

# Improvisational music therapy for depression

<b>Submission date</b> 24/01/2018	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 26/01/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 08/03/2021	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Plain English summary as of 19/11/2018:

### Background and study aims

Depression is among the leading causes of disability worldwide. Not all people with depression respond adequately to standard treatments. An innovative therapy that has shown promising results in controlled trials is music therapy. Based on a previous trial that suggested beneficial effects of Integrative Improvisational Music Therapy (IIMT) on short- and medium term depression symptoms as well as anxiety and functioning, this trial aims to determine potential mechanisms and enhancements of its effects by examining specific variations to IIMT.

### Who can participate?

Adults aged 18–55 years of age with a primary diagnosis of depression.

### What does the study involve?

All participants receive 6 weeks of biweekly IIMT, where they are invited to improvise music and reflect on those improvisations with a music therapist in a one-to-one setting. Potential enhancements to IIMT include: home-based listening to recorded improvisations from IIMT sessions to facilitate integration of therapeutic processing into daily life; and resonance frequency breathing, a breathing exercise at the beginning of each session to facilitate emotional expression and processing.

### What are the possible benefits and risks of participating?

Decrease of depression scores is expected in all groups, as IIMT as such is already known to be effective in the treatment of depression. Participants in the added treatment conditions are expected to improve more than the ones receiving only traditional IIMT. Participation in therapy is likely to trigger difficult emotions, yet this is considered to be a normal part of therapy and known to be beneficial for recovery.

### Where is the study run from?

The study is run at the music therapy clinic of the Department of Music, Art and Culture Studies at the University of Jyväskylä, Finland.

### When is study starting and how long is it expected to run for?

June 2016 to July 2020

Who is the main contact?

Prof. Jaakko Erkkilä  
jaakko.erkkila@jyu.fi

Previous plain English summary:

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**Study website**

<https://www.jyu.fi/hytk/fi/laitokset/mutku/tutkimus/tutkimusprojektit/no-pain-no-gain>

## Contact information

**Type(s)**

Scientific

**Contact name**

Prof Jaakko Erkkilä

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**Type(s)**

Public

**Contact name**

Mr Markku Pöyhönen

**Contact details**

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+358 405 707007  
[markku.i.poyhonen@jyu.fi](mailto:markku.i.poyhonen@jyu.fi)

## **Additional identifiers**

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

298678

## **Study information**

**Scientific Title**

No pain no gain: Internal mechanisms of Integrative Improvisational Music Therapy in the treatment of depression

**Acronym**

NPNG

## **Study objectives**

Based on previous research, Integrative Improvisational Music Therapy (IIMT) has been shown to be effective in the treatment of depression. In this study we hypothesize that the outcome of IIMT used for depression can be improved by the addition of two elements: listening back at home to improvisations created during therapy (listening homework) and starting the sessions with Resonance Frequency Breathing (RFB).

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Ethical board of the Central Finland health care district, 07/09/2017, ref: 17U/2017

## **Study design**

Interventional randomised controlled trial

## **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 contact details to request a participant information sheet.

## **Health condition(s) or problem(s) studied**

Depression with or without co-morbid anxiety

## **Interventions**

Interventions as of 19/11/2018:

The trial uses a 2x2 factorial design, in which the conditions are derived from either the presence or non-presence of listening back to improvisations (listening homework) and Resonance Frequency Breathing (RFB). All groups receive IIMT. In addition, one treatment group receives listening homework (LH) as an additional component, the second treatment group receives RFB as an additional component, and the third treatment group receives both of these as an additional component.

All the four groups are offered IIMT as usual. Similarly, all the groups are equal in terms of frequency of sessions (bi-weekly), number of therapy sessions (12), length of sessions (60 minutes). The total length of the therapy processes in each groups is about 6 weeks. The follow-up for each of the groups takes place at 6 months from the ending of the therapy.

Group 1: Integrative Improvisational Music Therapy (IIMT); 12 bi-weekly sessions, 60 minutes each; delivered by qualified music therapists;  
Improvisational Integrative Music Therapy (IIMT) is a treatment model developed at our site (Department of Music, Art and Culture studies, University of Jyväskylä, Finland). IIMT consists of a) 5 to 10 minutes of initial discussion, b) improvising (clinical improvisation) in client-therapist dyad with easily approachable instruments (djembe drums and digital keyboards), and c) discussing the experiences triggered by the improvisations. In IIMT, the number and length of the improvisations vary depending on the client's situation and the phase of the therapy process. Occasionally, clients may have difficulties to verbalize their experiences, in which case the interaction may rely more on music (improvising). It may also be the other way around, whereby a client has a strong need to verbalize his/her musical experiences, thus creating less room for music. Thus, though based on a single music therapy technique (clinical improvisation), IIMT offers flexibility as well.

