

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

The Influence of Sport, Cognitive and Music rehabilitation on Depression, Balance, Quality of Life, attention and working memory in male schizophrenic

Protocol summary

Study aim

Determining the effect of cognitive, sports and music interventions on improving depression and balance in male schizophrenic patients

Design

The current research was a semi-experimental type with a pre-test and post-test design, which was implemented with seven groups

Settings and conduct

The current research was a semi-experimental type with a pre-test and post-test design, which was implemented with seven groups. The statistical population of the research was male schizophrenic patients referred to the Urmia Psychiatric Center, and the statistics of these patients in the period of 2 months was 263. 60 schizophrenic patients with an average age of 39.12 ± 8.90 were selected as samples from the target statistical population and randomly divided into 7 groups of 12 including 1) aerobic exercise group 2) cognitive rehabilitation group 3) Music group 4) Aerobic training + cognitive rehabilitation group 5) Aerobic training + music group 6) Cognitive rehabilitation + music group 7) Aerobic training + cognitive rehabilitation + music group were divided.

Participants/Inclusion and exclusion criteria

The ability to understand and speak. presence of dementia(MMSE score >25 Get a score of 11 or above on the Beck Depression Inventory,

Intervention groups

1) Aerobic exercise group 2) Cognitive rehabilitation group 3) Music group 4) Aerobic exercise group + cognitive rehabilitation 5) Aerobic exercise group + music 6) Cognitive rehabilitation + music group 7) Aerobic exercise group + cognitive rehabilitation + music

Main outcome variables

depression balance Quality of Life attention, working

memory

General information

Reason for update

A primary outcome variable has been added

Acronym

IRCT registration information

IRCT registration number: **IRCT20190908044722N2**

Registration date: **2024-01-15, 1402/10/25**

Registration timing: **retrospective**

Last update: **2024-11-16, 1403/08/26**

Update count: **2**

Registration date

2024-01-15, 1402/10/25

Registrant information

Name

Razieh Khanmohamadi

Name of organization / entity

The university of Urmia

Country

Iran (Islamic Republic of)

Phone

+98 86 3221 4311

Email address

r.khanmohamadi@ut.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-01, 1402/06/10

Expected recruitment end date

2023-12-31, 1402/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Influence of Sport, Cognitive and Music rehabilitation on Depression, Balance, Quality of Life, attention and working memory in male schizophrenic

Public title

The Influence of Sport, Cognitive and Music rehabilitation on Depression and Balance in male schizophrenic

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

The ability to understand and speak Get a score of 11 or above on the Beck Depression Inventory

Exclusion criteria:

presence of dementia(MMSE score \leq 25

Age

No age limit

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

Simple random sampling

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**

Ethics committee of Sport Sciences Research Institute

Street address

No. 3, Fifth Alley, Miramad Street, Tehran

City

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Province

Tehran

Postal code

1587958711

Approval date

2023-09-20, 1402/06/29

Ethics committee reference number

IR.SSRC.REC.1402.136

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

schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

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

Depression score using Beck depression questionnaire

Timepoint

Before and after the intervention

Method of measurement

Beck questionnaire

2**Description**

Dynamic balance

Timepoint

Before and after the intervention

Method of measurement

timed up and Go Test (TUG)

3**Description**

Schizophrenia Quality of Life Scale Revision 4

Timepoint

Before and after the intervention

Method of measurement

This scale , created it to measure HRQOL in individuals diagnosed with schizophrenia. Incorporated in two domains, psychosocial feelings (22 items) and cognition and vitality (11 items)

4**Description**

Continuous Performance Test (CPT)

Timepoint

Before and after the intervention

Method of measurement

The CPT, is a psychological test used to assess a person's sustained attention, attention deficits and vigilance. It typically involves a computer-based task where the participant is required to respond to specific stimuli while ignoring distractors or non-target stimuli

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Description

N-back test

Timepoint

Before and after the intervention

Method of measurement

During the n-back test, a visual stimulus is presented on the screen in the form of a randomly appearing sequence of numbers. It is necessary for the subject to verify if the stimulus currently being presented corresponds to the stimulus from the previous phase or not

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: aerobic exercise group

Category

Rehabilitation

2

Description

Intervention group 2: Cognitive rehabilitation group

Category

Rehabilitation

3

Description

Intervention group3: music group

Category

Rehabilitation

4

Description

Intervention group4: Aerobic exercise + cognitive rehabilitation group

Category

Rehabilitation

5

Description

Intervention group 5: Aerobic training + music group

Category

Rehabilitation

6

Description

Intervention group: Cognitive rehabilitation + music group

Category

Rehabilitation

7

Description

Intervention group: Aerobic exercise + cognitive rehabilitation + music group

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Urmia mental hospital

Full name of responsible person

Fatima Shamsali

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Selmas Road

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

the University of Urmia

Full name of responsible person

Razieh KHanmohammadi

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Urmia University, Kilometer 11 of Cypress Road - West Azarbaijan Province -Urmia

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

the University of Urmia

Proportion provided by this source

10

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

The university of Urmia

Full name of responsible person

Razieh Khanmohammadi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Motor behavior

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Person responsible for scientific inquiries

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Other areas of specialty/work

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Person responsible for updating data

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The analysis of information obtained from the results of the interventions on balance and depression can be published

When the data will become available and for how long

From the time the article was published until a year later

To whom data/document is available

All researchers

Under which criteria data/document could be used

Provided Someone wants to do a similar research project

From where data/document is obtainable

r.khanmohamadi65@yahoo.com

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

Send request by email

Comments

