Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Nov 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 intervension 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

Email address

bahramy-z@razi.tums.ac.ir

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

City

Tehran

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

City

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

Zahra Bahramy bidoni

Position

Psychiatric resident

Other areas of specialty/work

Street address

Rozbeh hospital, Southern karegar street, Tehran

City

Tehran

Postal code

Phone

+98 21 5541 9151

Fax

Email

bahramy-z@razi.tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Science
Full name of responsible person
Abolfazl mohammadi
Position
PHD of clinical psychology
Other areas of specialty/work
Street address
Rozbeh hospital, Southern karegar street, Tehran
City
Tehran
Postal code
Phone
+98 21 5541 9151
Fax
Email
a-mohammadi@tums.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Science
Full name of responsible person
Zahra Bahramy bidoni
Position
Psychiatric resident
Other areas of specialty/work
Street address
Rozbeh hospital, Southern karegar street, Tehran
City
Tehran
Postal code
Phone
+98 21 5541 9151
Fax
Email
bahramy-z@razi.tums.ac.ir
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