Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Assessing the effect of blended family-based intervention education program on perceived social support among older adults with type 2 diabetes: Application of Social Cognitive Theory Model

Protocol summary

Summary

This study aimed at assessing the effect of blended family-based intervention education program on perceived social support among older adults with type 2 diabetes. Inclusion criteria were elders at aged 60 and above, living with at least one relative and consent to participate in the study. The study population was older adults with type 2 diabetes referred to health centers which selected 160 patients randomly 80 patients in intervention group and 80 patients in control group. In this study after pretest, educational intervention based on social cognitive theory will conduct in six 60-45 minutes' sessions in intervention group during two months. In this sessions will try to explain about diabetes, its complications, diabetes care and control and the importance of family support including foot care, foot ulcers prevention , Proper nutrition and diabetes medications and the removal of barriers in the absence of patient care regarding benefits and values of disease control. Designed questionnaire will inquire and filled by interviewer from elderly patients with type 2 diabetes and any educational intervention will not performed in the control group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015012112460N4**
Registration date: **2015-02-23, 1393/12/04**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-02-23, 1393/12/04

Registrant information

Name
Roya Sadedgi
Name of organization / entity
Tehran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 912 327 5692
Email address
sadeghir@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

vice chancellor for research of Tehran University of Medical Sciences

Expected recruitment start date

2014-05-25, 1393/03/04

Expected recruitment end date

2015-04-20, 1394/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the effect of blended family-based intervention education program on perceived social support among older adults with type 2 diabetes: Application of Social Cognitive Theory Model

Public title

Assessing the effect of blended family-based intervention education program on perceived social support among older adults with type 2 diabetes in Siyahkal city2014: Application of Social Cognitive Theory Model

Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: of age (60 years); Certified Diabetes; living with at least one relative (not alone);Mental illness is not known;satisfaction to participate in the study
Exclusion criteria: life without Spouse or One of the relatives;If you have 2 sessions of absence from training sessions, Dissatisfaction to participate in the study,Under 60 years
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: **160**
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
Ethics committee of Tehran University of Medical Sciences
Street address
Poursina Ave.
City
Tehran
Postal code
Approval date
2014-10-23, 1393/08/01
Ethics committee reference number
93/130/1793/ص

Health conditions studied

1

Description of health condition studied
Type 2 diabetes
ICD-10 code
(E10-E14)
ICD-10 code description
Diabetes mellitus typeII(Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description
Perceived social support in older people with type 2 diabetes
Timepoint
Before and 5 months after intervention
Method of measurement
Questionnaire

Secondary outcomes

1

Description
Perceived family support in older people with type 2 diabetes
Timepoint
Zero and five months later.
Method of measurement
Social Cognitive Theory of Structures

Intervention groups

1

Description
" Intervention group: The group education sessions (Using PowerPoint ,pamphlets ,Questions and Answers) for families of patients who are in the 45-60 minute sessions held, Try to be Content expressed on diabetes, Complications, Care and Control Diabetes And the importance of family ."
Category
Prevention

2

Description
" In the control group Based on the questionnaire inquired questions about any aspects of elderly patients with type 2 diabetes will be asked to complete And training for the families of these groups will be."
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Health centers within the city Siahkal
Full name of responsible person

Mohammad Reza Amini
Street address
Siahkal
City
Siahkal

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
vice chancellor for research of Tehran University of Medical Sciences
Full name of responsible person
Masoud Younesian
Street address
Central Organization of Tehran University of Medical Sciences
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
vice chancellor for research of Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Dr. Roya Sadeghi
Position
Academic staff
Other areas of specialty/work
Street address
School of Public Health, Tehran University of Medical Sciences
City
Tehran
Postal code
141556446
Phone
+98 21 4293 3210
Fax
Email
sadeghir@tums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Roya Sadeghi
Position
PhD
Other areas of specialty/work
Street address
School of Public Health, Tehran University of Medical Sciences
City
Tehran
Postal code
141556446
Phone
+98 21142933210
Fax
Email
sadeghir@tums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Roya Sadeghi
Position
PhD
Other areas of specialty/work
Street address
School of Public Health, Tehran University of Medical Sciences
City
Tehran
Postal code
141556446
Phone
+98 21142933210
Fax
Email
sadeghir@tums.ac.ir
Web page address

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