

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Evaluation of the effect of community Re-entry Program(CRP) on mental state and social function in chronic psychiatric patients

Protocol summary

Summary

(1)Objective: The effect of Community Re-entry Program on social function of patients with chronic mental disorders.(2)Design: The study was a randomized clinical trial which was conducted among patients (men and women) with chronic mental illness, attended daily rehabilitation centers in Hamadan, with a sample size of 40 patients (20 female and 20 male). (3) Setting and conduct:This randomized controlled clinical trial was conducted after making the necessary arrangements by outpatient rehabilitation centers of Hamadan, Iran. Based on the inclusion and exclusion criteria of the study, 40 patients (20 males and 20 females) were selected through purposive sampling and were randomly assigned to an intervention and a control group using block randomization method. Before randomization, occupational therapist asked members of both study groups to complete communication and interaction skills questionnaire and positive and negative syndrome scale. After randomization, patients in the intervention group took part in educational sessions in 2 groups of 6 people and 1 group of 8 people. The educational sessions were held in the rehabilitation centers twice a week (each lasting for 60-90 minutes) for two months. Post-test was performed using Assessment Of communication And Interaction Skill (ACIS) questionnaire at the end of the study (two months) and also two weeks later to do follow-up. Patients in the control group only received the rehabilitation centers' routine treatments (occupational therapy, psychotherapy, and pharmacotherapy).(4)The inclusion criteria:1- Having schizophrenia and mood disorders based on DSM-IV diagnostic criteria approved by a psychiatrist, 2-Aged between 20-65 years, 3- Affected by the disease for at least two years, not having history of recurrence, hospitalization, and change in medications in the past two months, 4-having willingness to participate in the study. The exclusion criteria:1- Having history of any acute medical conditions and neurological damages, 2-Suffering from mental

retardation. (5) Intervention: Running 16 sessions of Community Re-entry Program(CRP) for patients in this group. The control group did not receive aforementioned program. (6)Main outcome measures: Social function and mental state

General information

Acronym

CRP

IRCT registration information

IRCT registration number: **IRCT2016051424468N2**

Registration date: **2016-05-30, 1395/03/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-05-30, 1395/03/10

Registrant information

Name

Farkhondeh Jamshidi

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 1571

Email address

f.jamshidi@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology Hamadan University of Medical Sciences

Expected recruitment start date

2015-04-07, 1394/01/18

Expected recruitment end date

2015-06-02, 1394/03/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of community Re-entry Program(CRP) on mental state and social function in chronic psychiatric patients

Public title

Effect of Community Re-entry Program(CRP) on Chronic Mental Illnesses

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : 1- diagnostic Confirmation of chronic psychiatric disorders by a psychiatrist according to the DSM-IV diagnostic criteria; 2- Aged between 20 and 65 years; 3- At least 2 years passed from the onset of the illness and being in the chronic phase of the disease without a history of symptoms' recurrence , psychotic attack, hospitalization and medical regimen change within last 2 weeks; 4-having the desire to participate in the research and cooperate in all phases of evaluations. Exclusion criteria: 1- Extrapyramidal system disorders (tremor, balance disorders, acute and delayed dystonia, Parkinsonism syndrome) so that social activity is prevented; 2- deafness, blindness and sensation disability that can not be compensated with assistant devices; 3- history of any neurological illness and injuries (such as head trauma, coma, Alzheimer's disease, any type of dementia, epilepsy or stroke); 4-Mental retardation; 5- Electroconvulsive therapy (ECT) in the last 6 months; 6- lack of desire to continue the trial

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

This study was a randomized clinical trial with available samples. Samples were randomized into two groups

using block randomization method

Secondary Ids**1****Registry name**

-

Secondary trial Id

-

Registration date

empty

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

Ethics committee of Hamadan University of Medical Sciences

Street address

Shahid Fahmideh BLV, Pajohesh Intersection, Hamadan, University of Medical Sciences

City

Hamadan

Postal code

-

Approval date

2014-12-24, 1393/10/03

Ethics committee reference number

16/35/4793/پ

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

Chronic Mental Disorder

ICD-10 code

F30, F31,

ICD-10 code description

Bipolar affective disorder, Manic episode, Depressive episode, Schizophrenia

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

social function

Timepoint

Before and one week after intervention

Method of measurement

Assessment Of communication And Interaction Skill (ACIS) questionnaire

2**Description**

mental state

Timepoint

Before and one week after intervention

Method of measurement

Positive And Negative Syndrome Scale(PANSS)

Secondary outcomes**1****Description**

-

Timepoint

-

Method of measurement

-

Intervention groups**1****Description**

Intervention Group: Community Re-entry Program,16 sessions, two 60-minute to 90-minute sessions per week

Category

Rehabilitation

2**Description**

Control group: Did not received Community Re-entry program

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Kowsar Alvand and Tabesh rehabilitation Centers

Full name of responsible person

Moradi Ghane

Street address

No. 19, Najarkhaneh Alleys, Sizdah khaneh, Hamedan

City

Hamadan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor for Research and Technology,
Hamadan University of Medical Sciences

Full name of responsible person

Saeed Bashirian

Street address

Opposite the People's Park, Shahid Fahmideh BLV,
Pajohesh Intersection, Vice Chancellor for Research,

University of Medical Sciences, Hamadan

City

Hamadan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for Research and Technology, Hamadan
University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Hamadan University of Medical Sciences

Full name of responsible person

Farkhondeh Jamshidi

Position

Instructor of rehabilitation

Other areas of specialty/work**Street address**

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Master of Science

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Contact

Name of organization / entity

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Frkhondeh Jamshidi

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty