Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effectiveness of volleyball exercises on executive function and daily living skills in people with schizophrenia.

Protocol summary

Study aim
The aim of this study was to investigate the effectiveness of volleyball on executive performance and daily living skills of patients with schizophrenia.

Design
Clinical trial with control group, with parallel, randomized groups, on 28 patients, simple randomization as coded envelopes has been used.

Settings and conduct
Daily Center for Neuropsychiatric Patients in Nowshahr. The control group received conventional occupational therapy, including targeted, creative, and recreational activiti. The intervention group played volleyball in addition to these interventions. Volleyball was held 60 minutes. Assessment tools used for both control and intervention groups three times ; pre and post intervention and follow up.

Participants/Inclusion and exclusion criteria
The inclusion criteria : diagnosed with schizophrenia based on Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) criteria. permission from psychiatric specialist to participate. An intelligence score above 70 based on the adult version of the Wechsler scale. The exclusion criteria: Patients who had drug interactions three months before the intervention.

Intervention groups
The control group received routine occupational therapy interventions. The intervention group played volleyball in addition to these interventions.

Main outcome variables
executive function ; daily living skills

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191102045312N1**
Registration date: **2020-05-26, 1399/03/06**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-26, 1399/03/06**
Update count: **0**

Registration date
2020-05-26, 1399/03/06

Registrant information

Name
Maryam Khazaeipoul

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 11 5232 4810

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-12-22, 1398/10/01

Expected recruitment end date
2020-05-19, 1399/02/30

Actual recruitment start date
2019-12-26, 1398/10/05

Actual recruitment end date
2020-06-19, 1399/03/30

Trial completion date
2020-06-19, 1399/03/30

Scientific title
The effectiveness of volleyball exercises on executive function and daily living skills in people with schizophrenia.

Public title
Investigating the effect of volleyball on schizophrenia

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

diagnosed with schizophrenia based on Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) criteria. permission from psychiatric specialist to participate. An intelligence score above 70 based on the adult version of the Wechsler scale

Exclusion criteria:

Patients who had drug interactions three months before the intervention.

Age

From **20 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **28**

Actual sample size reached: **28**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly divided into control and intervention groups.

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

Iran National Committee For Ethics in Biomedical Research

Street address

Rehabilitation faculty of Tehran University of Medical Sciences, Picheshemiran, Enghelab Ave, Tehran

City

Tehran

Province

Tehran

Postal code

1148965111

Approval date

2019-12-25, 1398/10/04

Ethics committee reference number

IR.TUMS.FNM.REC.1398.157

Health conditions studied

1

Description of health condition studied

Schizophrenia

ICD-10 code

F20-F29

ICD-10 code description

Schizophrenia, schizotypal and delusional disorders(F20-F29)

Primary outcomes

1

Description

Executive Function

Timepoint

Pre and post intervention and follow up(One month after the intervention)

Method of measurement

Loewenstein Occupational Therapy Cognitive Assessment

2

Description

Daily Living Skills

Timepoint

Pre and post intervention and follow up(One month after the intervention)

Method of measurement

The Functional Independence Measure

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: conventional occupational therapy, including targeted, creative, and recreational activities and played volleyball in addition to these interventions. Volleyball was held 60 minutes, in three days a week, for 2 months.

Category

Rehabilitation

2

Description

Control group: The control group received conventional occupational therapy, including targeted, creative, and recreational activities.participants were blind to therapies they received.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Comprehensive Rehabilitation Center for Chronic Psychiatric Patients Dr. Gharib (Daily)

Full name of responsible person
Maryam Khazaei Poul

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
AmirAli Sohrabpour

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Vice chancellor for education,7th floor,Tehran University of Medical Sciences, Ghods St., Keshavarz Blvd

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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
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Maryam Khazaei Poul

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Occupational Therapy

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Person responsible for scientific inquiries

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Latest degree

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Other areas of specialty/work

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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

Due to the principles of fiduciary duty.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

After identifying individuals, the scores of executive function and daily living activities and information related to the main outcome of the study are shared.

When the data will become available and for how long

Start access after printing the results.

To whom data/document is available

Researchers working in academic and scientific institutions,Occupational therapists, infected patients and caregivers.

Under which criteria data/document could be used

The output of this project will be in the form of an article that will be made available to the public after its publication.All stakeholders, including researchers, occupational therapists, and psychologists, are allowed to request unidentified personal data. There is no restriction on the use of documents and statistical analysis of unidentifiable personal data. Conditions for submitting an application: Specify the field of work Mention the reasons for the request

From where data/document is obtainable

Maryamkhazaeipoul@yahoo.com Maryam Khazaei Poul

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

There is no specific process that will be made available to the public for free after the article is published.After reviewing the request to receive unidentifiable data, the information will be received by the applicant within one week.

Comments