

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

The effect of metacognitive therapy in patient with schizophrenia

Protocol summary

Summary

Objectives: The effect of Metacognitive therapy (MCT) in positive and negative symptoms, function and quality of life of patients with schizophrenia **Design:** Non randomized, non placebo controlled, single center. **Setting and conduct:** Consent is collected from each patient participating in the research projec. **Diagnosis** is confirmed with The Structured Clinical Interview for DSM-IV (SCID). The first phase of the baseline assessment performed by the tools [Insight scale (IS) / Positive and Negative Syndrome Scale (PANSS) / Psychotic Symptom Rating Scales (PSYRATS) / Global Assessment of Functioning (GAF) / Quality of Life Inventory (QOLI) / Peters et al Delusions Inventory (PDI)]. **Post intervention** assessment with basic assessment tools and treatment satisfaction questionnaire will be done within two weeks after end of intervention. The initial follow up assessments at 3 months post intervention and secondary follow up 6 months after the intervention will be done. All assessments before and after therapeutic intervention, as well as MCT is performed by a psychiatric assistant. **Participants:** Five patients diagnosed with schizophrenia will be selected from Rozbeh hospital outpatient clients. **Inclusion criteria:** Age 18 to 45 years; Diagnosis of schizophrenia according to DSM 5; Be educated at least secondary school; Patient have positive signs; Medicinal changed over the past month and in the last two months have Electroconvulsive therapy (ECT); The patient's condition is stable and no acute psychosis. **Exclusion criteria:** Borderline intellectual function, mental retardation; Dependence on drugs or alcohol; Neurological disease; Formal thought disorder, Hostility and extreme aggression; In case of worsening of symptoms or need to change medication or dosage **Intervention:** The treatment will be done for at least four weeks; two sessions per week (number of sessions is at least 8 and up to 16 sessions). Each session lasting an hour. Meta cognitive therapy is performed individually in the hospital. The treatment plan will be done based on the treatment protocol provided by Professor Stephen

Moritz and Professor Todd Woodward. Main outcome measures: Positive symptoms, negative symptoms, delusions dimensions, quality of life, function, insight into illness.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016110330678N1**

Registration date: **2017-01-15, 1395/10/26**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-01-15, 1395/10/26

Registrant information

Name

Zahra Bahramy bidoni

Name of organization / entity

Tehran University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 21 5541 9151

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Recruitment status

Recruitment complete

Funding source

Research Vice Chancellor of Tehran University of Medical Sciences

Expected recruitment start date

2017-01-20, 1395/11/01

Expected recruitment end date

2017-02-19, 1395/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of metacognitive therapy in patient with schizophrenia

Public title

The effect of metacognitive therapy in patient with schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age 18 to 45 years; diagnosis of schizophrenia according to The Diagnostic and Statistical Manual of Mental Disorders (DSM) 5 is approved by the psychiatrist's interview; Be educated at least secondary school (8 years); The patient has positive symptoms (symptoms are moderate to high in the initial tests); no change in medication over the past month and in the last two months has not received ECT; patient's condition is stable and no acute psychosis Exclusion criteria: Borderline intellectual functioning or mental retardation based on the history and interviews; Drug or alcohol; Severe neurological disease (epilepsy, Parkinson's, dementia, Multiple sclerosis and any movement disorder); Forms of thought disorder, Hostility and extreme aggression; In case of worsening of symptoms or need to change the medication

Age

From **18 years** old to **45 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 Medical Sciences Ethics Committee

Street address

Tehran University of Medical Sciences, Ghods street, Keshavarz Blvd., Tehran

City

tehran

Postal code**Approval date**

2015-12-05, 1394/09/14

Ethics committee reference number

IR.TUMS.REC.1394.1337

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

Before the intervention, after intervention, three months and six months after intervention

Method of measurement

PANSS and PSYRATS scale

2**Description**

Negative symptoms

Timepoint

Before the intervention, after intervention, three months and six months after intervention

Method of measurement

PANSS scale

3**Description**

Dimensions of delusions and hallucinations

Timepoint

Before the intervention, after intervention, three months and six months after intervention

Method of measurement

PDI questionnaire

4**Description**

Insight

Timepoint

Before the intervention, after intervention, three months and six months after intervention

Method of measurement

BIS scale

5

Description

Quality of life

Timepoint

Before the intervention, after intervention, three months and six months after intervention

Method of measurement

QOLI questionnaire

6

Description

Global Functioning

Timepoint

Before the intervention, after intervention, three months and six months after intervention

Method of measurement

Global Assessment of Functioning

Secondary outcomes

1

Description

Satisfaction with treatment

Timepoint

After the intervention, three months and six months after intervention

Method of measurement

Treatment Satisfaction Questionnaire

Intervention groups

1

Description

The treatment will be done for at least four weeks; two sessions per week (number of sessions is at least 8 and up to 16 sessions). Each session lasting an hour. Meta cognitive therapy is performed individually in the hospital. The treatment plan will be done based on the treatment protocol provided by Professor Stephen Moritz and Professor Todd Woodward.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Rozbeh hospital

Full name of responsible person

Zahra bahramy bidoni

Street address

Rozbeh hospital, Southern karegar street, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Masud Yunesian

Street address

Tehran University of Medical Science, Ghods street, Keshavarz Blvd., Tehran

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Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Tehran University of Medical Sciences

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

Tehran University of Medical Science

Full name of responsible person

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Position

Psychiatric resident

Other areas of specialty/work

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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