

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

The effectiveness of cognitive-behavioral group therapy on improving metacognitive beliefs, insight and adherence of treatment and reducing pressure in caregivers of patients with schizophrenia

Protocol summary

Study aim

Effect of cognitive-behavioral group therapy on improving metacognitive beliefs, insight, adherence therapy and reducing the stress of caring for schizophrenic patients

Design

A clinical trial with a control group, with parallel, non-random groups, on 36 patients. In this way, each new patient is placed in one of the research groups, respectively.

Settings and conduct

The present study will be performed in Shiraz Psychiatric Hospital. In the intervention group, the treatment program will be performed by an therapist in seven sessions. Each session begins with an initial discussion and question and then continues for an hour and a half on the topic of the same discussion session. And at the end of each session, summarized information about the same session is given to patients Will be located.

Participants/Inclusion and exclusion criteria

Inclusion: Having diagnostic criteria for schizophrenia disorder Age between 18 and 50 years Minimum secondary education Not receiving electroconvulsive therapy No entry: Mental retardation Brain Injury Serious thoughts of suicide The onset of the acute phase of the disease

Intervention groups

In the intervention group, the treatment program will be performed by an experienced group therapist in seven sessions (three times a week) based on a treatment protocol adapted from Robert Paul Lieberman's 16-session community return program. In order to investigate the effect of therapist's attention, the placebo group of therapist's attention will watch documentaries without psychological background for seven sessions and will discuss the subject of the film. The control group will also receive only their usual

treatments, which include a visit to a psychiatrist

Main outcome variables

Reducing the pressure on caregivers, increasing the level of insight and adherence to treatment of schizophrenic patients, improving the patient's metacognitive beliefs

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210912052449N1**

Registration date: **2022-01-11, 1400/10/21**

Registration timing: **retrospective**

Last update: **2022-01-11, 1400/10/21**

Update count: **0**

Registration date

2022-01-11, 1400/10/21

Registrant information

Name

samad fereidooni

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 9834 6905

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psysamadf@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2021-11-21, 1400/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of cognitive-behavioral group therapy on improving metacognitive beliefs, insight and adherence of treatment and reducing pressure in caregivers of patients with schizophrenia

Public title

The effectiveness of cognitive-behavioral group therapy on patients with schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having diagnostic criteria for schizophrenia disorder, according to DSM 5 Age range between 18 and 50 years Having at least a middle school degree Not receiving electroconvulsive therapy (at least two months before and during hospitalization) Not receiving psychological treatments at the same time as entering the study or 3 months before entering the study Patient and family consent to participate in the study Living with a family member (at least three months before hospitalization)

Exclusion criteria:

Patients who are in the acute phase of the disease Patients who are active substance abusers Having serious suicidal thoughts Having any serious medical condition (to prevents further treatment) Mental retardation Brain damage More than one group absence session Comorbidity of substance dependence disorder Comorbidity of other psychiatric disorders

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **36**

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**

Ethics committee of Shiraz University of Medical Sciences

Street address

Zand St., in front of Palestine St., the central building of Shiraz University of Medical Sciences

City

shiraz

Province

Fars

Postal code

7134814336

Approval date

2021-12-05, 1400/09/14

Ethics committee reference number

IR.SUMS.REC.1400.673

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

Schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

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

Metacognitive Beliefs Score in Adrienne Wells Metacognitive Beliefs Questionnaire

Timepoint

Assessment of metacognitive beliefs at the beginning of the study (before the intervention) and after the intervention and three months after the intervention

Method of measurement

Adrienne Wells Metacognitive Beliefs Questionnaire

2**Description**

Insight level score based on Insight and Treatment Attitudes Questionnaire

Timepoint

Assessment of the patient's level of insight at the beginning of the study (before the intervention) and after the intervention and three months after the intervention

Method of measurement

Insight and Treatment Attitudes Questionnaire

3**Description**

Score of adherence to treatment on the Medication Adherence Rating Scale

Timepoint

Assessment of patient adherence to treatment at the beginning of the study (before the intervention) and after the intervention and three months after the intervention

Method of measurement

Medication Adherence Rating Scale

4

Description

Care pressure level score based on Novak care pressure questionnaire

Timepoint

Assessment of the level of care pressure at the beginning of the study (before the intervention) and after the intervention and three months after the intervention

Method of measurement

Novak Care Pressure Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: In the intervention group, the treatment program will be performed by an experienced group therapist in seven sessions with 15 minutes of rest (three times a week) based on a treatment protocol adapted from Robert Paul Lieberman's 16-session community return program. This program is an "Independent and Social Life Skills" program developed by the Center for Psychiatric Rehabilitation Clinical Research at UCLA. Each session begins with an initial discussion and question and then continues for an hour and a half on the topic of the same discussion session. Topics discussed in each session include the following: Session 1: The nature of mental disorders, stigmatization and normalization, Session 2: Communication and expression skills, Session 3: Symptoms of the disorder and symptoms of recurrence, Session 4: Medication, Benefits and side effects, Session 5: Stress management skills, Session 6: Rehabilitation and self-care skills, Session 7: Preparation for discharge.

Category

Rehabilitation

2

Description

Intervention group 2: In order to evaluate the effect of the therapist's attention, the therapist's placebo group will watch documentaries without a psychological background for seven sessions in the presence of the therapist and will discuss the subject of the film.

Category

Rehabilitation

3

Description

Control group: The control group will also receive only their usual treatments, which include a visit to a psychiatrist.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz Psychiatric Hospital

Full name of responsible person

Samad Fereidooni

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Leila Razeghian Jahromi

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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

Shiraz University of Medical Sciences
Proportion provided by this source
40
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
Shiraz University of Medical Sciences
Full name of responsible person
Samad Fereidooni
Position
Non-faculty PhD
Latest degree
Ph.D.
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

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

Statistical Analysis Plan

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

By identifying individuals, information will only be published in groups

When the data will become available and for how long

6 months after the end of the research

To whom data/document is available

The data will be available only for the Vice Chancellor for Research of Shiraz University of Medical Sciences

Under which criteria data/document could be used

Only treatment planning for study participants

From where data/document is obtainable

Principal Investigator

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

After the individual application was approved by the Vice

Chancellor for Research of Shiraz University of Medical Sciences

Comments