Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of hospital base nursing home care on severity of symptoms in bipolar 1dischargheد patients at 22 bahman hospital in qazvin in1398

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 1discharghed patients at 22 bahman hospital in qazvin in1398

Public title

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

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Fax

Email
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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.

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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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Email
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Person responsible for scientific inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person
Arghvan Raeisolhagh

Position
Nurse

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Person responsible for updating data

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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