Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Jun 2026

The Effectiveness of Community Re-entry Program On Therapeutic Outcomes in Raazi Psychiatric Center Hospitalized Schizophrenic Patients, in Comparison with Conventional Psychiatric Treatment

Protocol summary

Study aim

1) Determine the effectiveness of the community return program on the therapeutic components of schizophrenia patients. The therapeutic components of this study are: Awareness of the nature of disease and drug information, readiness for discharge, ability to plan daily, quality of life, adhesion, frequency of PRN, frequency of physical inhibition, positive and negative syndrome, disability, stigma and duration Hospitalization 2) Comparison of the effectiveness of the return program to the community on the above-mentioned therapeutic outcomes, with the effectiveness of conventional psychiatric treatment in Razi Psychoanalytic Center.

Design

In this study, 80 schizophrenic patients admitted to the Razi Psychiatric Center were randomly assigned to experimental and control groups and assigned a code to each participant to hide the intervention group

Settings and conduct

This study is carried out in the inpatients units of the Raazi Psychiatric Center, in which the principles of double-blindedness are implemented. In order to ensure that double-blinded principles are implemented, the implementation and scoring of research tools and all measures , the implementation of tools and conducting interviews and other evaluation and measures in the experimental and control groups are carried out by neutral evaluators, Who are unaware of the implementation of therapeutic intervention in the experimental group and the group (trial or control) in which the patients are assigned. The intervention in the experimental group will be provided by trained instructors who will be unaware of the experimental or control assignment of the participants undergoing training. Meanwhile, subjects are unaware of being present in the experimental, or in the control group. Researcher (investigator) will score tools after implementation and interpret the findings of other measurement and evaluation methods used in this research. In order to prevent the bias in scoring tools and interpreting the results, the situation is provided so that a person is completely unaware of the logic of the present research and its evaluations, receiving the tools completed and the results of the interviews and evaluations from evaluators along with a list of patients and their belonging to test groups and controls and Deliver them to the researcher. The same person, after scoring tools and interpreting the results of the interviews and other evaluations performed, is responsible for communicating data with the patients in the experimental and control groups to prepare them for statistical analysis.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) Diagnosis of schizophrenia based on medical records 2) at least a prior hospitalization and passing two years from onset 3) Age range between 22-60 years 4) tolerance for group discipline and inclination for group activity 5) Having family Exclusion criteria: 1) Comorbidity with personality and substance related and addictive disorders 2) Having self management skills

Intervention groups

This study consists of an intervention group and a control group that participants in the intervention group are in addition to conventional psychiatric treatment subject to a community re-entry program, while the control group participants receive only conventional psychiatric treatment

Main outcome variables

Increasing awareness about the nature of disease and drug information, readiness for discharge, the ability to design a daily plan, and quality of life Decreased adhesion, PRN frequency, frequency of physical inhibition, positive and negative syndrome, disability, stigma and hospitalization time

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180103038207N1**
Registration date: **2018-03-04, 1396/12/13**
Registration timing: **registered_while_recruiting**

Last update: **2018-03-04, 1396/12/13**
Update count: **0**

Registration date

2018-03-04, 1396/12/13

Registrant information

Name

Davood Arab Ghahestany

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 3341 6084

Email address

psychosis@uswr.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-18, 1396/11/29

Expected recruitment end date

2018-03-16, 1396/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of Community Re-entry Program On Therapeutic Outcomes in Raazi Psychiatric Center Hospitalized Schizophrenic Patients, in Comparison with Conventional Psychiatric Treatment

Public title

The Effectiveness of Community Re-entry Program (CRP) in Treatment of Schizophrenia

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of schizophrenia based on medical records Age range between 22-60 years Having family Tolerance for group disciplines and inclination for group activities At least a prior hospitalization and passing two years from onset

Exclusion criteria:

Comorbidity with personality substance related and addictive disorders Having self management skills

Age

From **22 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

When the names of the patients who were selected in full-scale and according to the inclusion and exclusion criteria from hospitalized patients in the non-educational acute units of Razi Educational Medical Psychiatric Hospital reached number 10, they are listed and grouped in even and odd number according to their order in list. Then the even and odd names are assigned in the subject and control groups based on throwing the coin (tap or line), so that the first throw is done for the odd names and the tap event are assigned to experimental group and the line event in the control group. . By randomly assigning the odd persons in the list according to this method, the assignment group of even names is determined by itself and in a random fashion.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is carried out in the inpatients units of the Raazi Psychiatric Center, in which the principles of double-blindedness are implemented. In order to ensure that double-blinded principles are implemented, the implementation and scoring of research tools and all measures , the implementation of tools and conducting interviews and other evaluation and measures in the experimental and control groups are carried out by neutral evaluators, Who are unaware of the implementation of therapeutic intervention in the experimental group and the group (trial or control) in which the patients are assigned. The intervention in the experimental group will be provided by trained instructors who will be unaware of the experimental or control assignment of the participants undergoing training. Meanwhile, subjects are unaware of being present in the experimental, or in the control group. Researcher (investigator) will score tools after implementation and interpret the findings of other measurement and evaluation methods used in this research. In order to prevent the bias in scoring tools and interpreting the results, the situation is provided so that a person is completely unaware of the logic of the present research and its evaluations, receiving the tools completed and the results of the interviews and evaluations from evaluators along with a list of patients and their belonging to test groups and controls and Deliver them to the researcher. The same person, after scoring tools and interpreting the results of the

interviews and other evaluations performed, is responsible for communicating data with the patients in the experimental and control groups to prepare them for statistical analysis.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of University of Social Welfare and Rehabilitation Sciences

Street address
kodakyar Ave., daneshjo Blvd.

