

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

The investigation of Occupational engagement of people with mental illness participating in center based on Club House model

Protocol summary

Study aim

The investigation of Occupational engagement of people with mental illness participating in center based on Club House model

Design

The clinical trial has a control group with randomized double-blind parallel groups. The sample size includes 32 people in two control and intervention groups, and the random number table method is used for randomization

Settings and conduct

Interventions will be held in the psychosocial occupational therapy clinic of the Rehabilitation Faculty of Iran University of Medical Sciences and the day care center of Iran Psychiatric Hospital. The intervention period will be held for 2 months, two 3-hour sessions per week. Clubhouse program activities are done in groups and include cooking, artistic activities such as painting and drawing, etc., health services such as sports, administrative activities, accounting and maintenance of the center and working with computers. and the research team is also in contact with their family members and counseling is done if needed. Evaluations are done using COPM and POES tools by an occupational therapy expert. who is not aware of the grouping of people. The participants are also unaware of the main intervention.

Participants/Inclusion and exclusion criteria

Eligible: Up to 18 years old, Have a psychiatric diagnosis, Having informed consent, In a certain range of psychosocial function (Global Assessment Function)
Ineligible: People who have dementia and substance abuse as their primary diagnosis

Intervention groups

In the intervention group, all interventions based on the Clubhouse model are performed In the control group, all the interventions that are common in daily occupational therapy centers

Main outcome variables

Rhythm of activity and rest: Occupational performance environment and diversity, Social environment; Social

interaction; Interpretation; Level of meaningful activities.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230820059199N1**

Registration date: **2023-08-26, 1402/06/04**

Registration timing: **prospective**

Last update: **2023-08-26, 1402/06/04**

Update count: **0**

Registration date

2023-08-26, 1402/06/04

Registrant information

Name

elahe hojati Abed

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 7124

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-01, 1402/06/10

Expected recruitment end date

2023-10-02, 1402/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	The investigation of Occupational engagement of people with mental illness participating in center based on Club House model
Public title	Interventions based on the Clubhouse model in mental patients
Purpose	Supportive
Inclusion/Exclusion criteria	
Inclusion criteria:	Have a psychiatric diagnosis and enter the plan with written consent. People who are in a certain range of psychosocial function (Global Assessment Function) with the general function assessment scale should be included in the groups. People who cannot enter the plan, people who have dementia and substance abuse as their primary diagnosis, or who do not agree to participate in the plan.
Exclusion criteria:	
Age	From 18 years old to 65 years old
Gender	Both
Phase	N/A
Groups that have been masked	• Participant • Outcome assessor
Sample size	Target sample size: 32
Randomization (investigator's opinion)	Randomized
Randomization description	The participants are divided into two groups by a simple randomization method. The randomization tool is a table of random numbers. The participants are divided into two control and intervention groups with a 1:1 allocation. Concealment is done using sealed and waxed opaque envelopes.
Blinding (investigator's opinion)	Double blinded
Blinding description	Participants invited to the intervention and use of supportive interventions are blinded to study groups. Because both groups receive supportive interventions. Two occupational therapy experts who evaluated the data and outcome were blinded to the intervention groups.
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran university medical of sciences

Street address

occupational therapy department, Faculty of Rehabilitation Sciences, Iran University of Medical Sciences, Shah Nazari St., Maddkaran St., Mader Square, Mirdamad, Tehran

City

Tehran

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1545913487

Approval date

2023-01-22, 1401/11/02

Ethics committee reference number

IR.IUMS.REC.1401.844

Health conditions studied

1

Description of health condition studied

People with Chronic Mental Disease, Illness, Disorder, Disability

ICD-10 code

F20-F99

ICD-10 code description

Mental and behavioural disorders: Schizophrenia, schizotypal and delusional disorders, Mood [affective] disorders, Neurotic, stress-related and somatoform disorders, Behavioural syndromes associated with physiological disturbances and physical factors, Di

Primary outcomes

1

Description

Level of engagement in occupation in Profile of Occupational Engagement in people with Severe mental illness

Timepoint

Before the start of the intervention, After the start of the intervention and 2 months after the intervention

Method of measurement

Profile of Occupational Engagement in people with Severe Mental Illness

Secondary outcomes

1

Description

Level of performance in Canadian Occupational

Performance Measure

Timepoint

Before the start of the intervention, After the start of the intervention and 2 months after the intervention

Method of measurement

Canadian Occupational Performance Measure

2

Description

Level of satisfaction in Canadian Occupational Performance Measure

Timepoint

Before the start of the intervention, After the start of the intervention and 2 months after the intervention

Method of measurement

Canadian Occupational Performance Measure

Intervention groups

1

Description

Intervention group: The intervention period will be held for 2 months, two sessions a week for 3 hours. The intervention program for the implementation of the Clubhouse model is such that it creates a modified environment for people with mental problems to strengthen their confidence and ability to fully participate in society by joining it. Clubhouse program activities are done in groups and include cooking, artistic activities such as painting and drawing, etc., health services such as sports, administrative activities, accounting and maintenance of the center and working with computers. In addition to group activities, the participants are provided with individual support to make the activities meaningful, and the research team is also in contact with their family members and counseling is done if needed.

Category

Rehabilitation

2

Description

Control group: The sessions are held in the form of art education (painting, fabric design, ornamental bracelets and music...) and occupational therapy for two days a week during 2 months in 3-hour sessions.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

occupational therapy in mental health of IUMS School of Rehabilitation Science

Full name of responsible person

Elahe Hojati Abed

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Reza Falak

Street address

Iran University of Medical Sciences, 5th floor of the central headquarters, Hemat Highway, next to Milad Tower, Tehran

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falak.r@iums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Elahe Hojati Abed

Position

Assistant Professor of occupational therapy

Latest degree

Ph.D.

Other areas of specialty/work

Occupational Therapy

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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)**

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

Yes - There is a plan to make this available

Title and more details about the data/document

Part of the data, such as information related to the main outcome, which is the level of employment in the occupational employment profile of chronic mental patients

When the data will become available and for how long

6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Any use of the data is permitted provided that the principal investigator of the study is informed.

From where data/document is obtainable

Elahe Hojati Abed- Department of Occupational Therapy, School of Rehabilitation Sciences, Iran Medical Sciences- Email address

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

6 months after the results are published, the applicant can receive a part of the data to the address specified by

the main researcher by sending her/his request to the email address mentioned.

Comments