

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Comparison of impact of Pictorial and Teach-back educational strategies on knowledge about diabetes disease, adherence to medication and diet among people with diabetes type 2 and low health literacy attending to diabetes unit of Imam Khomeini hospital in saqqez

Protocol summary

Summary

(1) Objectives: to examine the impact of Pictorial and Teach-back educational strategies on knowledge about diabetes disease, adherence to medication and diet among people with diabetes type 2 and low health literacy attending to diabetes unit of Imam Khomeini hospital in saqqez. (2) Design: a randomized clinical trial (3) Setting and Conduct: 127 people with diabetes type 2 and low health literacy from Unit of Diabetes, Imam Khomeini Hospital in Saqqez were enrolled and allocated to three arms of study (control, Pictorial and Teach-back groups). Questionnaires was used to gathering demographic data, the level of functional health literacy in adults (TOFHLA), knowledge on the subject of diabetes, adherence to medication and diet. The validity and reliability of Questionnaires were assessed and confirmed through content validity and test- retest methods. Data analysis was performed using ANOVA and Paired t test in SPSS software version 16. (4) Participants including major eligibility Criteria: Inclusion criteria Obtaining health literacy score<59; afflicted to Diabetes type 2; age over 18; able to read and write; Exclusion criteria Lack of dementia; visual or learning disability; no afflicted to diabetes type one; no participation in other research project. (5) Intervention: intervention groups received diabetes education by Teach Back and Pictorial methods respectively, the control group received regular diabetes education offered by Diabetes Unit. (6) Main Outcome Measures: knowledge on the subject of diabetes, adherence to medication and diet.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201108684N1**

Registration date: **2012-02-07, 1390/11/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-02-07, 1390/11/18

Registrant information

Name

Reza Negarandeh

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6642 1685

Email address

rnegarandeh@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences, Vice Chancellor for Research

Expected recruitment start date

2011-07-23, 1390/05/01

Expected recruitment end date

2011-10-07, 1390/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of impact of Pictorial and Teach-back educational strategies on knowledge about diabetes disease, adherence to medication and diet among people with diabetes type 2 and low health literacy attending to diabetes unit of Imam Khomeini hospital in saqqez

Public title

comparison of two educational methods

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria obtain health literacy score<59; afflicted to Diabetes type 2; age over 18; able to read and write; Exclusion criteria lack of dementia; visual or learning disability; no afflicted to diabetes type one; no participation in other research project.

Age

From **18 years** old to **90 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **135**

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

Vice Chancellor for Research, Tehran University of Medical Sciences, Keshavarz Blvd.,Tehran

City

Tehran

Postal code**Approval date**

2010-08-08, 1389/05/17

Ethics committee reference number

599/130/89/3

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

Diabetes mellitus

ICD-10 code

E10-E11- E

ICD-10 code description

Diabetes mellitus

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

Knowledge about Diabetes Disease

Timepoint

Before and six weeks after finishing intervention

Method of measurement

Researcher developed questionnaire for knowledge

2**Description**

adherence to Diet

Timepoint

Before and six weeks after finishing intervention

Method of measurement

Researcher developed questionnaire for diet

3**Description**

adherence to medication

Timepoint

Before and six weeks after finishing intervention

Method of measurement

Morisky standard questionnaire for adherence to medication

Secondary outcomes

empty

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

Pictorial educational strategy is a method that educator use of pictorial for teaching Key concepts without using medical terminology or jargons.

Category

Other

2**Description**

Participants in control group were received only routine diabetes education.

Category

N/A

3

Description

Teach-back educational strategies Teach-back is a way to confirm that you have explained to the patient what they need to know in a manner that the patient understands. Patient understanding is confirmed when they explain it back to you.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Unit of Diabetes, Imam Khomeini Hospital in Saqqez

Full name of responsible person

Hassan Mahmoodi

Street address

Unit of Diabetes, Imam Khomeini Hospital, Saqqez, Iran.

City

Saqqez

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences, Vice chancellor for Research

Full name of responsible person

Dr. Akbar Fotouhi

Street address

Vice chancellor for Research, Tehran University of Medical Sciences, Keshavarz Blvd.

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, Vice chancellor for Research

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. Reza Negarandeh

Position

PhD

Other areas of specialty/work

Street address

Faculty of Nursing and Midwifery, Mirkhani St., Tohid Sq., Tehran, Iran.

City

Tehran

Postal code

Phone

+98 21 6642 1685

Fax

Email

rnegarandeh@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. Reza Negarandeh

Position

PhD

Other areas of specialty/work

Street address

Faculty of Nursing and Midwifery, Mirkhani St., Tohid Sq., Tehran, Iran.

City

Tehran

Postal code

Phone

+98 21 6642 1685

Fax

+98 21 6642 1685

Email

rnegarandeh@tums.ac.ir

Web page address

Person responsible for updating data

Contact

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