

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### Comparison of Impact of In-person training and Educational Booklet Methods on Adherence to Therapeutic Regimen and Health-related Quality of Life in Patient with Type 2 Diabetes

#### Protocol summary

##### Study aim

Determining the effect of in-person training and educational booklet methods on adherence to the treatment regimen and health-related quality of life in patients with type 2 diabetes

##### Design

In this study, 120 patients with type 2 diabetes who are referred to the Diabetes Clinic and thus eligible to enter the study, are selected. Participants are randomly divided into three groups: in-person training, training with educational booklet and control, and each participant is assigned a code.

##### Settings and conduct

The research population in this study is all patients with type 2 diabetes who referred to Jahrom Diabetes Clinic. The researcher identified the eligible diabetic patients and collected the information through demographic questionnaires health-related quality of life in diabetic patients, and the diabetic diet follow-up questionnaire by means of interviewing after getting their informed consent . The researcher interviewed three days a week and in the morning after the visit was completed. In the intervention phase, the same subjects were trained in the same way (in-imperson training and educational booklet), and the control group received the usual training in the clinic. In the post-intervention phase, two weeks after the pre-test, the questionnaire was re-submitted to the patients and the results was compared with the pre-test

##### Participants/Inclusion and exclusion criteria

inclusion criteria : definitive diagnosis of type 2 diabetes, at least diagnosis and treatment initiation for six months, minimum age 30. Conditions of exclusion criteria : Unwillingness to the continuation of study , visual impairment and hearing impairment

##### Intervention groups

In the intervention phase, researcher trained three

groups the same subjects with different methods (in-person training and educational booklet) and the control group received the common training the clinic. Educational subjects include diabetes diagnosis, therapies, how to use drugs, insulin therapy, recommendations for the prevention of hypoglycemia and hyperglycemia, training for controlling blood glucose, exercise, etc. In the in-person training group, training time was considered to be 20 to 30 minutes. In the group that the members of it were trained by means of educational booklet, the same subjects were taught by means of simple and understandable pictures and texts. In the post-intervention phase, two weeks after the pre-test, the questionnaire was returned to the patients and the results were compared with the pre-test.

##### Main outcome variables

Adherence to Therapeutic Regimen and the improvement of the quality of life .

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171204037745N1**

Registration date: **2018-02-16, 1396/11/27**

Registration timing: **retrospective**

Last update: **2018-02-16, 1396/11/27**

Update count: **0**

##### Registration date

2018-02-16, 1396/11/27

##### Registrant information

##### Name

raziyeh rostami

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

**Phone**  
+98 71 5433 7301

**Email address**  
r.rostami@jums.ac.ir

**Recruitment status**  
**Recruitment complete**

**Funding source**

**Expected recruitment start date**  
2016-10-22, 1395/08/01

**Expected recruitment end date**  
2016-12-20, 1395/09/30

**Actual recruitment start date**  
2016-10-22, 1395/08/01

**Actual recruitment end date**  
2017-12-21, 1396/09/30

**Trial completion date**  
empty

**Scientific title**  
Comparison of Impact of In-person training and Educational Booklet Methods on Adherence to Therapeutic Regimen and Health-related Quality of Life in Patient with Type 2 Diabetes

**Public title**  
"Effect of In-person training and Educational Booklet on Adherence to Therapeutic Regimen and Quality of Life in Diabetes"

**Purpose**  
Education/Guidance

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
The definitive diagnosis of type 2 diabetes The minimum diagnosis and initiation of treatment for type 2 diabetes for 6 months At least 30 years old The absence of diagnosed psychiatric disorders The ability to attend classes, and answering questions The possibility of follow-up after the intervention  
**Exclusion criteria:**  
Unwillingness to participate in the study Visual and auditory disorders

**Age**  
From **30 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **120**  
Actual sample size reached: **120**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Considering the number of groups studied, there were three groups. Thus, the size of each block is three ( three members in each block). In terms of number of blocks, the factorial rule is used, the number of blocks (6 × 1 × 2 × 6) is 6 blocks, the number of samples from blocks

(with placement) to the number of samples was obtained.

