

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 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 Lemberman'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

##### Street address

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

##### City

Isfahan

##### Province

Isfahan

##### Postal code

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

**Street address**

Behavioral Sciences Resaerch Center, Isfahan  
University of Medical Sciences, Isfahan, Iran

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**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****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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Vice chancellor for research, Isfahan University of  
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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 scientific inquiries****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Gholam Reza Kheirabadi

**Position**

Assistant Professor of Psychiatry

**Latest degree**

Specialist

**Other areas of specialty/work**

Psychiatrics

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity****Person responsible for general inquiries****Contact**

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**Full name of responsible person**

Gholam Reza Kheirabadi

**Position**

Assistant Professor of Psychiatry

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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**

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 syudy

**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**