Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Nov 2026

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

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. Patienta 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 wich could be decreased to 3 patients due to drop out in follow up visits. The patients would be selected in outpatients 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 sigh and symptoms, treatment, PANSS score (positive and negative syndrome scale), GAF (global assessment of function), QOL score (question form of WHO regarding quality 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
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Roozbeh Hospital- Tehran University of Medical Sciences
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Iran (Islamic Republic of)
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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 effectivness of cognitive behavioral therapy in combination with Pharmacotherapy on symptom control and quality of life in patients with schizophreneia

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 classificationand interview ; age between 20 to 50 ˈat 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Science ،Deputy of resaerch
Full name of responsible person
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Street address
Enghelab Avenue.Ghods street.Tehran University Of Medical Sciences
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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
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
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Psychiatrist.Assistant professor
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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