

# 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, adherence, 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 adherence, 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

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#### 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**  
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## Person responsible for scientific 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**  
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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  
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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

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