Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The Effect of Home Visitation on Patient Self-Efficacy and Family Psychological Burden of Schizophrenia Patients

Protocol summary

Study aim
Determine the effect of home visit on patient self-efficacy and family psychological burden of schizophrenia patients
Design
This study was a randomized clinical trial with two groups (intervention and control), pre and post-test design, and not-blinded.
Settings and conduct
This study was conducted on 60 schizophrenia patients who referred to Ebne- Sina hospital of Mashhad that were randomly divided into two groups (n = 30).
Participants/Inclusion and exclusion criteria
Inclusion criteria: Lack of mental retardation. Exclusion criteria: Not attending in the post test.
Intervention groups
Intervention group: in intervention group, was conducted home visitation according to community mental health team management for 2 months (6 sessions of 45 to 60 minutes) for patients. Control group: in control group, was conducted routine education (with educational pamphlet) for 2 months, too.
Main outcome variables
Patient Self-Efficacy Family Psychological Burden

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180114038353N1**
Registration date: **2018-04-24, 1397/02/04**
Registration timing: **retrospective**

Last update: **2018-04-24, 1397/02/04**
Update count: **0**
Registration date
2018-04-24, 1397/02/04

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2017-11-06, 1396/08/15
Expected recruitment end date
2018-01-05, 1396/10/15
Actual recruitment start date
2017-11-06, 1396/08/15
Actual recruitment end date
2018-01-05, 1396/10/15
Trial completion date
empty

Scientific title
The Effect of Home Visitation on Patient Self-Efficacy and Family Psychological Burden of Schizophrenia Patients

Public title
The Effect of Home Visitation on Patient Self-Efficacy and Family Psychological Burden of Schizophrenia Patients
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Having schizophrenia according to DSM-5. The family members of the patient are caring for him.
Exclusion criteria:
Experience emotional crisis such as divorce and death of loved ones.

Age
From **18 years** old to **60 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Actual sample size reached: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
The patient divided to intervention and control group with simple randomization method (with lottery).
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 Mashhad University of Medical Sciences
Street address
Mashhad University of Medical Sciences, Vice chancellor for research, Ghoraishy Building, University St
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Mashhad
Province
Razavi Khorasan
Postal code
1234567899
Approval date
2017-11-01, 1396/08/10
Ethics committee reference number
IR.MUMS.REC.1396.277

Health conditions studied

1

Description of health condition studied
Self-Efficacy
ICD-10 code
ICD-10 code description

2

Description of health condition studied
Psychological Burden
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Self-Efficacy
Timepoint
Before the intervention and the end of second month
Method of measurement
Chronic Disease Self-Efficacy Scale

2

Description
Psychological Burden
Timepoint
Before the intervention and the end of second month
Method of measurement
Zarit Burden Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: in intervention group, was conducted the home visit program according to community mental health team management for 2 months (6 sessions of 45 to 60 minutes) for patients. This program includes providing pharmaceutical and non-pharmaceutical services, providing services group and by psychiatrist, community psychiatrist, social worker, occupational therapist and psychologist, and in some cases general practitioner.
Category
Prevention

2

Description
Control group: in control group, was conducted routine education (with educational pamphlet) for 2 months, too.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center

Ebn-e Sina Hospital
Full name of responsible person
Fateme Mohareri
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Javad Abootorabi
Position
Nurse
Latest degree
Bachelor
Other areas of specialty/work
Nursery
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Person responsible for scientific inquiries

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Person responsible for updating data

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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

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The study report published in the dissertation form and article for researcher.

When the data will become available and for how long

The start of access is 6 months after the announcement of the results.

To whom data/document is available

Researchers at university centers

Under which criteria data/document could be used

Data is authorized only with permission from the author of the articles and with the source.

From where data/document is obtainable

Javad Abootorabi, School of Nursing and Midwifery, Mashhad Faculty of Nursing and Midwifery, Ebn-e Sina St, Doktora Crossroads, Contact Number: 00989151579378, E-Mail: AbootorabyBJ1@mums.ac.ir

What processes are involved for a request to access data/document

After submitting a request, the request is reviewed and, if the request is accepted, is answered within 1 month.

Comments