

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Survey of efficacy and effectiveness of after discharge services and severe and chronic patients phone call follow up performed by the nursing staff

Protocol summary

Summary

the objective of this study is to compare the clinical outcomes and cost-effectiveness of model of case-manager services (home-visit) for serious mentally ill patients by nurses. The target population is the individuals with schizophrenia and bipolar mood disorders spectrum living in Tehran. 180 participants will be selected from mental hospitals or wards after discharge or from outpatients services and randomly located into three groups. In the first group, the intervention will be carried out by nurses 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 side effects of drugs are reported to the patient's psychiatrist. In the second group by having a phone call, patient have been recalled for their next visit in the clinic. In the third group no intervention will be provided. The instruments of YMRS, FEIS, PANSS, caregiver's knowledge questionnaire, KELS, quality of life questionnaire, SF-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: **IRCT201110261959N5**

Registration date: **2012-01-19, 1390/10/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-01-19, 1390/10/29

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

mental health research center of Tehran (Pardise Hemat) university of medical sciences, Shahid Beheshti university of medical sciences, Tehran (Pardise Hemat) university of medical sciences

Expected recruitment start date

2007-12-01, 1386/09/10

Expected recruitment end date

2009-03-01, 1387/12/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Survey of efficacy and effectiveness of after discharge services and severe and chronic patients phone call follow up performed by the nursing staff

Public title

Treatment follow up of severe and chronic 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 her/his psychiatric 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)

Randomized

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**

Research Center of Shahid Beheshti University of Medical Science

Street address

near of Taleghani Hospital, Evin, Chamran

City

Tehran

Postal code**Approval date**

2008-06-15, 1387/03/26

Ethics committee reference number

54/26/3/87

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 disorders

ICD-10 code

F31

ICD-10 code description

Bipolar affective disorders

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 of 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

Intervention groups, calling case managers, include nurses and phone following. The participants receive home-visits by a case-manager monthly for 12 consecutive months. The first group includes nurses. They supervise the patient's drug treatment according to the patient's 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. In the second group, by having a phone call, patients have been recalled for their next visit in the clinic. The control group is the third group that 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

Prevention

2

Description

In the control group no intervention will be provided. They are contacted by telephone each 3-month to complete the cost questionnaire and asking probability of admission at 3-month ago. The patients receive the treatment facilities which are available "as usual services" from society.

Category

Prevention

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

Safiye Amin

Street address

Niayesh St. Sattarkhan Ave. Tehran

City

Tehran

3

Recruitment center

Name of recruitment center

Razi Hospital

Full name of responsible person

Dr. Arash Mirabzadeh

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mental Health Research Center

Full name of responsible person

Mehdi Nasr Esfahani

Street address

Mansuri st. Niayesh st. Sattarkhan ave. Tehran
Psychiatric Institute

City

Tehran

Grant name**Grant code / Reference number**

5773/26/26/پ

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

Shahid Beheshti University of Medical Science

Full name of responsible person

Alireza Zahiroddin

Street address

near of Taleghani Hospital, Evin, Chamran

City

Tehran

Grant name**Grant code / Reference number**

3/877-ع-ر

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

Yes

Title of funding source

Shahid Beheshti University of Medical Science

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

Tehran(Pardise Hemat) University of Medical Science

Full name of responsible person

Dr.Abolfazl Khosravi

Street address

Between Sheikh Fazlollah and Chamran, Shahid
Hemat

City

Tehran

Grant name**Grant code / Reference number**

161 / م/ت

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

Yes

Title of funding source

Tehran(Pardise Hemat) University of Medical Science

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

Tehran university of medical science-Tehran
psychiatric Institute

Full name of responsible person

Dr.Seyed Kazem Malakouti

Position

Fellow,Geriatric psychiatry

Other areas of specialty/work**Street address**

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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