**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 Yasuj University of Medical Sciences

**Street address**  
Yasuj-Boulevard, Shahid Motahari-Yasouj University of Medical Sciences

**City**  
Yasuj

**Province**  
Kohgiluyeh-va-Boyerahmad

**Postal code**  
7591741417

**Approval date**  
2016-07-02, 1395/04/12

**Ethics committee reference number**  
IR.YUMS.REC.1395.10

**Health conditions studied**

**1**

**Description of health condition studied**  
type 2 diabetes

**ICD-10 code**  
E11

**ICD-10 code description**  
Type 2 diabetes mellitus

**Primary outcomes**

**1**

**Description**  
adherence to therapeutic regimen

**Timepoint**  
At the beginning of the study and 14 days after the intervention

**Method of measurement**  
adherence to therapeutic regimen Questionnaire

## 2

### **Description**

health-related quality of life

### **Timepoint**

At the beginning of the study and 14 days later

### **Method of measurement**

health-related quality of life questionnaire in patients with type 2 diabetes

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: In the case study group, training was considered for 20 to 30 minutes. The content of 3 sessions that was conducted for the patients in the face-to-face training group is as follows: Description of diabetes disease, treatments, how to use drugs, insulin therapy, recommendations for the prevention of hypoglycemia and hyperglycemia, training for blood glucose control, exercise.

#### **Category**

Other

### 2

#### **Description**

Intervention group: educational booklet: In the educational booklet group, the same subjects as in-person training group were taught using simple and understandable pictures and texts.

#### **Category**

Other

### 3

#### **Description**

Control group: The control group received the usual training in the clinic. the standard training includes the training related to diet , medication use and the use of insulin that patients receive at the doctor's office.

#### **Category**

N/A

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Health centers in Jahrom city

##### **Full name of responsible person**

Raziyeh Taheri

##### **Street address**

Imam Ali Street

##### **City**

Jahrom

#### **Province**

Fars

#### **Postal code**

7415113465

#### **Phone**

+98 71 5446 0455

#### **Email**

r.rostami@jums.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Yasouj University of Medical Sciences

##### **Full name of responsible person**

Vice chancellor of research and technology

##### **Street address**

Yasouj University of Medical Sciences, Shahid Motahari Blvd

##### **City**

Yasuj

##### **Province**

Kohgilouyeh-va-Boyerahmad

##### **Postal code**

7591994799

##### **Phone**

+98 74 3334 6078

##### **Email**

r.rostami@jums.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Yasouj University of Medical Sciences

#### **Proportion provided by this source**

100

#### **Public or private sector**

Public

#### **Domestic or foreign origin**

Domestic

#### **Category of foreign source of funding**

empty

#### **Country of origin**

#### **Type of organization providing the funding**

Academic

### 2

#### **Sponsor**

##### **Name of organization / entity**

Yasouj University of Medical Sciences

##### **Full name of responsible person**

Vice chancellor of research and technology

##### **Street address**

Yasouj University of Medical Sciences, Shahid Motahari Blvd

##### **City**

Yasuj

**Province**

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Yes

**Title of funding source**

Yasouj University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding**

Academic

**Person responsible for general inquiries****Contact****Name of organization / entity**

Yasouj University of Medical Sciences

**Full name of responsible person**

Raziyeh Taheri

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Yasouj University of Medical Sciences, Shahid Motahari Blvd

**City**

Yasuj

**Province**

Kohgilouyeh-va-Boyrahmad

**Postal code**

7591994799

**Phone**

+98 74 3333 7230

**Fax****Email**

r.rostami@jums.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Yasouj University of Medical Sciences

**Full name of responsible person**

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**Province**

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**Postal code**

7591994799

**Phone**

+98 74 3333 7230

**Email**

rroostami@jums.ac.ir

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to

make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available