Group 2: IIMT as above plus listening homework (LH) between sessions  
LH combines music making (clinical improvisation) and music listening (listening back to the recorded clinical improvisations). Based on clinical experience and literature both from music psychology and music therapy fields, we assume that when combined in this way, these interventions have mutually complementary effect on therapeutic processing. LH may particularly promote the self-reflective processing of the emotions and personal experiences expressed through the improvisation.

Group 3: IIMT as above plus Resonance Frequency Breathing (RFB), at the beginning of each IIMT session  
RFB consists in slow breathing at someone's resonance frequency, which is the frequency that maximises HRV. This typically happens around six breaths/min. RFB instantly reduces people's stress levels by shifting the autonomic nervous system towards parasympathetic (rest-and-digest) dominance. Since the optimal breathing speed under which resonance is achieved is different from person to person, it needs to be established on an individual basis through a breathing assessment.

Group 4: IIMT as above plus LH and RFB as above.

Depression is measured using the MADRS (Montgomery-Åsberg Depression Rating Scale) at baseline, 6 weeks and 6 months.

Previous interventions:

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**Group 4: IIMT as above plus LH and RFB as above.**

Participants are assessed before the intervention, six weeks after the intervention and attend a 12 month follow up.

## **Intervention Type**

Behavioural

## **Primary outcome measure**

Primary outcome measure as of 19/11/2018:

Depression is measured using the MADRS (Montgomery-Åsberg Depression Rating Scale) at baseline, 6 weeks and 6 months.

Previous primary outcome measure:

Depression is measured using the MADRS (Montgomery-Åsberg Depression Rating Scale) at baseline, six weeks and 12 months

## **Secondary outcome measures**

Secondary outcome measures as of 19/11/2018:

1. Anxiety is measured using Hospital Anxiety and Depression Scale at baseline, 6 weeks and 6 months.
2. Quality of Life is measured using RAND-36 at baseline, 6 weeks and 6 months.
3. Functioning is measured using Global Assessment of Functioning (GAF) at baseline, 6 weeks

and 6 months.

4. Self-perceived depression levels are measured using a clinician questionnaire at each session of the intervention.

Previous secondary outcome measures:

1. Anxiety is measured using Hospital Anxiety and Depression Scale at baseline, six weeks and 12 months.

2. Quality of Life is measured using RAND-36 at baseline, six weeks and 12 months.

3. Functioning is measured using Global Assessment of Functioning (GAF) at baseline, six weeks and 12 months.

4. Self-perceived depression levels are measured using a clinician questionnaire at each session of the intervention.

**Overall study start date**

01/08/2016

**Completion date**

31/08/2020

## Eligibility

**Key inclusion criteria**

Participant inclusion criteria as of 19/11/2018:

1. Participants must have depression as their primary diagnosis, according to the categories F32 or F33 of the ICD-10

2. Age range: 18-55 years

3. Gender: Both

4. If diagnosed alongside the depression, anxiety will also be included, as both pathologies present a high level of co-morbidity

5. Musical skills or any form of musical background are not required; their presence, however, does not constitute a reason for exclusion

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**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

55 Years

**Sex**

Both

**Target number of participants**

68

**Total final enrolment**

70

**Key exclusion criteria**

1. Psychosis
2. Combinations of psychiatric disorders in which depression cannot be defined as the primary disorder
3. Acute and severe substance misuse
5. Severe depression preventing the clients from participating in the measurements or engaging in verbal conversation

**Date of first enrolment**

01/02/2018

**Date of final enrolment**

31/10/2018

**Locations****Countries of recruitment**

Finland

**Study participating centre**

**Music Therapy Clinic for Research and Training, Finnish Centre for Interdisciplinary Music Research, Department of Music, Art and Culture Studies**

PO Box 35 (M), FI-40014

University of Jyväskylä

Jyväskylä

Finland

40014

**Sponsor information****Organisation**

University of Jyväskylä



**Sponsor details**

P.O. Box 35  
Jyväskylä  
Finland  
40014

**Sponsor type**

University/education

**ROR**

<https://ror.org/05n3dz165>

**Funder(s)****Funder type**

Government

**Funder Name**

Academy of Finland

**Alternative Name(s)**

Suomen Akatemia, Finlands Akademi, Academy of Finland, AKA

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Universities (academic only)

**Location**

Finland

**Results and Publications****Publication and dissemination plan**

The main publication will be submitted to an international journal in the field of psychiatry. The publication will include the main results based on our primary and secondary outcome measures.

**Intention to publish date**

31/08/2021

**Individual participant data (IPD) sharing plan**

At this point make the data will not be made available for outsiders based on data repository. This is due to ethical details/restrictions. We will work for getting part of our data accessible but it may mean amendments to our ethical permission, which takes too much time and effort at this stage. So, data repository is not available but may be in future concerning certain parts of data.

## IPD sharing plan summary

Not expected to be made available

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	29/04/2019	01/05/2019	Yes	No
<a href="#">Results article</a>	results	16/02/2021	08/03/2021	Yes	No