

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### The effect of music therapy on the severity of positive and negative symptoms and function of patients with chronic schizophrenia

#### Protocol summary

##### Study aim

The effect of music therapy on the severity of positive and negative symptoms and function of patients with chronic schizophrenia

##### Design

Clinical Trial, No control group, single- blind study , consisted of 43 patients who underwent the intervention for 6 months

##### Settings and conduct

In the present study, 43 patients with schizophrenia will be selected from the patients of Parham Kashan Psychiatric Care Center. They will undergo music therapy sessions. Patients and Clinical caregiver are unaware of method of intervention and one of the colleagues plays the music and does the pre-test and post-test. They do not have a control group and all are subject to intervention. In addition, patients receive their medication during this period as usual.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Chronic schizophrenia patients with no previous music therapy experience, Patients with a history of 1 to 2 years of residence in the center, Patients who have not received any new treatment in the past 6 months Exclusion criteria: Patients with hearing impairment, Patients with vision impairment, Patients with movement disturbance, Patients with mental retardation

##### Intervention groups

The intervention group includes 43 patients with schizophrenia. There is no control group and all patients are in the intervention group. The intervention group undergoes music therapy sessions, the type of music is pop, which is played 3 times a week and 45 minutes in each session for six months.

##### Main outcome variables

Score of Global Assessment of Functioning(GAF), Score of Brief Psychiatric Rating Scale (BPRS) , Score of Positive and Negative Symptom Scale(PANSS)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200218046532N1**

Registration date: **2022-08-11, 1401/05/20**

Registration timing: **retrospective**

Last update: **2022-08-11, 1401/05/20**

Update count: **0**

##### Registration date

2022-08-11, 1401/05/20

##### Registrant information

##### Name

Mohamad Latifi Meybodi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 5554 9111

##### Email address

latifi-m@kaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-04-18, 1399/01/30

##### Expected recruitment end date

2020-10-21, 1399/07/30

##### Actual recruitment start date

2020-04-18, 1399/01/30

##### Actual recruitment end date

2020-10-21, 1399/07/30

##### Trial completion date

2020-10-21, 1399/07/30

##### Scientific title

The effect of music therapy on the severity of positive and negative symptoms and function of patients with chronic schizophrenia

**Public title**

Effect of music on patients with schizophrenia

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Chronic schizophrenia patients with no previous music therapy experience Patients with a history of 1 to 2 years of residence in the center Patients who have not received any new treatment in the past 6 months

**Exclusion criteria:**

Patients with hearing impairment Patients with vision impairment Patients with movement disturbance Patients with mental retardation

**Age**

No age limit

**Gender**

Male

**Phase**

N/A

**Groups that have been masked**

- Participant
- Care provider

**Sample size**

Target sample size: **43**

Actual sample size reached: **40**

**Randomization (investigator's opinion)**

N/A

**Randomization description****Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Participants in this study know they are participating in a study But they do not know which symptoms are to be examined or which symptoms are the purpose of music therapy. Also, the clinical caregivers working in this center are unaware of the manner and type of intervention. One of the project partners plays music for the patients in each session and examines the severity of their symptoms before and after the intervention.

**Placebo**

Not used

**Assignment**

Single

**Other design features****Secondary Ids**

empty

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

Ethics committee of Kashan University of Medical

Sciences

**Street address**

Kashan University of Medical Sciences, Ghotb e Ravandi Blvd, Kashan Town

**City**

Kashan

**Province**

Isfahan

**Postal code**

8715988141

**Approval date**

2020-04-15, 1399/01/27

**Ethics committee reference number**

IR.KAUMS.MEDNT.REC.1399.001

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

Schizophrenia

**ICD-10 code**

F20

**ICD-10 code description**

Schizophrenia

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

Score of Global assessment of functioning ( GAF)

**Timepoint**

The variables are measured at the beginning of the intervention and 6 months after beginning of music therapy.

**Method of measurement**

Global assessment of functioning ( GAF)

**2****Description**

Score of Brief Psychiatric Rating Scale (BPRS)

**Timepoint**

The variables are measured at the beginning of the intervention and 6 months after beginning of music therapy.

**Method of measurement**

Brief Psychiatric Rating Scale (BPRS)

**3****Description**

Score of Positive and Negative Symptom Scale (PANSS)

**Timepoint**

The variables are measured at the beginning of the intervention and 6 months after beginning of music therapy.

**Method of measurement**

Positive and Negative Symptom Scale (PANSS)

## Secondary outcomes

empty

## Intervention groups

1

### Description

The intervention group includes 43 patients with schizophrenia There is no control group and all patients are in the intervention group.The intervention group undergoes music therapy sessions, the type of music is pop, which is played 3 times a week and 45 minutes in each session for six months.

### Category

Rehabilitation

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Parham Psychiatric Patient Care Center

#### Full name of responsible person

Dr Afshin Ahmadvand

#### Street address

2 km Noshadabad Ave ,Shohada Square, Vali Asr Square, Kashan.

#### City

Kashan

#### Province

Isfahan

#### Postal code

8715949152

#### Phone

+98 31 5558 5020

#### Email

parham\_kashan@yahoo.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Kashan University of Medical Sciences

#### Full name of responsible person

Hamidreza Banafshe

#### Street address

Kashan University of Medical Sciences,Ghotb ravandi Boulevard.

#### City

Kashan

#### Province

Isfahan

#### Postal code

8715981151

#### Phone

+98 31 5544 3020

#### Email

info@kaums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Kashan University of Medical Sciences

#### Proportion provided by this source

100

#### 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

Kashan University of Medical Sciences

#### Full name of responsible person

Mohamad Latifi Meybodi

#### Position

resident

#### Latest degree

Medical doctor

#### Other areas of specialty/work

Psychiatrics

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Beheshi Hospital,Ghotb ravandi Boulevard

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latifi.meybodi@gmail.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Kashan University of Medical Sciences

#### Full name of responsible person

Mohamad Latifi Meybodi

#### Position

resident

#### Latest degree

Medical doctor

#### Other areas of specialty/work

Psychiatrics

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Kashan University of Medical Sciences  
**Full name of responsible person**  
Mohamad Latifi Meybodi  
**Position**  
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**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
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**Postal code**  
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**Email**  
latifi.meybodi@gmail.com

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

No more information

### 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

No - There is not a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Not applicable

### Data Dictionary

Not applicable

### Title and more details about the data/document

Information about the main outcome can be shared.

### When the data will become available and for how long

6 months after the publication of the results

### To whom data/document is available

Everyone has access to data and documentation

### Under which criteria data/document could be used

Use of data is permitted for comparative and systematic studies

### From where data/document is obtainable

To receive information, send your request to Kashan University of Medical Sciences at kaums.ac.ir

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

To receive information, first submit a request to Kashan University of Medical Sciences. After confirmation, the applicant can receive the documents via email to latifi.meybodi@gmail.com from Dr. Mohammad Latifi Meybodi

### Comments