Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

Clinical Trial of the Effectiveness of Psycho educational Therapy on the Positive and Negative Symptoms of people with Chronic Schizophrenia Disorder

Protocol summary

Study aim

This study aims to investigate the effectiveness of psycho educational treatment on the positive and negative symptoms of patients with chronic schizophrenia.

Design

The training will be run by a psychiatrist assistant who is familiar with psychological training techniques, within 6 weeks of each week, 1 session, 1-5 hours per hour. Patients will be evaluated before the intervention, after the end of the intervention session and one month after the intervention, with Beck Depression Inventory, Beck Anxiety Inventory, SF-36, and Positive and Negative Syndrome Scale. After sampling by available method, the samples were randomly divided into two groups of case and control. Given that the total sample size is 48, 12 blocks of 4 are prepared by the statistical expert. This study is a phase 3 clinical trial.

Settings and conduct

The clinic of Shafa hospital / Patients will be included in the study after obtaining informed consent, observing the criteria for entry and exit from the study.

Participants/Inclusion and exclusion criteria

The study population includes all outpatient psychiatric patients with chronic schizophrenia who referred to the healing hospital during the recovery period (all patients referring to the Shafa Hospital based on DSM-5 criteria for the diagnosis of chronic schizophrenia) And in controlled condition - patients should have at least cycle education - age of patients aged 18-35 - not suffering from any other medical and psychological illness - willingness to enter the study - lack of substance and alcohol .

Intervention groups

Intervention group: The intervention group will be treated as common with psychotherapy based on psychological training. Control group: Individuals in the routine drug therapy group (olanzapine will receive 20 to 25 mg twice daily or risperidone 6 mg daily twice daily).

Main outcome variables

Positive and negative symptoms of schizophrenia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150427021965N12**
Registration date: **2019-08-26, 1398/06/04**
Registration timing: **registered_while_recruiting**

Last update: **2019-08-26, 1398/06/04**
Update count: **0**

Registration date

2019-08-26, 1398/06/04

Registrant information

Name

Homa Zarrabi

Name of organization / entity

Guilan University of Medical Sceinces,«Kavosh » Cognitive Behaviour Sciences and Addiction Researc

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-23, 1398/05/01

Expected recruitment end date

2019-10-23, 1398/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical Trial of the Effectiveness of Psycho educational Therapy on the Positive and Negative Symptoms of people with Chronic Schizophrenia Disorder

Public title

Psycho educational Therapy and Positive and Negative Symptoms of patients with Chronic Schizophrenia Disorder

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

All patients referred to the clinic of the Shafa Hospital who has a diagnosis of chronic schizophrenia based on DSM-5 criteria and in controlled conditions. Members must have at least elementary education. Patients aged 18-35 years old Have the desire to enter the study.

Exclusion criteria:

Having other psychiatric disorders Having physically debilitating disease

Age

From **18 years** old to **35 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly divided into two groups with psychiatric intervention based on psychological training and control group. Given that the total number of samples is 24, 6 blocks of 4 are provided by a statistic expert. Then the assistant allocates patients into each group through closed envelopes. The intervention group will be under the common treatment (medical treatment) along with psychotherapy based on psychological training, and the control group will only be treated as commonly.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Blinding will not be done in this study. Patients and therapists are aware of the study. After sampling by available method, the specimens were randomly divided into two groups of case and control. Given that the total number of samples is 24, 12 blocks are provided by expert statistician. Blocking will be used to create the number of samples assigned to each treatment group.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

Old Building of School of Health, In front of the 17th Shahrivar Hospital, Shahid Siadati Avenue, Namjoo St.

City

Rasht

Province

Guilan

Postal code

41446-66949

Approval date

2019-06-26, 1398/04/05

Ethics committee reference number

IR.GUMS.REC.1398.133

Health conditions studied

1

Description of health condition studied

Schizophrenia Disorder

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes

1

Description

Positive symptoms of schizophrenia disorder

Timepoint

Patients will be evaluated before the intervention, after the end of the intervention session and one month after the intervention.

Method of measurement

Patients will be evaluated by Positive and Negative Syndrome Scale (PNSS).

2

Description

Negative symptoms of schizophrenia disorder

Timepoint

Patients will be evaluated before the intervention, after the end of the intervention session and one month after the intervention.

Method of measurement

Patients will be evaluated by Positive and Negative Syndrome Scale (PNSS).

3

Description

Depression symptoms

Timepoint

Patients will be evaluated before the intervention, after the end of the intervention session and one month after the intervention.

Method of measurement

Patients will be evaluated by Beck Depression Scale.

4

Description

Symptoms of Anxiety

Timepoint

Patients will be evaluated before the intervention, after the end of the intervention session and one month after the intervention.

Method of measurement

Patients will be evaluated by Beck Anxiety Scale.

5

Description

Quality of Life

Timepoint

Patients will be evaluated before the intervention, after the end of the intervention session and one month after the intervention.

Method of measurement

Patients will be evaluated by SF36.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group will be treated as common with psychotherapy based on psychological training. The training will be run by a psychiatrist assistant who is familiar with psychological training techniques, within 6 weeks of each week, 1 session, 1-5 hours per hour. Patients will be evaluated before the intervention, after the end of the intervention session and one month after the intervention, with BDI depression tests, BAI anxiety, SF-36 quality of life, and positive and negative PANSS symptoms. The intervention will take place in a group. In this research, an interventional program for psychological training will be used based on study (20) and will be organized in 6 sessions of 1-5 / 1 hour and weekly. The following is provided below for the implementation of the training sessions: Session 1: Explain the nature of the schizophrenia and its symptoms. Second session: Explaining the cause of schizophrenia and the importance of family role in emotional support of patients. Session 3: An explanation of the drug treatment and the importance of continuing it in the recovery process. Session Four: Identifying starters and the risk of recurrence. Session 5: Problem-Solving Interventions in Patients. Session Six: Identify Stressful and Emerging Factors and Train Stress Management Techniques.

Category

Rehabilitation

2

Description

Control group: Individuals in the routine drug therapy group (Olanzapine will receive 20 to 25 mg twice daily, or Risperidone 6 mg daily twice daily).

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa hospital clinic

Full name of responsible person

Homa Zarrabi

Street address

15 khordad avenue, Shafa Hospital

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Rasht

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41939-55599

Phone

+98 13 3366 6268

Email

kavosh1400@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Homa Zarrabi

Street address

15 khordad St, Shafa hospital

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55599 -41939

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Research assistance University of Medical Sciences

Proportion provided by this source
50

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
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Aida Yahyazadeh
Position
Expert
Latest degree
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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data will be coded and unidentifiable, will be shared.

When the data will become available and for how long
Start the access period 3-6 months after printing the results

To whom data/document is available

All physicians and paramedics in the field of psychology

Under which criteria data/document could be used

For more information on rehabilitation methods for patients with psychiatric disorders

From where data/document is obtainable

Postal address: Shafa Hospital, 15 Khordad Street, Rasht, Iran - Email address: Kavosh1400@gmail.com

What processes are involved for a request to access data/document

The demandant will be responded to by the moderator after 3-5 days.

Comments