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Improvisational music therapy for depression

Submission date
24/01/2018

Recruitment status
No longer recruiting

Registration date
26/01/2018

Overall study status
Completed

Last Edited
08/03/2021

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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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Contact information

Type(s)
Scientific

Contact name
Prof Jaakko Erkkilä

ORCID ID

https://orcid.org/0000-0003-1130-837X

Contact details
Department of Music, Art and Culture Studies
University of Jyväskylä
P.O. Box 35
Jyväskylä
Finland
40014
+358 400 542395
jaakko.erkkila@jyu.fi

Type(s)
Public

Contact name
Mr Markku Pöyhönen

Contact details
Department of Music, Art and Culture Studies
University of Jyväskylä
P.O. Box 35
Jyväskylä
Finland
40014
+358 405 707007
markku.i.poyhonen@jyu.fi

Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))
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.

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. Ager 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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
55 years

Sex
All

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

ROR
https://ror.org/05n3dz165

Funder(s)

Funder type
Government

Funder Name
Academy of Finland

Alternative Name(s)
Academy of Finland, Suomen Akatemia, Finlands Akademi, AKA

Funding Body Type
Government organisation

Funding Body Subtype

Research institutes and centers

Location
Finland

Results and Publications

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?
Results article	results	16/02/2021	08/03/2021	Yes	No
Protocol article	protocol	29/04/2019	01/05/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes