

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)

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+98 71 5433 7301

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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

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+98 71 5446 0455

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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

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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

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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

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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