

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Comparing the Outcomes and Cost-effectiveness of Two Model of Case-manager system for Severe Mentally Ill Patients: general practitioner and nurses.

#### Protocol summary

##### Summary

The objective of this study is to compare the clinical outcomes and cost-effectiveness of two models of case-manager services (home-visit) for serious mentally ill patients by general practitioners and nurses. The target population is the individuals with schizophrenia and bipolar mood disorders spectrum living in Karaj. 180 participants will be selected from mental hospitals or wards after discharge or from outpatients services and randomly allocated into three treatment groups. In the first group, the intervention will be carried out by general practitioners by providing 12-month consequences home-visit. In each visit, the patients will be supervised for their medication prescribed by the patient's psychiatrist, the patient and caregivers are trained, the symptoms of disease and the drugs side effects are reported to the patient's psychiatrist, and finally drugs are prescribed if urgently needed. In the second group, except for prescribing drugs, the same services will be provided by a nurse. In the third group no intervention will be provided. The instruments of YMRS, FEIS, PANSS, caregiver's knowledge questionnaire, KELS, quality of life-36, CSQ-8, GHQ, cost questionnaire will be used to measure clinical outcomes and cost-effectiveness of the interventions.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138807251959N3**  
Registration date: **2010-08-31, 1389/06/09**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2010-08-31, 1389/06/09

##### Registrant information

###### Name

Seyed Kazem Malakouti

###### Name of organization / entity

Iran University of Medical Science - Tehran Psychiatric Institute

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6655 0200

###### Email address

malakouti.k@iums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Ministry of Health, Mental Health Bureau, Family Research Institute of University of Shahid Beheshti, Mental Health Research Center, Mental Health Research Network, University of Social Welfare and Rehabilitation.

##### Expected recruitment start date

2010-03-06, 1388/12/15

##### Expected recruitment end date

2010-09-22, 1389/06/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing the Outcomes and Cost-effectiveness of Two Model of Case-manager system for Severe Mentally Ill Patients: general practitioner and nurses.

##### Public title

Aftercare Services for severe mentally ill patients

### **Purpose**

Health service research

### **Inclusion/Exclusion criteria**

Inclusion criteria: Presence of schizophrenia or bipolar spectrum disorders, age 15-60 years old, having at least one hospitalization history for exacerbation in her/his past history, need for aftercare services according to his/her psychiatrist due to low level of compliance

Exclusion criteria: having organic brain disorder, having concurrently substance use disorders, using similar services from other sources

### **Age**

From **15 years** old to **60 years** old

### **Gender**

Both

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **180**

### **Randomization (investigator's opinion)**

N/A

### **Randomization description**

### **Blinding (investigator's opinion)**

Double blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Tehran Psychiatric Institute Ethic Committee

