

Effects of Music Therapy for Prison inmates

Submission date 28/05/2008	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 30/06/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 24/01/2023	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Christian Gold

Contact details
GAMUT, Unifob Health
Lars Hilles gt. 3
Bergen
Norway
5015
-
christian.gold@grieg.uib.no

Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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 electrocardiogram (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)

Key secondary outcome(s)

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Male

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

Norway

5015

Sponsor information

Organisation

Helse Bergen, Haukeland University Hospital (Norway)

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

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