

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### Effect of hospital base nursing home care on severity of symptoms in bipolar 1 discharged patients at 22 bahman hospital in qazvin in 1398

#### Protocol summary

##### Study aim

Improving mental health of type 1 bipolar patients and their support after discharge

##### Design

Samples will be randomly divided into intervention and control groups. the sample selection sequences will be determined by the project statistical consultant using random allocation software consisting of 15 hex blocks, which will be placed in each block of three sample groups. Envelopes are numbered from one to 90 (sample size) in order to cover the process of random assignment of group names.

##### Settings and conduct

We have two intervention and control groups. the demographic and Yang questionnaires were filled out by patients after discharge and then performed for three months and then at the end of three months again the patients completed the Yang questionnaire to assess the severity of symptoms. month is considered as both groups fill in the questionnaire monthly without intervention. the study will be conducted at 22 Bahman psychiatric hospital.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria for this study are patient and family informed consent and bipolar definitive diagnosis of type 1 (mood disorder phase 1) and having at least 18 years of age and mental disability. discard the research and also complete the questionnaire if it is incomplete.

##### Intervention groups

Includes nursing care aimed at promoting the mental health of the patient, accessing basic mental health care, evaluating the patient's mental health, family support and education, and patient support and education.

##### Main outcome variables

Rapid return to pre-disease performance and patient return to society and prevention of recurrence of a faulty cycle of recurrence and readmission and reduction of hospital bed occupation and imposing high treatment costs for the family and treatment system

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190928044911N1**

Registration date: **2020-02-01, 1398/11/12**

Registration timing: **retrospective**

Last update: **2020-02-01, 1398/11/12**

Update count: **0**

##### Registration date

2020-02-01, 1398/11/12

##### Registrant information

##### Name

Arghvan Raeisolhagh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 28 3377 2524

##### Email address

a.raeisolhagh@qums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-12-06, 1398/09/15

##### Expected recruitment end date

2020-01-20, 1398/10/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of hospital base nursing home care on severity of symptoms in bipolar 1 discharged patients at 22 bahman hospital in qazvin in 1398

**Public title**

Effect of hospital base nursing home care on severity of symptoms in bipolar 1 discharged patients

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients' inclusion criteria for this study: patient and family informed consent Bipolar type I definite diagnosis (mood disorder phase 1) Having at least 18 years of age Mental disability

**Exclusion criteria:**

The exclusion criteria can also be withdrawn completely at any time when the patient or his / her family refuses to participate in the study The questionnaire will be excluded if is incomplete.

**Age**

From **18 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **90**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Samples will be randomly divided into intervention and control groups. The sample selection sequences will be determined by the project statistical consultant using random allocation software consisting of 15 hex blocks which will be placed in each block of three sample groups. In order to cover the process of random assignment of the names of groups placed in envelopes, these envelopes are numbered from one to 90 and arranged in a box, respectively, by the researcher making sampling during the envelope content. However, the envelope content represents the study groups, and the samples will be selected from the first envelope in order of number after entering the study and, depending on the envelope content, will fall into one of the study groups.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

National Committee on Ethics in Biomedical Research of Qazvin University of Medical Sciences

**Street address**

Bahonar Blvd.

**City**

Qazvin

**Province**

Qazvin

**Postal code**

3419759811

**Approval date**

2019-11-21, 1398/08/30

**Ethics committee reference number**

IR.QUMS.REC.1398.192

**Health conditions studied****1****Description of health condition studied**

Bipolar type 1( manic phase )

**ICD-10 code**

F31

**ICD-10 code description**

Bipolar disorder

**Primary outcomes****1****Description**

Severity of symptoms in bipolar 1

**Timepoint**

Evaluation of severity of symptoms before and after intervention for 3 months and then for monthly follow-up for 6 months.

**Method of measurement**

Yang questionnaire

**Secondary outcomes****1****Description**

Severity of symptoms in bipolar 1

**Timepoint**

Evaluation of severity of symptoms before and after intervention for 3 months and then for monthly follow-up for 6 months.

**Method of measurement**

Yang questionnaire

**Intervention groups**

## 1

### Description

Intervention group: for three months (home nursing care) includes promotion of patient mental health, access to basic mental health care, evaluation of patient mental health, family support and education, and patient support and education. telephone calls are made every 15 days and patient and family appointments are made monthly.

### Category

Rehabilitation

## 2

### Description

Control group: In the control group, no interventions are performed by the investigator. Patients receive their routine treatments.

### Category

Rehabilitation

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Qazvinu niversity of medical sciences, 22 bBahman Psychiatric Hospital

#### Full name of responsible person

Arghavan Raeisolhagh

#### Street address

Second floor, Block 8 , Farabi of 54 unit, Rahmat alley, Salman Farsi Street, Valfajr St, Kosar town

#### City

Qazvin

#### Province

Qazvin

#### Postal code

3471945473

#### Phone

+98 28 3377 2524

#### Fax

#### Email

a.raeisolhagh@gmail.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Qazvin University of Medical Sciences

#### Full name of responsible person

Manochehr Mahram

#### Street address

Bahonar Blvd.

#### City

Qazvin

#### Province

Qazvin

#### Postal code

3419759811

#### Phone

+98 28 3337 5518

#### Fax

+98 28 3337 5518

#### Email

chancellor@qums.ac.ir

#### Web page address

http://qums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Qazvin University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

*empty*

#### Country of origin

#### Type of organization providing the funding

Academic

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Qazvin University of Medical Sciences

#### Full name of responsible person

Arghvan Raeisolhagh

#### Position

Nurse

#### Latest degree

Bachelor

#### Other areas of specialty/work

Nursery

#### Street address

Second floor, Block 8 , Farabi of 54 unit, Rahmat alley, Salman Farsi Street, Valfajr St, Kosar town

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Qazvin University of Medical Sciences

**Full name of responsible person**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Arghvan Raeisolhagh

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available