

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

The effect of home nursing care on the quality of life in patient with major depression referring to educational-treatment 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-treatment 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-treatment 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

AgeFrom **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

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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 aliluleiyla@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**Person responsible for updating data****Contact****Name of organization / entity**

Oroumia University of Medical Sciences

Full name of responsible person

Molood Radfar

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