

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Comparison of the Effect of Psychoeducation with Continuous Care Model on Satisfaction of Patients with Schizophrenia and the Patient's caregiver from Mental Health Services Provision

Protocol summary

Study aim

Comparison of the Effect of Psychoeducation with Continuous Care Model on Satisfaction of Patients with Schizophrenia and the Patient's caregiver from Mental Health Services Provision

Design

This clinical trial with control group, three groups, single blind, randomized by blocked method, was performed on 150 patients with schizophrenia (75 people) and their main caregivers (75 people). Thus, each group consisted of 25 patients with schizophrenia and 25 main caregivers.

Settings and conduct

This clinical trial conducted in three groups, including psychoeducation, continuous care model, and control group by single blind at Ibn Sina Psychiatric Hospital in Mashhad. The researcher who performs the study statistics was blind to the study conditions.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The patient's main caregiver should be a first-degree relative and responsible for medical follow-up and patient care at home; Have at least a third-grade education. Exclusion criteria: main caregiver with mental disorders and taking medication in this area.

Intervention groups

In the psychoeducation group, sessions were designed and conducted for patients based on the content of the psychoeducation program for Patients with Schizophrenia at the Department of Psychiatry, University of Olomoch, Czech Republic sessions. In the main caregiver, psychoeducation sessions were designed and implemented according to Atkinson and Coia (1995) schizophrenic patients' family psychoeducation content. In the continuous care model group, both patients and main caregivers were trained separately based on Fazlullah Ahmadi's (2001) continuous care model. The control group received the routine care.

Main outcome variables

Satisfaction of patients with schizophrenia; Satisfaction of main care patients with schizophrenia.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180509039597N2**

Registration date: **2020-08-14, 1399/05/24**

Registration timing: **retrospective**

Last update: **2020-08-14, 1399/05/24**

Update count: **0**

Registration date

2020-08-14, 1399/05/24

Registrant information

Name

Azam Salarhaji

Name of organization / entity

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Iran (Islamic Republic of)

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salarha961@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-11, 1398/02/21

Expected recruitment end date

2020-05-10, 1399/02/21

Actual recruitment start date

2019-05-22, 1398/03/01

Actual recruitment end date

2020-01-20, 1398/10/30

Trial completion date

2020-06-27, 1399/04/07

Scientific title

Comparison of the Effect of Psychoeducation with Continuous Care Model on Satisfaction of Patients with Schizophrenia and the Patient's caregiver from Mental Health Services Provision

Public title

Comparison of the Effect of Psychoeducation with Continuous Care Model on Satisfaction

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

The desire of both the patient and the main caregiver to participate in the study The patient's main caregiver should be a first-degree relative and responsible for medical follow-up and patient care at home. Have at least a third-grade education

Exclusion criteria:

Physical, hearing, and visual impairments that interfere with the learning process The main caregiver of the patient with mental disorders and medication in this area

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **150**

Actual sample size reached: **144**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling was performed by Permuted block randomization method. Eligible patients were selected by convenience sampling and divided into three groups A, B and C by a researcher who was blind to the study. Then, 13 six- blocks were determined as a combination of groups A, B and C (AABBCC, BBCCAA, CCAABB, BACABC, ACABBC, etc.) and a number between 1 and 13 was assigned to each block. Based on the table of random numbers, the order of entry of blocks into the study and assignment of patients to intervention and control groups was determined. After selecting each patient, her main caregiver was included in the study and was placed in one of the intervention or control groups according to the patient.

Blinding (investigator's opinion)

Single blinded

Blinding description

The researcher who performs the study statistics be blind to the study conditions.

Placebo

Not used

Assignment

Parallel

Other design features

In this study, both the patient and the main caregiver will be intervened

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mashhad University of Medical Sciences

Street address

Vice chancellor for research, Mashhad University of Medical Sciences, next to the Hovezeh Cinema, University avenue, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

913881394

Approval date

2019-05-11, 1398/02/21

Ethics committee reference number

IR.MUMS.REC.1398.036

Health conditions studied**1****Description of health condition studied**

Schizophrenia

ICD-10 code

F20-F29

ICD-10 code description

Schizophrenia, schizotypal and delusional disorders

Primary outcomes**1****Description**

Satisfaction of patients with schizophrenia

Timepoint

Before the intervention, the time of discharge of the patient from the hospital, one month after the discharge of the patient from the hospital, two months after the discharge of the patient from the hospital

Method of measurement

The Verona Service Satisfaction Scale (VSSS) (2000) in patients

Secondary outcomes

1

Description

Satisfaction of the main caregiver

Timepoint

Before the intervention, the time of discharge of the patient from the hospital, one month after the discharge of the patient from the hospital, two months after the discharge of the patient from the hospital

Method of measurement

the Verona Service Satisfaction Scale (VSSS) (2000) in relatives

Intervention groups

1

Description

Intervention group: both the patient and the main caregiver received psychoeducation. Thus, psychoeducation sessions were designed based on the content of the psychoeducation program for patients with schizophrenia at the department of psychiatry, university of Olomouc, Czech republic. According to this protocol, sessions in groups of 10 people held during 6 sessions of one hour and twice a week as a group discussion when the patient is hospitalized. Also, in the main caregiver, psychoeducation sessions were held during 10 two-hour sessions in groups of 10 people, according to the Atkinson and Coia (1995) schizophrenic patients' family psychoeducation content.

Category

Prevention

2

Description

Intervention group: both the patient and the main caregiver received continuous care model. Patients and main caregivers separately was taught based on Fazlullah Ahmadi's continuous care model (2001) during four stages of identification (one two-hour session), sensitization (6 sessions and each 2-hour session), control (once every two weeks) and evaluation (at each stage) for 12 weeks.

Category

Prevention

3

Description

Control group: they received the routine care

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad, Ibn Sina psychiatric hospital

Full name of responsible person

Dr Fateme Mohareri

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Next Astan Ghods Naghlie, end Hor Ameli of the street, Mashhad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical 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

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

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

Mashhad University of Medical Sciences

Full name of responsible person

Abbas Heidary

Position

Faculty of Education, Mashhad University of Medical Sciences

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Name of organization / entity

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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

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Information on the main outcome is available for sharing

When the data will become available and for how long

One year after printing results

To whom data/document is available

My data will only be available to researchers working in academic and academic institutions

Under which criteria data/document could be used

Data will be available with permission from Mashhad University of Medical Sciences

From where data/document is obtainable

Vice chancellor for research, Mashhad University of Medical Sciences

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

You must apply for a deputy of Mashhad University of Medical Sciences

Comments