Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The effectiveness of recovery-oriented cognitive therapy with and without cognitive remediation in individuals with schizophrenia disorder.

Protocol summary

Study aim
The effectiveness of recovery-oriented cognitive therapy with and without cognitive remediation in individuals with schizophrenia disorder.

Design
A concealed, randomized, single-blinded controlled clinical trial with a parallel-group design

Settings and conduct
the participants from Razi hospital will complete the basic assessment such as the Schizophrenic Negative and Positive Symptoms Scale, attitude Scale, Neuropsychologic assessment, Quality of Life Mental Health Recovery, Hope Scale. then Intervention groups A will undergo recovery-oriented cognitive therapy and Intervention B groups will also be treated recovery-oriented cognitive therapy with cognitive rehabilitation after intervention phase post-treatment assessment will conduct.

Participants/Inclusion and exclusion criteria
1. 20-60 years 2. most of the symptoms are negative. 4. Ability to reading and writing Exclusion: 1. Brain damage, mental retardation, a physical disability 2. Neurological disease 3. seriously affected by the side effects of psychiatric medications. 4. Dissatisfaction with participating in the study. 5. The patient is in the acute phase of the disease. 6. Receive electroshock at least 6 months before the study and during treatment. 7. Be currently undergoing other psychological interventions.8. The patient is severely affected by abuse, poisoning, or deprivation.

Intervention groups
The intervention of recovery-oriented cognitive therapy with and without cognitive rehabilitation (comparison group as control) for patients with schizophrenia and to improve negative and positive symptoms, dysfunctional beliefs, neuro-cognitive, disability, quality of life, improvement of mental health, recovery, hope will be conducted.

Main outcome variables
Negative and positive symptoms, dysfunctional beliefs, neurocognitive, quality of life, improved mental health, recovery, hope.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200701047974N1**
Registration date: **2020-07-02, 1399/04/12**
Registration timing: **prospective**

Last update: **2020-07-02, 1399/04/12**
Update count: **0**

Registration date
2020-07-02, 1399/04/12

Registrant information

Name
Ali Ebrahimi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 3307 7230

Email address
alipsychologist69@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-07-22, 1399/05/01

Expected recruitment end date
2020-10-22, 1399/08/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of recovery-oriented cognitive therapy with and without cognitive remediation in individuals with schizophrenia disorder.

Public title

The effectiveness of recovery-oriented cognitive therapy with and without cognitive remediation in individuals with schizophrenia disorder.

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

20-60 years Diagnosis of schizophrenia based on DSM-5 criteria At least two years have passed since the onset of schizophrenia and most of the symptoms are negative. The score of positive and negative symptoms of the patient in SAPS tests (positive symptom assessment scale) and SANS (negative symptom evaluation scale) should be above the cutting point of 35 and 24, respectively. Ability to reading and writing

Exclusion criteria:

Brain damage, mental retardation, physical disability that interferes with the assessment process. Neurological disease (epilepsy, Alzheimer's, dementia, Parkinson's, MS, etc.) due to which the person being under treated The patient is seriously affected by the side effects of psychiatric medications that interfere with the study process. Dissatisfaction with participating in the study The patient is in the acute phase of the disease Receive an electroshock at least 6 months before the study and during treatment Be currently undergoing other psychological interventions The patient is severely affected by abuse, poisoning or deprivation of any kind of drug (smoking is not considered a exclusion criterion).

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

In the present study, adaptive randomization methods used based on the variables of the aid of the thesis that provide decisions based on the division of individuals into two groups of interventions on a case-by-case basis. (Woman) Age (in four age groups: 30-20, 40-31, 50-41, 60-51), and severity of negative and positive symptoms (in 5 levels: (1) suspicious, (2) mild, (3) Medium, (4) obvious, (5) severe) are important variables in this study. The characteristics of the first patient in the mentioned variables are recorded. the next individuals are assigned to the groups in such a way that the difference between the groups is minimal in terms of these important variables, and thus the imbalance can be minimized.

Blinding (investigator's opinion)

Single blinded

Blinding description

Those assessing outcomes and data Analyzer not being able to check the patient status and blinded to the research condition so this study will be a single-blind study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of University of Social Welfare and Rehabilitation Sciences

Street address

kodakyar Ave., daneshjo Blvd.,Evin

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Postal code

1985713871

Approval date

2020-06-22, 1399/04/02

Ethics committee reference number

IR.USWR.REC.1399.103

Health conditions studied

1

Description of health condition studied

schizophrenia disorder

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes

1

Description

Negative Symptoms

Timepoint

Per-intervention, mid intervention and post-intervention and follow up

Method of measurement
Scale for Assessment of Negative Symptoms (SANS)

2

Description
Positive Symptoms
Timepoint
Per-intervention, mid intervention and post-intervention and follow up
Method of measurement
Scale for Assessment of Positive Symptoms (SAPS)

3

Description
Neurocognitive impairment
Timepoint
Per-intervention, mid intervention and post-intervention and follow up
Method of measurement
MATRICES

4

Description
Dysfunctional Attitude
Timepoint
Per-intervention, mid intervention and post-intervention and follow up
Method of measurement
Dysfunctional Attitude Scale (DAS)

5

Description
Real-World Functioning
Timepoint
Per-intervention, mid intervention and post-intervention and follow up
Method of measurement
WHO DAS .2

6

Description
Quality of life
Timepoint
Per-intervention, mid intervention and post-intervention and follow up
Method of measurement
Self-report quality of life measure for people with schizophrenia

7

Description
Mental Health Recovery
Timepoint
Per-intervention, mid intervention and post-intervention and follow up
Method of measurement
Mental Health Recovery Measure

8

Description
Recovery
Timepoint
Per-intervention, mid intervention and post-intervention and follow up
Method of measurement
Recovery Self-Assessment–Revised (RSA-R)

9

Description
Hope
Timepoint
Per-intervention, mid intervention and post-intervention and follow up
Method of measurement
The Schizophrenia Hope Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group1: Intervention groups A will undergo recovery oriented cognitive therapy (CT-R). The program is designed to run individually or in groups, and will run for 14 sessions, averaging 30 minutes and 2 sessions per week.
Category
Treatment - Other

2

Description
Intervention group2: Intervention B groups will also be treated for 14 minutes, an average of 30 minutes, and 2 sessions per week with ecovery oriented cognitive therapy (CT-R) with cognitive rehabilitation (CT-R + CR).
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi psychiatric hospital
Full name of responsible person
Ali Ebrahimi
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kodakyar Ave., daneshjo Blvd.,Evin,
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Phone
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Email
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
University of social welfare and rehabilitation sciences

Full name of responsible person
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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
University of social welfare and rehabilitation sciences

Proportion provided by this source
10

Public or private sector
Private

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
University of social welfare and rehabilitation sciences

Full name of responsible person
Ali Ebrahimi

Position
PhD candidate

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

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

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

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

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