

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

The effectiveness of cognitive behavioral therapy in combination with Pharmacotherapy on symptom control and quality of life in patients with schizophrenia

Protocol summary

Summary

This is an interventional study with before-after design. Patients with schizophrenia and without any neurological and medical disorders, aged from 20 to 50, with at least 8 classes education will be included. The diagnosis will be done according to the structured interview with SCID. Patients will be enrolled in the study only after obtaining informed consent. Patients with any history of substance abuse will be excluded. The sample size would be 5 patients which could be decreased to 3 patients due to drop out in follow up visits. The patients would be selected in outpatient clinics in Roozbeh Psychiatric Hospital. At the first visit, the patients will fill out the IS score (Insight of patient to his/her disease and signs and symptoms, treatment, PANSS score (positive and negative syndrome scale), GAF (global assessment of function), QOL score (question form of WHO regarding quality of life score)). In further visits, the cognitive-behavioral intervention would be performed by a resident of psychiatry for 14 to 16 sessions (2 sessions per week) according to Nicola Wright's book. The sessions would be recorded and supervised by a CBT specialist. Only audio files of sessions would be kept after completion of sessions and would be accessed only by CBT therapist and the supervisor. The patients would be evaluated at the end of all sessions and 3 months after, with score sheets.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016110627691N2**
Registration date: **2017-04-07, 1396/01/18**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-04-07, 1396/01/18

Registrant information

Name

Zahra Mirsepassi

Name of organization / entity

Roozbeh Hospital- Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2017-01-19, 1395/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of cognitive behavioral therapy in combination with Pharmacotherapy on symptom control and quality of life in patients with schizophrenia

Public title

combination of cognitive behavioral therapy and

medication in treatment of schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with schizophrenia disorder according to DSM- IV -TR classification and interview ; age between 20 to 50 'at least 8 classes education; Patients will enrolled in the study only after obtaining informed consent; CBT will be the only psychosocial intervention which will be provided to these patients. Exclusion criteria: , with at least 8 classes education; Patients with any history of substance abuse ; .patients with any history of neurological or medical disorders

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **5**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran university of Medicalsciences

Street address

Medical school ,poorsina sreet,16 Azar avenue,Tehran,Iran

City

Tehran

Postal code

Approval date

2016-07-12, 1395/04/22

Ethics committee reference number

IR.TUMS.REC.1395.2769

Health conditions studied

1

Description of health condition studied

schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes

1

Description

positive symptoms

Timepoint

at the first and after termination of cognitive behavioral therapy sessions and 12 weeks after the last sessions

Method of measurement

positive and negative syndrome scale

2

Description

negative symptoms

Timepoint

at the first and after termination of cognitive behavioral therapy sessions and 12 weeks after the last sessions

Method of measurement

positive and negative syndrome scale

Secondary outcomes

1

Description

Quality of life

Timepoint

at the first and after termination of cognitive behavioral therapy sessions and 12 weeks after the last sessions

Method of measurement

World Health organizatin-Quality of life

2

Description

Insight

Timepoint

at the first and after termination of cognitive behavioral therapy sessions and 12 weeks after the last sessions

Method of measurement

Insight scale

3

Description

Global functional patients

Timepoint

at the first and after termination of cognitive behavioral therapy sessions and 12 weeks after the last sessions

Method of measurement

Global Assessment of functioning scale

Intervention groups

1

Description

Cognitive behavioral therapy for patients with schizophrenia , 14 to16 sessions (2 sessions per week) individually ,according to Nicola wright protocol

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Day center.Roozbeh Hospital

Full name of responsible person

Zahra Mirsepassi

Street address

Day center.Roozbeh Hospital.South KargarAvenue.Tehran.Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Science ,Deputy of resaerch

Full name of responsible person

Zahra Mirsepassi

Street address

Enghelab Avenue.Ghods street.Tehran University Of Medical Sciences

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Science ,Deputy of resaerch

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

Roozbeh Hospital

Full name of responsible person

Zahra Mirsepassi

Position

Psychiatrist.Assistant professor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Web page address**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