Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effectiveness of telephone follow-up in comparison of treatment as usual on admission rate, duration of hospital stay and psychopathology severity in people with severe mental disorders in 18 to 65 years in Iran: A randomized control trial

Protocol summary

Summary

This study aim to determine whether telephone follow-up reduce the number of re hospitalizations, length of hospital stay, and psychopathology severity in patients with severe mental disorders. This is a randomized parallel group controlled trial. Patients with schizophrenia, schizoaffective and bipolar disorder in the age range of 15 to 65 years will be recruited. The patients have to be living with a family member and they should not suffer from severe physical or neurological conditions or mental retardation at the same time. A total of 72 patients are recruited from inpatient units of Iran Mental Hospital that is a university affiliated hospital. There is equal allocation of participants between groups. The nature of these services is in such way that prevents blinding of participants. Thus, it was not possible to blind the clinician responsible for the follow-up evaluations to the intervention and control group patients because they were in direct contact with patients. But, the people in data analyzing group will be blind to the intervention and control group patients. After obtaining informed written consent, the patients are randomly allocated into intervention and control groups. The control group will receive treatment as usual (TAU) but the intervention group receives telephone follow-up in addition to TAU. Patients will be followed for 12 months after discharge and will be evaluated in admission and discharge time and also 6 and 12 months after discharge. The primary outcome measures are length of hospital stay and any psychiatric hospitalization in the 12 month follow-up.

General information

Acronym

TEFU

IRCT registration information

IRCT registration number: **IRCT2014051717730N1**
Registration date: **2015-01-09, 1393/10/19**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-01-09, 1393/10/19

Registrant information

Name

Belgheis Paad

Name of organization / entity

Iran University of Medical Sciences, Tehran Psychiatric Institute

Country

Iran (Islamic Republic of)

Phone

+98 21 6650 9024

Email address

drpad527@yahoo.com

Recruitment status

Recruitment complete

Funding source

Mental Health Research center, Vice Chancellor for Research of Iran University of Medicine Sciences

Expected recruitment start date

2014-09-12, 1393/06/21

Expected recruitment end date

2014-12-10, 1393/09/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effectiveness of telephone follow-up in comparison of treatment as usual on admission rate, duration of hospital stay and psychopathology severity in people with severe mental disorders in 18 to 65 years in Iran: A randomized control trial

Public title
Effectiveness of telephone follow-up on admission rate, duration of hospital stay and psychopathology severity in people with severe mental disorders in 18 to 65 years in Iran

Purpose
Health service research

Inclusion/Exclusion criteria
inclusion criteria includes: Patients with bipolar disorder (bipolar), schizophrenia and schizoaffective disorder patients experienced hospitalization at least once. It should be noted that the diagnosis is based on clinical diagnosis by a psychiatrist and faculty member at the last admission is considered; Age 18 to 65 years; living in a defined area; Living with family; Persian language; Patient and family satisfaction; The availability of a person for a year; Having a land line or cell line that is always available. Exclusion criteria : serious physical or neurological illnesses; To prevent any contamination of the results, the patient should not be participated in treatment programs and interventions for psychiatric patients during the last six months more than usual ;

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Randomization will be provided by an independent statistician at the Mental Health Research Center. Eligible patients are assigned to intervention or control groups with allocation concealment.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Iran University of Medical Sciences

Street address
Hemmat Highway, Iran University of Medical Sciences

City
Tehran

Postal code

Approval date
2014-09-10, 1393/06/19

Ethics committee reference number
93/6/19/24729

Health conditions studied

1

Description of health condition studied
schizoaffective disorders

ICD-10 code
F25

ICD-10 code description
Schizoaffective disorders

2

Description of health condition studied
Schizophrenia Disorder

ICD-10 code
F20

ICD-10 code description
Schizophrenia

3

Description of health condition studied
Manic episode, Bipolar affective disorder

ICD-10 code
F30, F31

ICD-10 code description
Manic episode, Bipolar affective disorder

Primary outcomes

1

Description
rehospitalization frequency

Timepoint
6 and 12 mounths after discharge

Method of measurement
Questionnaire

2

Description
lenght of hospital stay

Timepoint
6 and 12 mounths after discharge
Method of measurement
Questionnaire

Secondary outcomes

1

Description
Psychopathology severity
Timepoint
Admission time, discharge time, 6 and 12 months after discharge
Method of measurement
Questionnaire

Intervention groups

1

Description
Treatment as usual in addition to telephone follow up in intervention group
Category
Other

2

Description
Treatment as usual (routine visit) in control group
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Iran Mental Hospital
Full name of responsible person
Belgheis Paad
Street address
7th km of Karaj Special Road, Iran Mental Hospital
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mental Health Research Center, Vice Chancellor for Research of Iran University of Medical Sciences
Full name of responsible person
Mehrdad Eftekhar Ardebili
Street address
Mental Health Research Center, Shahid Mansouri Alley, Niayesh St., Sattarkhan Ave.
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mental Health Research Center, Vice Chancellor for Research of Iran University of Medical Sciences
Proportion provided by this source
100
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 Psychiatric Institute, Iran University of Medical Sciences
Full name of responsible person
Ahmad Hajebi
Position
MD, Associate Professor Of Psychiatry
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Person responsible for updating data

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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