

# Music therapy for depression

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<b>Registration date</b> 14/03/2008	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 26/10/2011	<b>Condition category</b> 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

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## Additional identifiers

## 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

### **Study type(s)**

Treatment

### **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(s)**

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.

## **Key secondary outcome(s)**

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 questionnaire 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.

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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 Jyväskylä (Finland)

**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

## 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?
<a href="#">Results article</a>	results	01/08/2011		Yes	No
<a href="#">Protocol article</a>	protocol	28/06/2008		Yes	No