

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparing the Effectiveness of Music Therapy with Cognitive Behavioral Therapy on Quality of Life Craving and Emotion Regulation in MMT Patients

Protocol summary

Study aim

Comparing the Effectiveness of Music Therapy with Cognitive Behavioral Therapy on Quality of Life, Craving and Emotion Regulation in MMT Patients

Design

A randomized controlled clinical trial with parallel groups

Settings and conduct

First, in coordination with the Tehran health care system, they are asked to refer to methadone maintenance practitioners who have at least one year of methadone maintenance treatment. Then the researcher interviews and The survey of entry and exit criteria will select 60 of them using available sampling method and will be randomly divided into three groups. Then the researcher will randomly select two groups as the experimental group and one group as the control group. Then one of the experimental groups will be trained in 8 sessions of music therapy and the other group will receive 8 sessions of cognitive behavioral therapy.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Addicts on methadone maintenance therapy, Male gender, No physical problems, No history of exposure to psychological training, Ages 18 to 40 years, No drug use; Exclusion criteria: Non-cooperation of the sample group or family at each stage of the research, Having physical and physical problems, History of psychiatric problems, Professional team athletes, Over 40 years old, Drug use

Intervention groups

For the first group of music therapy For the second group cognitive behavioral therapy In the third group, no intervention will be performed.

Main outcome variables

Quality of Life; Craving; Emotion Regulation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191030045280N1**

Registration date: **2020-01-22, 1398/11/02**

Registration timing: **registered_while_recruiting**

Last update: **2020-01-22, 1398/11/02**

Update count: **0**

Registration date

2020-01-22, 1398/11/02

Registrant information

Name

seyed reza eshaghi farahmand

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8822 1908

Email address

rezafarahmand@hotmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-13, 1398/09/22

Expected recruitment end date

2020-03-05, 1398/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Effectiveness of Music Therapy with Cognitive Behavioral Therapy on Quality of Life Craving and Emotion Regulation in MMT Patients

Public title

Comparing the Effectiveness of Music Therapy with Cognitive Behavioral Therapy on Quality of Life Craving and Emotion Regulation in MMT Patients

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Addicts on methadone maintenance therapy male gender No physical problems No history of exposure to psychological training Ages 18 to 40 years No drug use

Exclusion criteria:

Non-cooperation of sample group or family at each stage of research Having physical and physical problems A history of psychiatric problems Professional team athletes

Age

From **18 years** old to **40 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The block randomization method is performed by the statistical consultant as follows: randomization is performed in three groups: music therapy, cognitive behavioral therapy, and control: First, a list of eligible individuals is provided and coded. In block randomization, the number of participants in all groups will be very close together by making blocks of sequences so that the same number of participants are assigned to study groups within each group. We first code the groups in Latin letters as follows: A = music therapy, B = cognitive behavioral therapy, and C control group In this study with three groups A, B and C we create the following six groups and assign 1 to 6 each: ABC-ACB-BAC-BCA-CAB-CBA Then, using the random number table, we choose one of these blocks whenever the numbers 1, 2, 3, 4, 5, 6 appear, and if the other number appears, consider null and go to the next choice. . In fact, we have obtained a random sequence of numbers with a random number table that we consider the order of assignment for each number. This way the number of people in the groups will be approximately equal.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

IR.HUMS.REC.1398.303

Street address

North Karegar Street 17 Veteran Street 24 P 64

City

TEHRAN

Province

Tehran

Postal code

1437697419

Approval date

2019-11-30, 1398/09/09

Ethics committee reference number

IR.HUMS.REC.1398.303

Health conditions studied**1****Description of health condition studied**

Addiction

ICD-10 code

Z63.72

ICD-10 code description

Alcoholism and drug addiction in family

Primary outcomes**1****Description**

Quality of Life

Timepoint

Measurement will be done in pre-test, post-test and follow-up three months after post-test

Method of measurement

Quality of Life Scale Ware & Sherborne (1992)

2**Description**

Cognitive Emotion Regulation

Timepoint

Measurement will be done in pre-test, post-test and follow-up three months after post-test

Method of measurement

Cognitive Emotion Regulation Questionnaire Garnefski et al. (1992)

3

Description

Craving

Timepoint

Measurement will be done in pre-test, post-test and follow-up three months after post-test

Method of measurement

DDQ questionnaire Franken et al (2002)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group One: Music Therapy - For the first experimental group, 8 sessions of 90-minute music therapy will be taught in groups (Zadeh Mohammadi, 2010).

Category

Treatment - Other

2

Description

Second Group Intervention: Cognitive Behavioral Therapy - For the second group Cognitive Behavioral Therapy (Kathleen, 2002, translated by Poor Roodsari, 2002) will be administered in 8 sessions and each session for 90 minutes.

Category

Treatment - Other

3

Description

Control group: No Intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Addiction Clinic

Full name of responsible person

Hasan Ahadi

Street address

South Kurdistan Highway - 17th Street - Janbazan Street - 24p 61st 4th West

City

Tehran

Province

Tehran

Postal code

2246578941

Phone

+98 21 8822 1908

Email

rezafarahmand@hotmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Alireza Roosta

Street address

Islamic Azad University of Kish International Branch, Free Zone Organization Square, Sana'i Boulevard, Kish Island.

City

Kish

Province

Hormozgan

Postal code

7941775883

Phone

+98 76 4442 2720

Email

Info@laukishint.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

20

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Hasan Ahadi

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

South Kurdistan Highway - 17th Street - Janbazan Street - 24p 61st 4th West

City
Tehran
Province
Tehran
Postal code
2248795031
Phone
+98 21 8822 1908
Email
drhahadi5@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
Hasan Ahadi
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
South Kurdistan Highway - 17th Street - Janbazan Street - 24p 61st 4th West
City
Tehran
Province
Tehran
Postal code
2248795031
Phone
+98 21 8822 1908
Email
drhahadi5@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
Hasan Ahadi
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Psychology

Street address
South Kurdistan Highway - 17th Street - Janbazan Street - 24p 61st 4th West
City
Tehran
Province
Tehran
Postal code
2248795031
Phone
+98 21 8822 1908
Email
drhahadi5@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Only part of the data, such as information about the main outcome or the like, can be shared.

When the data will become available and for how long

Start of access period 6 months after printing results

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

Any type of analysis on the data delivered is permitted

From where data/document is obtainable

Seyed Reza Ishaqi Farahmand Postal address: Tehran - South Kurdistan - 17th Street - Janbazan Street - 24p 61st 4th West Email: rezafarahmand@hotmail.com Cell: 02188221908

What processes are involved for a request to access data/document

The request will be sent by email to:
drhahadi5@gmail.com

Comments