

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 28 3368 5170

##### Email address

nhajiaghaee@gmail.com

##### 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

Qazvin

### Province

Qazvin

### 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  
**Street address**  
Bahonar Blvd, Qazvin University of Medical Sciences  
**City**  
Qazvin  
**Province**  
Qazvin  
**Postal code**  
1531534199  
**Phone**  
+98 28 3334 4504  
**Email**  
mmsheikhi1@yahoo.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**  
Qazvin University of Medical Sciences  
**Full name of responsible person**  
Mohammad Reza Sheikhi  
**Street address**  
Bahonar Blvd, Qazvin University Of Medical Sciences  
**City**  
Qazvin  
**Province**  
Qazvin  
**Postal code**  
1531534199  
**Phone**  
+98 28 3334 4504  
**Email**  
mmsheikhi1@yahoo.com  
**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

**Name of organization / entity**  
Qazvin University of Medical Sciences  
**Full name of responsible person**  
Mohammad Reza Sheikhi  
**Position**  
Assistant Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Medical Education  
**Street address**  
Bahonar Blvd, Qazvin University of Medical Sciences  
**City**  
Qazvin  
**Province**  
Qazvin  
**Postal code**  
1531534199  
**Phone**  
+98 28 3334 4504  
**Email**  
mmsheikhi1@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Qazvin University of Medical Sciences  
**Full name of responsible person**  
Nasser Hajiaghaei  
**Position**  
Emergency Response  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Nursery  
**Street address**  
Rahahan Blvd, Pastor Ave, 22 bahman hospital  
**City**  
Qazvin  
**Province**  
Qazvin  
**Postal code**  
3414678113  
**Phone**  
+98 28 3355 5978  
**Email**  
nhajiaghaee@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Qazvin University of Medical Sciences

**Full name of responsible person**

Mohammad Reza Sheikhi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Education

**Street address**

Bahonar Blvd, Qazvin University Of Medical Sciences

**City**

Qazvin

**Province**

Qazvin

**Postal code**

1531534199

**Phone**

0098283344504

**Email**

mmsheikhi1@yahoo.com

**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