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Integrative music therapy for depression-related disorders

Submission date	Recruitment status	[X] Prospectively registered
10/04/2024	Recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/04/2024	Ongoing	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
19/06/2024	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
This study focuses on depression-related disorders often faced by working-age individuals. The RCT's intervention is targeted at those individuals who are in employment, in their studies, temporarily unemployed, on short-term sick leave or rehabilitation allowance, and who suffer from disorders, or problems that impair their overall ability to function. In the context of this study, depression-related disorders or problems mean depression, anxiety, work-related stress, and burnout. The interventions applied are integrative improvisational music therapy (IIMT), music listening (ML) added to the IIMT, vibroacoustic stimulation (VA) added to the IIMT, and both ML and VA added to the IIMT. All sessions will begin with a preparation exercise called Resonance Frequency Breathing (RFB) to enhance the effect of the therapy. Clinically trained music therapists will conduct the interventions. The study aims to investigate if the interventions reduce psychological distress and improve functioning and quality of life.

Who can participate?
Working-age adults aged between 18-65 years old with one or several of the following disorders: depression, anxiety, workplace stress, or burnout

What does the study involve?
All the participants will get the intervention for 6 weeks (biweekly sessions, 60 minutes each). The participants will be randomised into four groups that will have different modifications of the intervention (the plain IIMT group will be a waiting-list control). The primary outcome will measure psychological distress. Secondary outcomes will look at depression, anxiety, exhaustion, burnout, health-related quality of life and problems feeling emotions (alexithymia).

What are the possible benefits and risks of participating?
It is assumed that 1) the clients who receive IIMT will improve significantly more than the control group; 2) when ML precedes IIMT, it stimulates a client emotionally as well as raises personal themes thus making improvisational working more productive; 3) when VA precedes IIMT, it helps a client to release stress, and helps a client to make observations on both physical and mental domains of experiences; 4) when both ML and VA precedes IIMT, the combination effect is stronger than either of them alone; and, 5) productive improvising can be differentiated from non-productive, and that it is based on rhythmic aspects of music. Temporary weakening of the

client’s condition, issues dealing with RFB included in IIMT and issues dealing with VA are potential risks of participating in the study.

Where is the study run from?
The Music Therapy Clinic for Research and Training, at the Department of Music, Art and Culture Studies, at the University of Jyväskylä, Finland.

When is the study starting and how long is it expected to run for?
The study started in January 2022 and will run until December 2029. The recruitment of the participants will begin in May 2024.

Who is funding the study?
The Research Council of Finland and the University of Jyväskylä.

Who is the main contact?
Dr Esa Ala-Ruona, esa.ala-ruona@jyu.fi

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Research Council of Finland Grant 346210

Study information

Scientific Title
Music therapy for working-age people with depression-related disorders – a randomised controlled trial combined with mixed methods research

Acronym
iMTDep

Study objectives
Objective 1: Through this RCT, the aim is to find out whether Integrative Improvisational Music Therapy (IIMT), offered in four different modifications, improves the participant's condition. The study will also find out whether any of the modifications of the IIMT are superior to plain IIMT.
Objective 2: To understand whether certain musical responsiveness or personality profiles explain a client’s improvement in music therapy.
Objective 3: To increase understanding of the dynamics of therapeutic change by IIMT in its original form and with selected modifications.
Objective 4: To increase understanding of the essence, mechanisms and trajectories of work-related stress and burnout and their relationship to depression and anxiety.
Objective 5: To understand how functional connectivity in the brains of participants with depression changes before and after IIMT.

Hypothesis 1: All the experiment groups improve significantly better than the control group.
Hypothesis 2: Music listening (ML) + IIMT group improves significantly better than the IIMT-only group.
Hypothesis 3: Vibroacoustic treatment (VA) + IIMT group improves significantly better than the IIMT-only group.
Hypothesis 4: ML + VA + IIMT group improves significantly better than ML + IIMT, and VA + IIMT groups.
Hypothesis 5: Increased interaction between client and therapist in musical behaviour correlates positively with the improvement shown by the psychiatric outcome measures.
Hypothesis 6: Functional connectivity of participants with depression will change after the treatment and the change will be correlated with the improvement in the outcome measures.

Ethics approval required
Ethics approval required

Ethics approval(s)

approved 15/02/2024, Regional Medical Research Ethics Committee of Wellbeing Services County of Central Finland (Hospital Nova, Hoitajantie 3, Jyväskylä, 40620, Finland; +358142691811; eettinentoimikunta@hyvaks.fi), ref: 7U/2023

Study design
Interventional randomized 2 x 2 factorial trial with a waiting list control

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Depression related disorders, e.g. depression, anxiety, work related stress and burnout.

Interventions
The study is a randomised 2 × 2 factorial trial using four conditions: integrative improvisational music therapy (IIMT), IIMT enhanced with music listening (ML), IIMT enhanced with vibroacoustic treatment (VA), and IIMT enhanced with both ML and VA. All sessions regardless of the condition will begin with a preparation exercise called Resonance Frequency Breathing (RFB).

A therapy process consisting of 12 sessions, 60 minutes each, is offered to each of the groups. In addition, there will be a waiting-list control group to whom traditional IIMT will be offered after two months (equal to the approximate duration of the intervention) of the baseline measurements. There are overall four to five measurement points in this study: during the recruitment of the participants (baseline), 6 weeks after the beginning of the intervention (post-intervention), 6 months after the beginning of the intervention (first follow-up) and 12 months after the beginning of the intervention (second follow-up). The control group will have an additional measurement point 6 weeks after the baseline tests which also acts as a new baseline for the intervention.

The measures conducted during the recruitment of the participants will also be the ones that determine participants' eligibility for the study. In addition to the outcome measures demographics such as gender, age, and socio-economic background will be inquired at the beginning of the intervention. The health care professional, responsible for testing, will collect the health background information and possible changes in treatment and care during the testing appointments.

Intervention Type
Behavioural

Primary outcome(s)
Psychological distress measured using the Clinical Outcomes in Routine Evaluation - Outcome (CORE-OM) at baseline, 6 weeks, 6 months, and 12 months

Key secondary outcome(s))
The following secondary outcome measures are assessed at all time points at baseline, 6 weeks, 6 months, and 12 months:
1. Depression measured using the Montgomery Åsberg Depression Rating Scale (MADRS)

2. Anxiety measured using the Hospital Anxiety Depression Scale (HADS)
3. Exhaustion measured using the Karolinska Exhaustion Disorder Scale (KEDS)
4. Burnout measured using the Burnout Assessment Tool (BAT)
5. Health-related quality of life measured using the RAND 36-Item Health Survey
6. Alexithymia measured using the Toronto Alexithymia Scale (TAS-20)

Completion date
31/12/2029

Eligibility

Key inclusion criteria
Working-age adults (18-65 years of age) suffering from one or several of the following disorders:
1. Depression (ICD-10: F32 or F33), as screened by MADRS
2. Anxiety (ICD-10: F41), as screened by HADS-A
3. Work-place stress, or burnout, as screened by KEDS

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Key exclusion criteria
1. Psychosis
2. Personality disorder
3. Acute substance abuse
4. Difficulty in engaging in the study
5. Depression that is too severe for participation in therapy

Date of first enrolment
05/06/2024

Date of final enrolment
31/12/2028

Locations

Countries of recruitment
Finland

Study participating centre
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Sponsor information

Organisation
University of Jyväskylä

ROR
https://ror.org/05n3dz165

Funder(s)

Funder type
Government

Funder Name
Research Council 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

The datasets generated during and analysed during the current study are not expected to be made available for ethical restrictions.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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