

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of Community Re-Entry Program (CRP) on disability of Chronic Patients with Schizophrenia

Protocol summary

Disability Of Chronic Patients With Schizophrenia

Study aim

To assess the effect of Community Re-Entry Program (CRP) on disability of Chronic Patients with Schizophrenia

Design

The present study is a quasi-experimental study with pretest-post test design with control group and single blind. Samples were selected using convenience sampling and randomly assigned into two groups of intervention and control.

Settings and conduct

Location: Razi Hospital, University of Iran The method is that after obtaining informed consent, participants will be asked to complete a demographic questionnaire and a World Health Organization Disability Questionnaire before and after the intervention. In order to make a single blind study, the questionnaires will be completed before and after the intervention by a non-researcher and after receiving the necessary training to complete the questionnaire.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Based on the psychiatrist's diagnosis recorded in the case, , No symptoms of acute phase schizophrenia at the time of the interview, More than 5 years have passed since the illness, No symptoms of acute phase schizophrenia at the time of the interview, Don't be an active substance abuser, Do not have severe physical problems and mental retardation, The severity of the disorder is such that it is incapable of performing activities: Exclusion criteria: Existence Neurological diseases, orthopedic disorders, blindness and diabetes, Diagnosis of the disorder Bipolar type I and major depression, Mental Illness Following War Injury, Psychosis

Intervention groups

For the intervention group, 16 training sessions (3 sessions per week, 30-90 minutes per week) will be conducted by the instructor (researcher), videotape, and workbook (for patients) in the community; Control group: No training.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150615022745N2**

Registration date: **2019-10-31, 1398/08/09**

Registration timing: **retrospective**

Last update: **2019-10-31, 1398/08/09**

Update count: **0**

Registration date

2019-10-31, 1398/08/09

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6692 7171

Email address

ttaghavi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-01, 1397/07/09

Expected recruitment end date

2018-11-10, 1397/08/19

Actual recruitment start date

2018-10-01, 1397/07/09

Actual recruitment end date

2018-11-10, 1397/08/19

Trial completion date

2019-01-10, 1397/10/20

Scientific title

Effect of Community Re-Entry Program (CRP) on disability of Chronic Patients with Schizophrenia

Public title

Effect of Community Re-Entry Program (CRP) in Patients with Schizophrenia

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Based on the psychiatrist's diagnosis recorded in the case Age range 18 to 55 years No symptoms of acute phase schizophrenia at the time of the interview More than 5 years have passed since the illness No symptoms of acute phase schizophrenia at the time of the interview Don't be an active substance abuser Do not have severe physical problems and mental retardation The severity of the disorder is such that it is incapable of performing activities Family members (legal guardians) satisfaction with patient participation in research

Exclusion criteria:

Existence Neurological diseases, orthopedic disorders, blindness and diabetes Diagnosis of the disorder Bipolar type I and major depression Mental Illness Following War Injury Psychosis

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned into intervention and control groups by block allocation method. The allocation sequence will be generated using the free web site www.randomization.com. To generate the allocation sequence in this system, the number of subjects per block will be set to 4. In addition, the letters A will be assigned to the intervention group and B to the control group, and eventually the allocation sequence will be generated for each block by confirming the production of the allocation sequence in this system. The cards containing the blocks will then be inserted into the standard envelope. Thus, based on the eligible patient, an envelope will be removed by the researcher by accident, and the allocation will be determined.

Blinding (investigator's opinion)

Single blinded

Blinding description

The participants were Chronic Patients with Schizophrenia, who were unaware of the assignment in the study groups

Placebo

Not used

Assignment

Other

Other design features

=

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of School of Nursing Midwifery & Rehabilitation ,Tehran University of Medical Scien

Street address

School of Nursing Midwifery ,Tehran University of Medical Sciences. Nosrat st. Tohid sq. Tehran I.IRAN

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Tehran

Province

Tehran

Postal code

1419733171

Approval date

2018-09-01, 1397/06/10

Ethics committee reference number

IR.TUMS.FNM.REC.1397.096

Health conditions studied**1****Description of health condition studied**

Chronic schizophrenia

ICD-10 code

F20.5

ICD-10 code description

Residual schizophrenia

Primary outcomes**1****Description**

Disability rate in chronic schizophrenic patients

Timepoint

Before training and one month after training

Method of measurement

WHODAS 2 36i Disability Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Training Community Re-Entry Program in 16 meetings: Meeting 1: Introduction to Community Re-Entry Program: A review of the return to Community Re-Entry Program of familiarity with the program. Meeting 2: Symptoms of Disabling Mental Disorders: The purpose of this meeting is to learn about what drugs are prescribed, and what benefits are obtained with the consumption of drugs. Meeting 3: determined readiness for release: The purpose of this meeting is to learn about the symptoms and behaviors that people must know to prepare for their release. Meeting 4: Planning to Community Re-Entry Program: Patients can be involved in their release schemes by learning about their accommodation and finances. Meeting 5: Communicate with community: The purpose of this meeting is to establish personal communication with the individual in society that can serve as a service source and learn more about the resources and services available in society. Meeting 6: Dealing with stress in society: The purpose of this meeting is to know that stress can play an important role in the disease, and activities that can be used to cope with stress. Meeting 7: Plan a daily schedule: The purpose of this session is to learn the benefits of having a daily schedule and then prepare it. Meeting 8: practice an appointment and do it: The purpose of this session is to learn how to arrange an appointment with the doctor after release. Meeting 9: How drugs prevent recurrence of the disease: The purpose of the meeting is to learn what the reasons for treating the medication are for the cure and the general aims of prescribing drugs and their side effects, such as overweight and how to record a daily record of drug - sleep - sleep - creating, in their calibration sheet. Meeting 10: assessing the impact of prescription drugs: The purpose of the meeting is to learn the use of their grade - ratings checklist and to use these sheets to improve communication with the physician. Meeting 11: Drug - solving problems: The meeting is meant to learn how to recognise the problems caused by medication and to know what measures they should be taking to solve their drug problems, so that the drug should have the best effect. Meeting 12: Solving the Problems Side Effects of Drug Treatment: the meeting is meant to identify possible side effects of drugs and train people to discuss these complications. Meeting 13: identifying and determining warning symptoms for recurrence: The training session aims to teach members about the warning signs of the relapse. Meeting 14: Keeping track of warning Symptoms: The purpose of this meeting is to get people to examine their personal signaling symptoms on a daily basis, and understand that in detecting the symptoms, they need to find a person who can help them identify and examine signs of warning. Meeting 15: Emergency plan formulation: The purpose of the meeting is to teach members of the group to develop an emergency plan. Meeting 16: bring their plan into society: The purpose of the meeting is to enable people to describe their emergency plan and understand how to train all the skills they have learned in the Community Re-Entry Program.

Category

Rehabilitation

2

Description

Control group: In this group, there were no performed intervention, in order to compare the its results with the Experimental group

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran Psychiatric Care Center(hospital)

Full name of responsible person

Amir Abbas Keshavarz Akhlaghi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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1417653761

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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

Taraneh Taghavi Larijani

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for updating data**Contact****Name of organization / entity**

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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

No - There is not 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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The documentation is accessible to the research team, and after completion of the study, it could only be made available to the relevant sources with permission of the research team supervisor

When the data will become available and for how long

3 months after publishing the results

To whom data/document is available

Research team's supervisor, School of Nursing and Midwifery Research Deputy

Under which criteria data/document could be used

With the permission of the research team's supervisor

From where data/document is obtainable

Research team's supervisor

What processes are involved for a request to access

data/document

Contact with the research team's supervisor
Comments