Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of home nursing care on the quality of life in patient with major depression referring to educational-trearment Razi psychiatric center of Urmia in 2019-2020

Protocol summary

Study aim

Determining the effect of home nursing care on the quality of life of patients with major depression in 1399 in Razi Psychiatric Educational and Medical Center in Urmia

Design

A clinical trial with a control group, without blindness, randomized on 50 patients, was used to randomize the card in two ways: control and intervention and selection of each card by the participants.

Settings and conduct

The research population includes clients with a diagnosis of major depression in Razi Psychiatric Educational and Medical Center in Urmia. Using the available sampling method and taking into account the sample size, 50 people with inclusion criteria will be selected and randomly placed in two groups of intervention and control. The control group will not receive home nursing care. . The home care program for the intervention group will be 5 to 6 sessions once every two weeks for 1.5 to 2 hours over 3 months. The McGill Questionnaire will be completed again.

Participants/Inclusion and exclusion criteria

1.Definitive diagnosis of major depression recorded in the patient file 2. Willingness to collaborate in research 3. Lack of mental retardation based on the case 4. Living in the city of Urmia or Khoy 5. Age range 18 to 60 years 6. Able to speak Turkish or Persian and answer questionnaires 7. No drug addiction except smoking 8. Not living in a shelter covered by support centers

Intervention groups

The patient is randomly selected and receives nursing care in the intervention group every 3 months and every two weeks, and the control group does not receive any intervention.

Main outcome variables

Improving the quality of life; increasing efficiency; reducing the length of hospital stay; preventing recurrence and readmission

General information

Reason for update

The sampling date was selected from 17.5 and the date of receipt of the code is 22.5, while in practice the sampling was after obtaining the code and the reason for this difference was due to the registration of the sampling date and the requested edits after that by the center and interruption. has been created

Acronym

IRCT registration information

IRCT registration number: **IRCT20140212016564N13**
Registration date: **2020-08-12, 1399/05/22**
Registration timing: **prospective**

Last update: **2021-07-05, 1400/04/14**
Update count: **1**

Registration date

2020-08-12, 1399/05/22

Registrant information

Name

Molood Radfar

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 44 1275 4961

Email address

radfar.m@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2020-08-15, 1399/05/25
Expected recruitment end date
2020-08-29, 1399/06/08
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of home nursing care on the quality of life in patient with major depression referring to educational-trearment Razi psychiatric center of Urmia in 2019-2020

Public title
The effect of home nursing care on the quality of life in patient with major depression referring to educational-trearment Razi psychiatric center of Urmia in 2019-2020
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
Definitive diagnosis of major depression recorded in the file Willingness to cooperate Lack of mental retardation Able to speak Persian or Turkish No drug addiction except smoking Lack of residence in accommodation covered by welfare Age between 18-60 years
Exclusion criteria:
Lack of patient consent to continue treatment Long-distance travel and transfer to another city Exacerbation of the disease and hospitalization
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Using the available sampling method and taking into account the drop in samples, 50 people with inclusion criteria were selected and randomly selected in the stages of preparation for discharge of patients who have a diagnosis of major depression in the file by selecting one of the two cards containing the group content. The intervention or control group is divided into two groups) will be divided into two groups of intervention and control. Thus, each of the intervention groups will have 25 people and the control group will have 25 people. The control group will not receive home nursing care. The groups will fit together and there will be the same number of people receiving ECT in both 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
Ethics Committee of Urmia University of Medical Sciences
Street address
Khoy Imam Hossein Square Shams Tabrizi dead end
City
KHOY
Province
West Azarbaijan
Postal code
5818736461
Approval date
2019-10-07, 1398/07/15
Ethics committee reference number
IR.UMSU.REC.1398.268

Health conditions studied

1

Description of health condition studied
major depression
ICD-10 code
F06.3
ICD-10 code description
Mood disorder due to known physiological condition

Primary outcomes

1

Description
Quality of life
Timepoint
Before intervention and 3 months later and 6 months after
Method of measurement
Quality of life score in MC GILL questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Home nursing care Implementation of home care program for the intervention group in 5 to 6 sessions once every two weeks for 1.5 to 2 hours for 3 months depending on the needs of patients and telephone follow-up program in the first month After discharge 3 times a week, in the second month 2 times a week and in the third month after discharge once a week.The care provided by the researcher includes client assessment, scheduling that includes counseling and training programs, and intervention programs. In educational programs, education is provided to the patient and family on how to use drugs and side effects, communication skills, social skills, self-care and help to better understand the disease and existing treatments. They will be face to face and orally.
Category
N/A

2

Description
Control group: They do not receive any intervention
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi Educational and Medical Center of Urmia
Full name of responsible person
Mahsa Koohi
Street address
Khoy Imam Hossein Square Shams Tabrizi dead end
City
KHoy
Province
West Azarbaijan
Postal code
5818736461
Phone
+98 44 3366 9694
Email
mahsa2144@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Iraj Mohebi
Street address
Nazlou road
City
Urmia
Province
West Azarbaijan
Postal code
571478334
Phone
+98 44 3275 4961
Email
mahsa2144@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Oroumia 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
Oroumia University of Medical Sciences
Full name of responsible person
Molood Radfar
Position
associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Khoy Imam Hossein Square Shams Tabrizi dead end
City
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Province
West Azarbaijan
Postal code
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Email
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Person responsible for scientific inquiries

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Full name of responsible person
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Phone
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Email
mahsa2144@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Molood Radfar
Position
associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
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mahsa2144@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Documentation will be published in the form of an article. All demographic characteristics such as age, sex, level of education, job position, suicide, receiving ECT can be published. Also, the quality of life in people can be published
When the data will become available and for how long
Access starts 3 months after the results are published
To whom data/document is available
Available to all researchers in the field of psychiatry
Under which criteria data/document could be used
Compare demographic characteristics with quality of life or two groups with each other
From where data/document is obtainable
Radfar: Associate Professor Mradfar1343@gmail.com Mahsa Koohi: Master of Urmia University of Medical Sciences mahsa2144@gmail.com-09382892144 Leila Aliloo: Assistant Professor Urmia University of Medical Sciences alilueiyla@gmail.com
What processes are involved for a request to access data/document
Send e-mail and in case of no response after one day by phone and coordination with research members and if you agree to provide information for about a week
Comments