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Music therapy for depression

Submission date	Recruitment status	[ ] Prospectively registered
21/02/2008	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
14/03/2008	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
26/10/2011	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Jaakko Erkkila

Contact details
Department of Music
P.O. Box 35 (M)
Jyväskylä
Finland
41520

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effect of improvisational music therapy in the treatment of depression

Study objectives
1. To examine if improvisational music therapy, added to standard care, helps patients to improve the level of depressive symptoms (primary outcome) compared to standard care only
2. To examine with psychiatric tests if music therapy improves general symptoms, alexithymia, functioning, and quality of life in these patients compared to standard care

Provided that significant effects are found:
3. To examine if music therapy cause changes in frontal asymmetry in rest electroencephalogram (EEG) (as a proxy/indicator of clinical changes in depression level)
4. To examine if clinical change is mediated by observable and measurable changes in music (produced in therapy) and its elements, in specific musical features, and in the interaction between the client and the therapist
5. To examine if these effects are mediated by changes in music perception (as measured in topographic EEG focusing on changes in frontal and limbic responses). In addition, a behavioural evaluation method is employed.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Keski-Suomen sairaanhoitopiiri (Central Finland Health Care District) Eettinen toimikunta (Ethical Board) on the 24th October 2007 (ref: Poytakirja 9/2007).

Study design
The study will be a single-blinded randomised controlled trial with two parallel arms

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Depression

Interventions
Participants:
Target number of participants with depression is 85 (N = 35 in experiment group, N = 50 in control group). An additional group (N = 15) without that condition will serve as a comparison group for some outcomes.

Interventions:
Experiment group:
Clients in the experimental group will participate in psychodynamic improvisational music therapy in individual setting. Music therapy is conducted twice in week, each session lasting 60 minutes. The target number of sessions is 20, however, the patients with fewer sessions are not excluded from data analysis (intention-to-treat principle). Active engagement during the course of therapy process is needed for up to three months. Patients will continue to receive treatment as usual (see below) while receiving music therapy.

Control group:
Patients will receive treatment as usual during the study period. Standard care may consist of medication (antidepressants) and psychiatric counselling.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Symptoms of depression will be measured with the Montgomery and Asberg Depression Rating Scale (MADRS). The MADRS is an interview-based scale consisting of 10 items and the total score varies between 0 and 60. This was measured before and three months after randomisation.

Secondary outcome measures
Secondary outcomes of general relevance for the patient:
1. Anxiety will be evaluated by the Hospital Anxiety and Depression Scale (HADS). The anxiety subscale (HADS-A) of this widely used, valid and reliable questionaire consists of seven items, whereby higher scores (from 0 - 21) indicate more anxiety.
2. General functioning will be measured using a blind rating with the GAF (global assessment of functioning)
3. Quality of life will be evaluated by the 36-item RAND scale (RAND-36). It maps well-being and functioning on eight dimensions.
4. Alexithymia will be evaluated with the 20-item Toronto Alexithymia Scale (TAS-20), which is a self-report questionnaire for the assessment of alexithymia

Secondary outcomes specifically linked to the assumed mechanisms of music therapy:
5. All the improvisations created in the therapy sessions will be recorded either as MIDI-data (mallet midi-controllers and midi-percussion) or as digital audio (Djembe drums). For the analysis of MIDI-data, a computational method called MTTB (Music Therapy Toolbox), particularly developed for analysis of music therapy improvisations in MIDI-format will be employed. The MTTB-method makes possible to automatically extract various musical features as well as some aspects of therapist-client interaction. Previously the method has been successfully utilised in the study based on the analysis of clinical improvisations by people with mental retardation. For the analysis of digital audio data, a computational method called MIR (Music Information Retrieval) will be employed. Like the MTTB, the MIR also makes possible to extract particular musical features from the music and musical interaction to be further interpreted. The method has not been utilised in clinical context before.
6. Collected video material is used as a resource for the interpretation of results, and for studying the processes. Master students and post-graduate students will conduct qualitative and quantitative content analyses. Focused microanalysis will be used for specific process-

related issues and for studying emotional transitions during the micro- and macro-level processes.
7. EEG measurement is applied based on the findings of earlier research on depression. Because of its timelocked correlations it has been found to be the measure of choice for music and brain research, instead of using imaging techniques that provide distinct spatial information (such as fMRI and PET) but lack on time and event-related correlation. Depression is found to be correlated with a hypoactivation of left brain activity and this may be attenuated after treatment. Secondly, a more distinct and variable spectral EEG pattern according to personality and specific reactions of theta variables in the treatment and control group are expected as mediators of change. EEG research recordings (pre-test directly after inclusion/before randomisation, post-test three months after randomisation) and its corresponding patient data of the clinical groups will be monitored by a clinical neurologist. Analysis of the EEG will focus on topographic distribution of spectral power and percentage of EEG frequencies. All subjects will listen to two sets of stimuli:
7.1. A randomised order of short pieces of instrumental music, excerpts of film sound tracks previously rated and categorised according to the emotional dimensions valence, tension and energy
7.2. An ordered set of short pieces of instrumental music according to five basic emotions (tender, anger, fear, sad, happy)
8. An evaluation of emotional qualities of music will be processed (pre-test directly after inclusion/before randomisation, post-test three months after randomisation and follow-up test 6 months after randomisation). In these behavioural experiments participants will listen two sets of music excerpts and self-rate those based on emotional qualities and characteristics of music. The first set of excerpts has been chosen based on basic emotions. The second set is based on the three-dimensional model of musical emotions. All stimulus examples have been tested and validated with non-clinical population. In experiment participants will listen excerpts in randomised order and self-rating those by using computer based self-rating patches.

All outcomes are measured before and three months after randomisation.

Overall study start date
10/03/2008

Completion date
30/06/2009

Eligibility

Key inclusion criteria
1. Adults (18 - 50 years of age), either sex
2. Participants must have a depression as the primary diagnosis according to the International Classification of Diseases (ICD) chapters F32 (depressive episode) to F33 (recurrent depressive disorder). In this study, depression is the primary focus of interest but because of the frequent comorbidity of depression and anxiety, also the latter, if occurring with primary diagnosis of depression, is included. This will be assessed by Mini-SCID (a structured clinical interview for Diagnostic and Statistical Manual of Mental Disorders, Third Edition, Revised [DSM-III-R]) administered by a clinical expert.
3. Musical skills or any given musical background are not required, although these do not prevent participating

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100 in total

Key exclusion criteria
1. Repeated suicidal behaviour
2. Psychosis
3. Acute and severe substance abuse
4. Severeness of depression: patients must be able to participate in measurements and verbal conversation

Date of first enrolment
10/03/2008

Date of final enrolment
30/06/2009

Locations

Countries of recruitment
Finland

Study participating centre
Department of Music
Jyväskylä
Finland
41520

Sponsor information

Organisation
University of Jyvaskyla (Finland)

Sponsor details

Department of Music
P.O. Box 35 (Building M)
Jyvaskyla
Finland
41520

Sponsor type
University/education

Website
http://www.jyu.fi/

ROR
https://ror.org/05n3dz165

Funder(s)

Funder type
Government

Funder Name
European Union (Belgium) - 6th Framework programme (Contract No: 028570 (NEST))

Funder Name
Academy of Finland (Finland) - Finnish Center for Excellence in interdisciplinary music research (ref: SA 20/510/2007)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	28/06/2008		Yes	No

Results article	results	01/08/2011	Yes	No