City
Tehran

Province
Tehran

Postal code
1985713834

Approval date
2017-07-09, 1396/04/18

Ethics committee reference number
IR.USWR.REC.1396.150

Health conditions studied

1

Description of health condition studied
Schizophrenia disorder (F25.2), Treatment and Rehabilitation

ICD-10 code
F25.2

ICD-10 code description

Primary outcomes

1

Description
Awareness of the nature of disease and drug information, and readiness for discharge

Timepoint
At the beginning of the study and after the end of the intervention

Method of measurement
community re entry program test

2

Description
Ability to design a daily schedule

Timepoint
At the beginning of the study and after the end of the intervention

Method of measurement
Depending on the ability to complete the daily schedule, the program returns to the community

3

Description
Quality of life

Timepoint
At the beginning of the study and after the end of the intervention

Method of measurement
Short form health questionnaire

4

Description
viscosity

Timepoint
During hospitalization period

Method of measurement
Based on the number of visits to the Nursing Station

5

Description
The number of times a venous or muscular injection of psychoactive substance to calm the patient (I.e. PRN)

Timepoint
At the end of intervention

Method of measurement
View patient records documentation

6

Description
The number of fixation

Timepoint
At the end of intervention

Method of measurement
View patient records documentation

7

Description
Positive and negative syndrome

Timepoint
At the beginning of the study and after the end of the intervention

Method of measurement
Positive and negative syndrome scale

8

Description
Inability

Timepoint
At the beginning of the study and after the end of the intervention

Method of measurement
World Health Organization disability assessment schedule 2.0

9

Description
Stigma
Timepoint
At the beginning of the study and after the end of the intervention
Method of measurement
Stigma scale Michael King

10

Description
Duration of hospitalization
Timepoint
After inserting the discharge order in the patient file
Method of measurement
View patient records documentation

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: It consists of 40 patients who, in addition to conventional psychiatric treatment according to hospital routines, are also subject to Community Reentry Program. The program for returning to the community consists of 16 sessions of 30 to 90 minutes as follows: By default, and based on the recommendation of the author, at least 3 sessions per week are to be held for patients and the participants should not exceed 8 persons. Session 1: Introducing the Return to Community Program. Session 2: Explain the signs and symptoms of schizophrenia spectrum disorders according to the diagnosis of the participants Session 3: Determine the readiness of patients for discharge. Session 4: Planning a Community Return Program. Session 5: Communicating with Society Session 6: Coping with Stress in the Community. Session 7: Designing a Daily Program. Session 8: Exercise Rendezvous (Visit) and Do It. Session 9: How do medications prevent recurrence Session 10: Assessing the Effect of Medications. Session 11: Solving Drug Problems. Session 12: Solving Drug Side Effects. Session 13: Determine the symptoms of recurrence. Session 14: Tracking the symptoms of recurrence. Session 15: Implementing the Emergency Plan. Session 16: Bring your plan to the community. In each of these sessions, educational activities are conducted in a variety of ways, including viewing videos and asking questions about its content, internship and exterior classes, oral education through lecture and verbal interaction between trainer and patients, and role playing along with motivational components with Including scenarios related to the daily lives of patients will be made on their own initiative. Meanwhile, classroom assignments and the content of the sessions are recorded in a booklet by the patients and will be provided to the patients after the end of the session.
Category
Rehabilitation

2

Description
Control group: It consists of 40 patients who receive only routine treatment of routine psychiatric treatment and are not subject to a community reunion program.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Raazi Psychiatric Center
Full name of responsible person
Davood Arab Ghahestany
Street address
Shahid rastegari Blvd., Taghi abad threeway, Moallem Sq., Raazi Psychiatric Center
City
Rey
Province
Tehran
Postal code
1866958891
Phone
+98 21 3341 6084
Email
psychosis@uswr.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
Arab, Amir Masoud, Ph. D.
Street address
kodakyar Ave., daneshjo Blvd.
City
Tehran
Province
Tehran
Postal code
1985713834
Phone
+98 21 2218 0083
Email
rd@uswr.ac.ir
Grant name
Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
University of social welfare and rehabilitation 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
University of social welfare and rehabilitation sciences
Full name of responsible person
Davood Arab Ghahestany
Position
Researcher
Latest degree
Master
Other areas of specialty/work
Psychology
Street address
Shahid rastegari Blvd., Taghi abad threeway, Moallem Sq., Raazi Psychiatric Center
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Rey
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1866958891
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Person responsible for scientific inquiries

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Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
Davood Arab Ghahestany
Position
Researcher
Latest degree
Master
Other areas of specialty/work
Psychology
Street address
Shahid rastegari Blvd., Taghi abad threeway, Moallem Sq., Raazi Psychiatric Center
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Postal code
1866958891
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Person responsible for updating data

Contact
Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
Davood Arab Ghahestany
Position
Researcher
Latest degree
Master
Other areas of specialty/work
Psychology
Street address
Shahid rastegari Blvd., Taghi abad threeway, Moallem Sq., Raazi Psychiatric Center
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psychosis@uswr.ac.ir

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
This item will based on the policies of recruitment center and related university
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not 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