduced functional outcome. Recent systematic reviews and meta-analysis have shown a significant beneficial effect of perioperative music on postoperative pain and anxiety. Also, several studies have shown a reduced need for intraoperative sedative medication, as well as a reduction in postoperative analgesic medication requirement, when perioperative music as a non-pharmacological intervention was used. This study will investigate the effect of perioperative music on the clinical outcome in proximal femur fracture patients. The main objective of this study is to investigate whether music as an intervention is effective in reducing the occurrence of postoperative delirium. Secondary objectives are the effects of perioperative music on pain, anxiety, medication use, postoperative complications, neurohormonal stress response, hospital length of stay, nursing home length of stay, 30-day mortality, 90-day readmission, 90-day functional ability to perform daily living activities and costs.

### Doel van het onderzoek

Proximal femur fractures are the most common fractures in the elderly. These elderly patients, often with significant comorbidity and polypharmacy, are at high risk for delirium, which increases the risk of other postoperative complications, a longer hospital stay and a reduced functional outcome. Perioperative music has a significant beneficial effect on anxiety and postoperative pain, which are risk factors of delirium. The main objective of this study is to investigate whether music as an intervention is effective in reducing the occurrence of postoperative delirium.

### Onderzoeksopzet

90-days

## Onderzoeksproduct en/of interventie

Perioperative recorded music

## Contactpersonen

### Publiek

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The Netherlands

### Wetenschappelijk

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Patients with a proximal femur fracture undergoing surgical treatment
- Age ≥ 65 years old
- Provision of written informed consent by patient or proxy

### Belangrijkste redenen om niet deel te kunnen nemen

## (Exclusiecriteria)

- Additional serious injuries or additional surgical procedures that may affect any of the outcome parameters
- Implant in situ in the affected hip
- Severe hearing impairment, defined as no verbal communication possible
- Patients unwilling or unable to comply with the intervention
- Preoperative planned hospital discharge and return to nursing home within 48 hours of admission
- Insufficient knowledge of the Dutch or English language to understand the study documents in the judgement of the attending physician or researcher
- Participation in another intervention study that might influence the duration of surgery or any of the outcome parameters

## Onderzoeksopzet

### Opzet

|                  |                         |
|------------------|-------------------------|
| Type:            | Interventie onderzoek   |
| Onderzoeksmodel: | Parallel                |
| Toewijzing:      | Gerandomiseerd          |
| Blinding:        | Open / niet geblindeerd |
| Controle:        | Geneesmiddel            |

### Deelname

|                         |                          |
|-------------------------|--------------------------|
| Nederland               |                          |
| Status:                 | Werving nog niet gestart |
| (Verwachte) startdatum: | 01-07-2018               |
| Aantal proefpersonen:   | 508                      |
| Type:                   | Verwachte startdatum     |

## Ethische beoordeling

Positief advies

Datum: 23-02-2018

Soort: Eerste indiening

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 52816

Bron: ToetsingOnline

Titel:

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

### In overige registers

| Register | ID             |
|----------|----------------|
| NTR-new  | NL6858         |
| NTR-old  | NTR7036        |
| CCMO     | NL64721.078.18 |
| OMON     | NL-OMON52816   |

## Resultaten