

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)

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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

Name of organization / entity
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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Iran University of Medical Science - Tehran Psychiatric
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Position
Fellow, Geriatric Psychiatry

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