

# 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.

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### Person responsible for scientific inquiries

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##### Name of organization / entity

Tehran University of Medical Sciences

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##### Position

PhD

##### Other areas of specialty/work

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##### 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*