Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The Effect of Education According to Roys Adaptation Model on the Quality of life of Family caregivers of Mental patients with a History of Admission to Mental Hospitals of Armed Force

Protocol summary

Study aim
This study aimed to investigate the effect of education based on the adaptive pattern on the quality of life of home-care carers in psychiatric patients.

Design
Clinical randomized controlled trials

Settings and conduct
A total of 50 home caregivers , military hospitals in Bushehr,available sampling method, two groups of tests and control. Quality of care was assessed by Sf-36 quality of life questionnaire before and one month after intervention. Data were analyzed using Spss software.

Participants/Inclusion and exclusion criteria
Inclusion criteria include the first-degree dependent who is the main caregiver and lives with the patient at home, with cyclical upsurges, having informed consent for participation in the study, having a child aged between 20-60 years without any physical defects, mental illness Or taking mental drugs, addiction and misinformation, the absence of another crisis, such as the divorce or death of loved ones in the last six months, and the care of a patient with a history of hospitalization in military hospitals. Exit criteria for absenteeism in more than one session, other critical events such as divorce or death of loved ones, participation in another educational program and reluctance to continue studying

Intervention groups
Educational intervention is performed in the experimental group. In the control group, no intervention will be performed

Main outcome variables
Quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190130042566N1**
Registration date: **2019-02-22, 1397/12/03**
Registration timing: **retrospective**

Last update: **2019-02-22, 1397/12/03**
Update count: **0**

Registration date
2019-02-22, 1397/12/03

Registrant information

Name
Sahar Nezameslami

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 77 3344 6894

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saharnezameslami@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-10-27, 1397/08/05

Expected recruitment end date
2018-12-26, 1397/10/05

Actual recruitment start date
2018-10-27, 1397/08/05

Actual recruitment end date
2018-12-26, 1397/10/05

Trial completion date
2019-01-25, 1397/11/05

Scientific title
The Effect of Education According to Roys Adaptation Model on the Quality of life of Family caregivers of

Mental patients with a History of Admission to Mental Hospitals of Armed Force

Public title
The effect of education of Roy adaptation model on quality of life
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Having ages 20-60 years Without any mental disorder or mental illness, addiction and background There is no other crisis such as the divorce or death of loved ones in the last six months The care of a mental disorder with a history of admission to military hospital
Exclusion criteria:
A family member who has previously been trained in adaptive behavior A member of the family who is undergoing neuro-psychological treatment
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **50**
Actual sample size reached: **46**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization using a random number table in such a way that two rows of rows and columns were arranged from 01 to 50, then by rotating the pencil tip of the selected numbers up to 25 persons were assigned to the control group. The remaining 25 were placed in the test group
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
50 subjects were randomly assigned to randomly assigned to two groups of test and control. The training test group was based on the adaptive pattern

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic committe of Aja of Medical Science
Street address
Navy Base,Bushehr
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Boushehr
Postal code
۷۵۱۸۶۳۳۱۱۳
Approval date
2018-12-23, 1397/10/02
Ethics committee reference number
IR.AJAUMS.REC.1397.064

Health conditions studied

1

Description of health condition studied
Quality of life
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Quality of life
Timepoint
Beginning of study and one month after the intervention
Method of measurement
Quality of life questionnaire Sf-36

Secondary outcomes

empty

Intervention groups

1

Description
An average weekly education was provided for 90 minutes in five consecutive sessions by an experienced researcher (nursing masters) and a clinical psychologist. All participants in the test group were trained in one class. Educational sessions were presented through lectures, questions and answers, discussion and discussion, expression of experiences, thoughts and feelings of caregivers about life with mental patients and giving educational pamphlets. The tool used for teaching slides and the place of training for the auditorium of Khatam-ol-Anbia Hospital was Navy .Educational materials in the field of incompatible behaviors include how to deal with the behavioral problems of psychiatric patients such as aggression, isolation and confinement, suicide and intercourse, sleep disorders and nutrition, irritability, hallucinations and delusions, measures when refusing the patient Drug use, anxiety and patient fears, family planning interventions, social skills, and apprenticeships. Also, training was provided in the form of a variety of psychiatric disorders, drug treatments and

drug-related side effects, and measures taken before and after non-pharmacological treatments such as ect.

Category

N/A

2

Description

Control group: Home careers do not receive psychological intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

khatamolanbia Naval force hospital

Full name of responsible person

Sahar Nezameslami

Street address

Navy base., Bushehr

City

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2

Recruitment center

Name of recruitment center

Amiralmomnin hospital of Air force

Full name of responsible person

Sahar Nezameslami

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Dr- Armin Zareeian

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Phone

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Email

f.soltannezhad@ajaums.ac.ir

Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Artesh 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

Artesh University of Medical Sciences

Full name of responsible person

Sahar Nezameslami

Position

Student

Latest degree

Bachelor

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
Tables of dimensions of quality of life and demographic variables

When the data will become available and for how long
2019

To whom data/document is available
Researchers working in academic institutions

Under which criteria data/document could be used
Nurses can use data and analysis methods

From where data/document is obtainable
saharnezameslami@yahoo.com

What processes are involved for a request to access data/document
Having a student card with a student number, or a valid university identification card

Comments