

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

The impact of family-centered group training based on the Atkinson-Coia model on the relapse and severity of symptoms in schizophrenic patients

Protocol summary

Study aim

The effect of family-centered group education (based on Atkinson and Coia model) on recurrence and severity of symptoms in schizophrenic patients admitted

Design

A randomized clinical trial, intervention and control groups, and sample size in each group: 50 patients.

Settings and conduct

This study was performed on 100 patients with schizophrenia in Qazvin 22 Bahman psychiatric hospital. The intervention group received their training from a psychiatric nurse. Before and after training sessions (6 months on a monthly basis), severity of symptoms was measured using PANSS questionnaire. Data were compared in different months in both groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria included definitive diagnosis of schizophrenia based on a psychiatrist's diagnosis, having at least one primary caregiver with no communication disorder and no prior psychiatric training. Exclusion criteria for the study were the dissatisfaction of the patient's primary caregiver to attend the training sessions or not to attend more than one.

Intervention groups

In the intervention group, in addition to drug therapy, family group training sessions, with the presence of the patient's primary caregiver, were held in three weekly sessions and each session for 90 minutes. The topics discussed at the meetings were in accordance with the Atkinson and Coia model. Important issues such as complete information about schizophrenia, relapse symptoms, treatments, patient-family, family and schizophrenia, rehabilitation, support organizations, and patient care. At the end of each session a question and answer session was conducted. In the control group only the usual drug therapy was unchanged and no educational intervention was performed.

Main outcome variables

Decrease in readmission; Decrease in patient-caregiver

involvement; Increase in family awareness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200220046561N1**

Registration date: **2020-03-12, 1398/12/22**

Registration timing: **retrospective**

Last update: **2020-03-12, 1398/12/22**

Update count: **0**

Registration date

2020-03-12, 1398/12/22

Registrant information

Name

Nasser Hajiaghaei

Name of organization / entity

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Iran (Islamic Republic of)

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+98 28 3368 5170

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-06-17, 1396/03/27

Expected recruitment end date

2018-03-19, 1396/12/28

Actual recruitment start date

2017-06-17, 1396/03/27

Actual recruitment end date

2018-03-19, 1396/12/28

Trial completion date

2018-05-02, 1397/02/12

Scientific title

The impact of family-centered group training based on the Atkinson-Coia model on the relapse and severity of symptoms in schizophrenic patients

Public title

The impact of family-centered group training based on the Atkinson-Coia model on the relapse and severity of symptoms in schizophrenic patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Definitive diagnosis of schizophrenia based on psychiatric diagnosis Having at least one primary caregiver with no communication impairment and no prior psychiatric training

Exclusion criteria:

The patient's primary caregiver's dissatisfaction with continuing to attend training sessions Absence of the patient's primary caregiver in more than one session of training sessions

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomized simple: Samples were divided into experimental and intervention groups by lottery (red and blue sheets).

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qazvin University of Medical Sciences

Street address

No92, 33 Ave,Shahid babaie Blvd, Qazvin Town

City

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Province

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Postal code

3414678113

Approval date

2017-06-08, 1396/03/18

Ethics committee reference number

IR.QUMS.REC.1395.34

Health conditions studied

1

Description of health condition studied

Severity of symptoms and Relapse of schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes

1

Description

Relapse of schizophrenia

Timepoint

6 and 9 months after the training program

Method of measurement

PANSS questionnaire

2

Description

Severity of the symptoms of schizophrenia

Timepoint

6 and 9 months after the training program

Method of measurement

PANSS questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Family-centered group training based on the Atkinson-Coia model

Category

Rehabilitation

2

Description

Control group: Drug therapy, without medication

changes
Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Qazvin 22 Bahman Hospital
Full name of responsible person
Mohamad Reaz Sheikhi
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Sponsors / Funding sources

1

Sponsor

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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
Qazvin University of Medical Sciences
Proportion provided by this source
60
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

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Person responsible for updating data

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Mental patient information is completely confidential

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

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable