

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The Effect of Community Re-entry Program on Quality of Life and Social functioning in People with Schizophrenia

Protocol summary

Study aim

the effectiveness of a community Re-entry program on quality of life and social functioning in people with schizophrenia.

Design

The present study is a quasi-experimental study with pre-test and post-test design which was performed on all schizophrenia patients admitted to rehabilitation centers in Tehran. For this purpose, 40 patients with schizophrenia admitted to Tolue Rehabilitation Center were selected by convenience sampling and were randomly assigned to experimental (n = 20) and control (n = 20) groups. At the beginning of the study, the two groups were matched for age and education variables.

Settings and conduct

The research group was trained by the researcher for two months, two sessions per week for 45 minutes in each session and a total of 16 sessions in the Tolue Rehabilitation Center. The control group continued their usual treatment

Participants/Inclusion and exclusion criteria

Inclusion criteria included psychiatrist's confirmation of diagnosis of schizophrenia with DSM 5 diagnostic criteria, at least two years after onset of illness, history of recurrence of symptoms, psychotic attacks and hospitalization, willingness to participate in research, ability to learn, and appropriate responses to explanations. It will be given.

Intervention groups

Experimental group received two sessions per week for a total of 16 sessions per week for 2 months

Main outcome variables

quality of life, social functioning

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190924044864N1**

Registration date: **2019-10-23, 1398/08/01**

Registration timing: **retrospective**

Last update: **2019-10-23, 1398/08/01**

Update count: **0**

Registration date

2019-10-23, 1398/08/01

Registrant information

Name

Zohreh Parsamoein

Name of organization / entity

The university of science and research of Tehran

Country

Iran (Islamic Republic of)

Phone

+98 21 4473 7015

Email address

zohrep@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-31, 1397/08/09

Expected recruitment end date

2018-11-05, 1397/08/14

Actual recruitment start date

2018-11-10, 1397/08/19

Actual recruitment end date

2019-01-09, 1397/10/19

Trial completion date

2019-01-09, 1397/10/19

Scientific title

The Effect of Community Re-entry Program on Quality of Life and Social functioning in People with Schizophrenia

Public title

The Effect of Community Re-entry Program on Quality of Life and Social functioning in People with Schizophrenia	
Purpose	Prevention
Inclusion/Exclusion criteria	
Inclusion criteria:	The psychiatrist confirmed the diagnosis of schizophrenia with DSM 5 diagnostic criteria at least two years after the onset of the disease a history of recurrence of symptoms, psychotic attacks and hospitalization ability to learn, and appropriate responses to the explanations. willingness to participate in research Participants must be men
Exclusion criteria:	Any psychiatric disorder other than schizophrenia The acute phase of the disease The presence of deafness and blindness and sensory disorders that cannot be remedied by the means. Get electric shock in the last 6 months Unwillingness to continue the evaluation Being a woman
Age	No age limit
Gender	Male
Phase	N/A
Groups that have been masked	No information
Sample size	Target sample size: 40 Actual sample size reached: 40
Randomization (investigator's opinion)	Randomized
Randomization description	Forty patients admitted to Tolue Rehabilitation Center who met the inclusion criteria were selected by convenience sampling and were randomly(balloting) assigned to experimental (n = 20) and control (n = 20) groups.
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not used
Assignment	Other
Other design features	This study investigates the effectiveness of rehabilitation programs on the prevention of psychiatric relapse in patients with schizophrenia and the management of treatment by patients themselves.
Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	Ethics Committee of Tehran Azad University of Science and Research
Street address	Shohada Hesarak Boulevard, University Square, Shahid Sattari Highw,Science and Research Branch, Islamic Azad University ,Tehran
City	Tehran
Province	Tehran
Postal code	1498753634
Approval date	2018-10-30, 1397/08/08
Ethics committee reference number	IR.IAU.SRB.REC.1397.073 دانشگاه آزاد واحد علوم و تحقیقات تهران
Health conditions studied	
<u>1</u>	
Description of health condition studied	schizophrenia
ICD-10 code	F20
ICD-10 code description	Schizophrenia
Primary outcomes	
<u>1</u>	
Description	Score of quality of life
Timepoint	after intervention
Method of measurement	SF36 questionnaire
<u>2</u>	
Description	Score of social functioning
Timepoint	after intervention
Method of measurement	Assessment of communication and intraction Skill
Secondary outcomes	empty
Intervention groups	
<u>1</u>	
Description	Intervention group: trained for 2 months, two sessions per week for a total of 16 sessions, as follows.1- Introducing a community-based return program - 2 symptoms of disabling mental disorders - 3 discharge readiness - 4 return planning Community - 5 Community

Relationships - 6 Community Stress Relief - 7 Planning a Daily Schedule - 8 Scheduling and Performing - 9 How Medication Prevents Recurrence10 - Evaluating the Effect of Prescription Drugs - 11 Solving Medication Problems - 12 Problem Solving Problems - 13 Identifying Recurrent Alert Signs - 14 Maintaining Alert Symptoms - 15 Emergency Plan Advancement - 16 Plan Yourself Take them inside the community, they were trained.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Tolue Rehabilitation Center

Full name of responsible person

Zohreh Parsamoein

Street address

No. 11, Kuhestan settlement,Blouck D1,After Entezami Science univercity,End of west hemmat,Tehran Town

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Phone

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Email

zohrep@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Ahmad Tajabadi

Street address

End of Shahid Sattari Highway - University Square - Shohada Hesarak Boulevard - Islamic Azad University - Science and Research Branch

City

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Postal code

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Email

zohrep@yahoo.com

Web page address

<http://sapp.ir/srbnewss>

Grant name

Grant code / Reference number

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

No

Title of funding source

personal

Proportion provided by this source

1

Public or private sector

Private

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

ZohrehParsamoein

Position

Student

Latest degree

Master

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Position

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Person responsible for updating data

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Latest degree

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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

Undecided - It is not yet known if there will be 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

All data obtained from the results are shared

When the data will become available and for how long

6 months after publishing the results

To whom data/document is available

All people

Under which criteria data/document could be used

Email the author if you do similar research to access data
and questionnaires.

From where data/document is obtainable

ZohrehParsamoein-09126850844

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

After the e-mail is sent to the author, the required
information is sent to the recipient for three days

Comments

All information is fully provided.