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# Effects of Music Therapy for Prison inmates

| Submission date | Recruitment status | [X] Prospectively registered |
|---|---|---|
| 28/05/2008 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 30/06/2008 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 24/01/2023 | Mental and Behavioural Disorders | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
N/A

## Study information

**Scientific Title**

Effects of Music Therapy for Prison inmates: a randomised controlled parallel group study

## Acronym
MT-PRIS

## Study objectives
It is hypothesised that regular sessions of group music therapy, compared to standard care, will have positive effects on prison inmates' emotion and behaviour.

As of 21/12/2009 this record was updated to include information on the second phase of this study, MT-PRIS2. All details can be found under the relevant sections with the title 'MT-PRIS2'. Due to this change, the anticipated end date of this record has been updated; the initial anticipated end date for the MT-PRIS trial was 31/12/2009 and the target number of participants for this phase only was 100 participants.

MT-PRIS2: Effects of music therapy for prison inmates - second phase:
More than 100 participants have been included in the pilot study MT-PRIS. The experiences from this phase have been valuable both in regards to the music therapy context as well as the broader context of the prison system. Therefore some changes have been made for the second phase of the project (see the interventions section below for more details on this).

These changes will ensure both good enough service provision at the prison and internally valid research results. Because the amended design will be more compatible with routine service provision, the study will be feasible over an extended time period, thus enabling a sufficient sample size and adequate statistical power.

MT-PRIS2 start and end dates and participant target:
The anticipated start and end dates of the MT-PRIS2 trial are as follows:
Anticipated start date: 31/12/2009
Anticipated end date: 31/12/2012
The target number of participants for the MT-PRIS2 trial is 180 participants.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
The National Committees for Research Ethics in Norway (REK Vest) approved on the 8th May 2008 (ref: 2008/4840-ANØL)

MT-PRIS2:
The National Committees for Research Ethics in Norway approved on the 12th November 2009 (ref: 2009/2040)

## Study design
Randomised controlled trial with parallel groups

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Prison/detention

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied
Prison inmates' emotion and behaviour

## Interventions
Participants in the experimental group will be approached by the music therapist to participate in music therapy groups. These will be conducted by an academically and clinically trained therapist who is trained in a psychodynamic model of music therapy and has previous experience in working with prisoners. The music therapist will attend weekly supervision sessions to ensure good quality of the work. With respect to intensity and contents, the therapy sessions may be conducted flexibly; frequency and duration of sessions and duration of the whole therapy will be decided by the music therapist in dialogue with the participants. Activities used in music therapy may include improvisation, other music making with instruments, singing and writing songs, listening to music, and verbal discussions related to the music experiences or other issues. The music therapist will write a record of the participants and activities used in each session, so that these data will be available for analysis. The music therapist will make notes of the therapy contents and will report if any unusual or problematic events have occurred in the session.

Participants assigned to the control group will not be approached by the music therapist. No alternative activity will be offered. Standard care will be provided to participants of all groups.

The interventions will continue until the day of release, therefore the duration will vary. The maximum duration will be the duration of the project (17 months).

MT-PRIS2:
Open group music therapy (OGMT) will be offered to all inmates, whether they choose to participate in the project or not. Those who decide to participate in the research project can specify their preference for participating or not participating in individual music therapy (IMT). Those who do not have a clear preference will be randomised to IMT or no IMT. If there are more new participants who prefer IMT than there are vacant slots for it, the respective participants will also be randomised.

## Intervention Type
Other

## Phase
Not Specified

## Primary outcome measure
1. Self-reports of anxiety, depression and mood: self-report measures will be used to measure anxiety, depression, and social relationships. The current level of anxiety state will be measured before and after selected sessions using the respective part of the State-Trait Anxiety Inventory

(STAI) (20 items). Variables that change more slowly will be measured after 1, 3, and 6 months (or at release). These include trait anxiety (STAI) (20 items), depression (the respective part of the Hospital Anxiety and Depression Scale [HADS]) (7 items), and social relationships (the respective subscale of the Q-LES-Q).
2. Physiological measures of heart rate variability (HRV) and heart rate (HR): these will be assessed every two weeks in the experimental group, and after 1, 3 and 6 months in the control group. Heart rate variability (HRV) will be used to objectively assess the level of anxiety, with high levels of HRV indicating high anxiety levels. Heart rate (HR) is an additional indicator of anxiety, although less reliable than HRV. HRV will be registered by using the Actiheart® System (Cambridge Neurotechnology Ltd), a compact lightweight device that records physical activity, HR, and variability of R-R inter-beat interval (IBI) if a relevant recording mode is selected. It calculates energy expenditure based on the activity and HR data. The Actiheart® clips onto a single electocardiogram (ECG) electrode with a short ECG lead to another electrode that picks up the ECG signal. The Actiheart® will be placed on the upper or lower chest.
3. State registry data: provided that additional funding will be available, data on arrest, conviction, and incarceration after release will be collected from official records and analysed. This material is available up to ten years.

MT-PRIS2:
1. For IMT groups only: HRV, HR and STAI measured every two weeks
2. For non-IMT groups only: HRV and HR measured after 1, 3 and 6 months and before release (post-test)
3. Both groups: STAI, HADS, Q-LES-Q measured after 1, 3 and 6 months and before release (post-test)

### Secondary outcome measures
No secondary outcome measures

### Overall study start date
30/07/2008

### Completion date
31/12/2012

## Eligibility

### Key inclusion criteria
1. Inmates at Bjørgvin prison, Bergen, Norway (adult males only)
2. Sufficient command of the Norwegian language
3. Informed consent to participate

MT-PRIS2:
1. Inmates at Bjørgvin prison, Bergen, Norway (adult males only)
2. Sufficient command of the Norwegian language
3. Informed consent to participate
4. Inmates have a sentence of 1 month or more

### Participant type(s)
Patient

### Age group

Adult

**Sex**
Male

**Target number of participants**
Approximately 280 participants (MT-PRIS: 100 participants; MT-PRIS2: 180 participants)

**Key exclusion criteria**
Does not comply with the above inclusion criteria.

**Date of first enrolment**
30/07/2008

**Date of final enrolment**
31/12/2012

# Locations

**Countries of recruitment**
Norway

**Study participating centre**
**GAMUT, Unifob Health**
Bergen
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5015

# Sponsor information

**Organisation**
Helse Bergen, Haukeland University Hospital (Norway)

**Sponsor details**
Kompetansesenter for sikkerhets-, fengsels- og rettspsykiatri
Klinikk for sikkerhetspsykiatri
Psykiatrisk divisjon
Sandviksleitet 1
Bergen
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**Sponsor type**

Hospital/treatment centre

**Website**
http://www.helse-bergen.no/avd/sikkerhetsfengselsogrettspsykiatri/

**ROR**
https://ror.org/03np4e098

# Funder(s)

**Funder type**
Government

**Funder Name**
Directorate for Health and Social Affairs (Norway)

**Funder Name**
Norwegian Correctional Services, Western Norway (Norway)

**Funder Name**
GC Rieber Foundation, Bergen (Norway)

**Funder Name**
University of Bergen (Norway)

# Results and Publications

**Publication and dissemination plan**
Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**
Not provided at time of registration

**IPD sharing plan summary**
Not provided at time of registration

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
| --- | --- | --- | --- | --- | --- |
| Results article | results | 01/12/2014 | | Yes | No |