

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The Effectiveness of the community reentry program on the positive and negative symptoms and improving the social skills of schizophrenic patients

Protocol summary

Study aim

Determining the effect of Lieberman's return program on reducing the positive and negative symptoms and improving social skills in people with schizophrenia

Design

Two arm parallel group randomised trial without blinded groups

Settings and conduct

This is an experimental study that will be conducted in 2017 at Khorshid hospital in Isfahan. The target population of the study is patients with schizophrenia who are under the care and treatment programs at the center.

Participants/Inclusion and exclusion criteria

A) inclusion criteria: • Patients with schizophrenia • Patient agrees to participate in the study • aged 18-60 years • Ability to read and write • Lack of mental retardation B-exclusion criteria: • Cancellation of the patient's presence in the study • Lack of participation in more than 3 sessions of the Lieberman's Community Return Program

Intervention groups

Patients in the first group are under the training of a return to the Lieberman community, and the second group, which is considered as the control group, continues to treat its usual treatment as a drug therapy. The groups are selected before and after the study using the Matsun social skills scale and the scale of assessment of positive and negative symptoms.

Main outcome variables

All patients were subjected to pretest and immediately and 3 months after intervention by using the Matsun social skills inventory and the negative and positive symptom scales. The changes in social skills score and positive and negative symptoms within each group and It is compared between the two groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090801002266N10**

Registration date: **2019-01-16, 1397/10/26**

Registration timing: **prospective**

Last update: **2019-01-16, 1397/10/26**

Update count: **0**

Registration date

2019-01-16, 1397/10/26

Registrant information

Name

Gholamreza Kheirabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 1222 2135

Email address

kheirabadi@bsrc.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2019-02-19, 1397/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of the community reentry program on the positive and negative symptoms and improving the social skills of schizophrenic patients

Public title

The Effectiveness of the community reentry program on the positive and negative symptoms and improving the social skills of schizophrenic patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Schizophrenic patients Patient agreement for study inclusion Aged 18-60 Lack of mental retardation Ability to read and write

Exclusion criteria:

Refuse of the patient from continuing the study Lack of participation in more than 3 sessions of the Lieberman's return to community program

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Not randomized

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Isfahan University of Medical Sciences

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Isfahan University of Medical Sciences, Hezar Jerib Avey, Isfahan, Iran

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8174673441

Approval date

2019-01-11, 1397/10/21

Ethics committee reference number

IR.MUI.MED.REC.1397.080

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

Schizophrenia

ICD-10 code

F20.9

ICD-10 code description

Schizophrenia, unspecified

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

The changes in social skills score and positive and negative symptoms within each group and It is compared between two groups.

Timepoint

Before, just after and three month after training

Method of measurement

Matson's Social Skills Questionnaire and Positive and Negative Symptom Scale

Secondary outcomes

empty

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

Intervention group: Schizophrenic patients who will train the Lieberman's return to community community program

Category

Lifestyle

2**Description**

Control group: This group of schizophrenic patients will not be train

Category

Treatment - Drugs

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

Khorshid Hospital

Full name of responsible person

Gholam Reza Kheirabadi

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

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Gholamreza Kheirabadi

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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

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Dr Gholam Reza Kheirabadi

Position

Psychiatrist/ Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Web page address

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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The total data of the participants will be available after being unidentifiable.

When the data will become available and for how long

Start of access immediately after publication

To whom data/document is available

All researchers who need this data

Under which criteria data/document could be used

All type of analysis are allowed and for receiving data you have to send Email to scientific person of this study

From where data/document is obtainable

Email: kheirabadi@bsrc.mui.ac.ir and phone number

00989131086637

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

It does not require any special work and it is quickly available

Comments