

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 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

Name

Javad Abootoraby

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

abootorabybj1@mums.ac.ir

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, Ghorashy Building, University St

City

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

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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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

Street address

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Person responsible for scientific inquiries

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Full name of responsible person

Saeed Vaghee

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Bachelor

Other areas of specialty/work

Nursery

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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