

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Determination the effect of family-centered empowerment model on elderlies with diabetes who are at falling risk in Bojnourd city

Protocol summary

Summary

The aim of the study is investigation of effect of family-centered empowerment model in diabetic elderly who are at risk of falling. Inclusion criteria consisted of 60 years old Elderly and older And completing screening questionnaire and earning score of 7 or higher and exclusion criteria is unwillingness of elderly and members of his family to empowerment program.30 elderly have been considered as the experimental group and the control group is the same number as control group. For experimental group, family-centered empowerment model has been done in eight-sessions of 45 minute for 1.5 months in four steps: perceived threat (severity and sensitivity), problem solving, educational participation and evaluation. Usual care and a training session are conducted for the control group. The test is conducted after a week, is tracked after three months. The primary outcome after the intervention is the empowerment score average.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016061728502N1**

Registration date: **2016-09-09, 1395/06/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-09-09, 1395/06/19

Registrant information

Name

Sakine Parvareshan

Name of organization / entity

Babol University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

University of Medical Sciences of Babol

Expected recruitment start date

2016-08-05, 1395/05/15

Expected recruitment end date

2016-09-05, 1395/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determination the effect of family-centered empowerment model on elderlies with diabetes who are at falling risk in Bojnourd city

Public title

The effect of family-centered empowerment model on elderlies with diabetes who are at falling risk in Bojnourd city

Purpose

Prevention

Inclusion/Exclusion criteria

elderly Inclusion criteria: Willingness to participate in research;60 years old elderly and older, The definitive diagnosis of type 2 diabetes with at least six months experience (tested and approved according to the doctor);having a case in related doctor's office; without having hearing and cognitive disorders based on AMT scale; reading and writing ability, Living with a family

and residents of the city; Willing and able to make phone calls to elderly and active family members; Without having debilitating complications of diabetes such as blindness, low vision, joint disease (arthritis, Rheumatoid arthritis); Completing screening questionnaire of falling and earning score of 7 or higher; Inclusion criteria of patients' families: active Family members who want to participate in its research and collaboration; reading and writing ability of active members (a family member; wife or husband, Daughter or a relative or close relative), A person who has the constant care of the elderly and elderly is comfortable with him, Exclusion criteria for this study: Unwillingness to continuing the corporate (the patient with family) in the empowerment program and Completing research tools, Nervous system such as Parkinson's disease and paralysis defects and musculoskeletal disorders of the patient, passing Diabetes Education courses by the patient and family

Age

From **60 years** old to **90 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**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**

Babol University of Medical Sciences

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-Babol University of Medical Sciences, Gangafrooz Street, Babol

City

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Postal code

47745-47176

Approval date

2016-06-18, 1395/03/29

Ethics committee reference number

mubabol.rec. 1395.79

Health conditions studied**1****Description of health condition studied**

diabet

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes**1****Description**

fall

Timepoint

1 month

Method of measurement

Screening Questionnaire fall

Secondary outcomes**1****Description**

Family-centered empowerment aspects, including the perceived threat (perceived severity, perceived susceptibility), problem solving, educational participation and evaluation methods.

Timepoint

Before the intervention, the empowerment questionnaire has been given . Then, for 1.5 months empowerment model has been done in 8 sessions of 45 minutes. One week and three months after the empowerment program, the questionnaire will be given again.

Method of measurement

questionnaire of family-centered empowerment

Intervention groups**1****Description**

For groups, family-centered empowerment model based on the four-step threat perceived self-efficacy, educational participation and evaluation should be

Category

Prevention

2**Description**

For routine care control group and a training session was conducted.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Endocrinologist's Office

Full name of responsible person

Mohsen Salimifar

Street address

North Khorasan, Bojnurd, north Shariati St, Hekmati
Av,physicians bulding, second floor

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Bojnoord

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Ali Bijani

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Gangafrooz Street, Babol University of Medical
Sciences

City

Babol

Grant name

Grant code / Reference number

9542222

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

Yes

Title of funding source

Babol University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

North Khorasan University of Medical Sciences

Full name of responsible person

Sakine Parvareshan

Position

Bachelor of Nursing, operating room manager, master
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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty