Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 disorde 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

Email address

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

Street address

Shiraz Psychiatric Hospital, Bajgah

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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

Street address

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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.

Other areas of specialty/work

Psychology

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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