

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 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 months after discharge

#### Method of measurement

Questionnaire

### 2

#### Description

length of hospital stay

**Timepoint**

6 and 12 months 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 Eftekhari 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

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

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

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## Person responsible for updating data

### Contact

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**City**  
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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*