

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Effect of an intervention based on Social Cognitive theory and Social-Ecology approach on promoting self-care behaviors of patients with diabetes typ 2 refering to Qom Diabetes Clinic on 2011

Protocol summary

Summary

The purpose of this study was to determine the effect of a Health promotion intervention on improving self-care behaviors of patient whit typ2 diabetes based on S.C.T theory in clinic of diabetes inKankar hospital. Inclusion criteria include Patient who have more than 1 yeardiagnosed diabetes; age range 30-70 year; using oral drug not injection. ExclusionCriteria: Hospitalization in researchduration; chang tretment regimen from oral to injection. 140 type 2 diabetic patients refering to diabetic clinic of Kamkar hospital in Qom were selected by a statistical consultant then allocated to intervention and non intervention groups. Education intervention include: training, group discussion, poster, pamphlet; performeded in intervention group. After 5 month outcomes includes Self-care behaviors and HbA1c compared in two groups

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111127352N4**

Registration date: **2012-01-30, 1390/11/10**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-01-30, 1390/11/10

Registrant information

Name

Mohammad Hossein Taghdisi

Name of organization / entity

Tehran University of Medical Sciences, Tehran, Iran

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-02-22, 1390/12/03

Expected recruitment end date

2012-03-22, 1391/01/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of an intervention based on Social Cognitive theory and Social-Ecology approach on promoting self-care behaviors of patients with diabetes typ 2 refering to Qom Diabetes Clinic on 2011

Public title

Effect of an Health promotion intervention on promoting self-care behaviors of patients with diabetes typ 2 refering to Qom Diabetes Clinic on 2011

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Patient who have more than 1 yeardiagnosed diabetes; age range 30-70 year; using oral drug not injection. ExclusionCriteria: Hospitalization in researchduration; change tretment regimen from oral to injection.

Age
From **30 years** old to **70 years** old
Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **140**

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
Tehran University of Medical Sciences

Street address
Deputy of Research, Tehran University of Medical Sciences, Keshavarz Blvd, Tehran, iran.

City
Tehran

Postal code

Approval date
2011-12-26, 1390/10/05

Ethics committee reference number
90-3-27-15219-41451

Health conditions studied

1

Description of health condition studied
Type 2 Diabetes mellitus

ICD-10 code
E11

ICD-10 code description
Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description
self-care Behavior

Timepoint
5month
Method of measurement
questionire

Secondary outcomes

1

Description
HbA1c

Timepoint
5 month after intervention

Method of measurement
bio chemical analyzis

Intervention groups

1

Description
Intervention for the experimental group: Self-care training , group discussio, Poster and pamphlet ,stress control trainingintervention

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Diabetic clinic

Full name of responsible person
Sorani Mohamad

Street address
Kamkar hospital, 19 Dey Ave, Qom, Iran

City
Qom

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Yonesian Masod

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City
Tehran

Grant name

Grant code / Reference number

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

Title of funding source

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

Health Faculty of Tehran University of Medical

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Tehran University of Medical Sciences

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Position

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Position

Phd in Health promotion

Other areas of specialty/work**Street 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