##### **Street address**

Shahied Mansuri St., Niayesh St., Sattarkhan Ave.,  
Tehran

##### **City**

Tehran

##### **Postal code**

1443813444

#### **Approval date**

2010-12-01, 1389/09/10

#### **Ethics committee reference number**

06/22/10/88

## **Health conditions studied**

### 1

#### **Description of health condition studied**

schizophrenia

#### **ICD-10 code**

F20

#### **ICD-10 code description**

Schizophrenia

### 2

#### **Description of health condition studied**

schizoaffective disorder

#### **ICD-10 code**

F25

#### **ICD-10 code description**

Schizoaffective disorders

### 3

#### **Description of health condition studied**

Bipolar affective disorder

#### **ICD-10 code**

F31

#### **ICD-10 code description**

Bipolar affective disorder

## **Primary outcomes**

### 1

#### **Description**

relapse and rehospitalization due to exacerbation of disorder

#### **Timepoint**

at the beginning and after 12 months of intervention

#### **Method of measurement**

observing the course of disease

### 2

#### **Description**

caregiver's knowledge

#### **Timepoint**

at the beginning and after 12 months of intervention

#### **Method of measurement**

caregiver's knowledge questionnaire

### 3

#### **Description**

caregiver's burden

#### **Timepoint**

at the beginning and after 12 months of intervention

#### **Method of measurement**

Family burden interview scale

### 4

#### **Description**

health of caregiver

#### **Timepoint**

at the beginning and after 12 months of intervention

**Method of measurement**

general health questionnaire

**5****Description**

patient's satisfaction from services

**Timepoint**

at the beginning and after 12 months of intervention

**Method of measurement**

client satisfaction questionnaire-8

**6****Description**

patient's quality of life

**Timepoint**

at the beginning and after 12 months of intervention

**Method of measurement**

quality of life questionnaire-36

**7****Description**

cost of treatment, cost-effective evaluation

**Timepoint**

at the beginning and after 12 months of intervention

**Method of measurement**

cost questionnaire

**8****Description**

life skills of patients

**Timepoint**

at the beginning and after 12 months of intervention

**Method of measurement**

KELZ life skill scale

**9****Description**

severity of psychopathology

**Timepoint**

before and after one year of intervention

**Method of measurement**

Young Mania Rating Scale (YMRS), Positive and Negative Syndrome Scale (PANSS)

**Secondary outcomes**

empty

**Intervention groups****1****Description**

The participants receive home-visit by a general practitioner monthly for 12 consecutive months. GPs supervise the patients' drug treatment according to the patients' psychiatrist prescription, train the patient and her/his caregivers according to 12-month topics, report

the patients mental status/drug side effects to the psychiatrist, and prescribe drugs in case of emergency and necessities.

**Category**

Prevention

**2****Description**

The participants receive home-visit by a nurse monthly for 12 consecutive months. Nurses supervise the patients' drug treatment according to the patients' psychiatrist prescription, train the patient and her/his caregivers according to 12-month topics, report the patients mental status/drug side effects to the psychiatrist

**Category**

Prevention

**3****Description**

The control group receives the treatment facilities which are available "as usual services" from society. They are contacted by telephone each 3- month to complete the cost questionnaire.

**Category**

N/A

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Rasool Akram hospital, inpatient and outpatient services

**Full name of responsible person**

Seyed Kazem Malakouti

**Street address**

Niayesh St., Sattarkhan Ave., Tehran

**City**

Tehran

**2****Recruitment center****Name of recruitment center**

Iran hospital

**Full name of responsible person**

Neda Esmaeli

**Street address**

Km 6, Karaj specific road, Tehran

**City**

Tehran

**3****Recruitment center****Name of recruitment center**

Razi Hospital

**Full name of responsible person**

Dr. Arash Mirabzadeh

**Street address**

**City**

Tehran

**4**

**Recruitment center**

**Name of recruitment center**

private offices of Dr. Hajian Motlagh, Dr. Abdollahsani, Dr. Bayat Makoo, Dr. Rastegar

**Full name of responsible person**

Seyed Kazem Malakouti

**Street address**

**City**

Tehran

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Mental Health Research Center

**Full name of responsible person**

Dr. Mehrdad Eftekhari

**Street address**

mansouri st. niayesh st. Sattarkhan Ave. Tehran  
Psychiatric Institute

**City**

tehran

**Grant name**

**Grant code / Reference number**

5773

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mental Health Research Center

**Proportion provided by this source**

**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*

**2**

**Sponsor**

**Name of organization / entity**

Mental Health Research Network

**Full name of responsible person**

Dr. Jafar Bolhari

**Street address**

Mansuri st. niayesh st. Sattarkhan Ave. Tehran  
Psychiatric Institute

**City**

Tehran

**Grant name**

**Grant code / Reference number**

3077

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mental Health Research Network

**Proportion provided by this source**

**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*

**3**

**Sponsor**

**Name of organization / entity**

University of Social welfare and rehabilitation

**Full name of responsible person**

Dr. Arash Mirabzadeh

**Street address**

Rey district, Amin Abad, Razi hospital

**City**

Tehran

**Grant name**

**Grant code / Reference number**

801/4/88/178

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

University of Social welfare and rehabilitation

**Proportion provided by this source**

**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*

**4**

**Sponsor**

**Name of organization / entity**

Family research institute, Shahid Beheshti University  
of Medical Sciences

**Full name of responsible person**

Dr. Narjes Chimeh

**Street address**

Daneshjoo Blvd., Yaman st., Chamran highway,

**City**

Tehran

**Grant name**

**Grant code / Reference number**

850/41

**Is the source of funding the same sponsor organization/entity?**  
Yes

**Title of funding source**  
Family research institute, Shahid Beheshti University of Medical Sciences

**Proportion provided by this source**

**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

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Iran University of Medical Sciences- Tehran  
Psychiatric Institute

**Full name of responsible person**  
Dr. Seyed Kazem Malakouti

**Position**  
Fellow, Geriatric Psychiatry

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Position**  
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**Other areas of specialty/work**

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## 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*