Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of two messages frame, gain frame or loss frame on knowledge; self-efficacy and self-care in patients with type 2 diabetes

Protocol summary

Summary

This study is a randomized clinical trial study in 2016 to comparison the effect of two messages frame, gain frame or loss frame on knowledge, self-efficacy and diabetic self-care in patients with type 2 diabetes. Inclusion criteria: Having diabetes for six months or more, Covered by diabetes control center, Having the ability to read and write and Exclusion criteria: unwillingness to participate in the study, Not gestational diabetes. The population of study includes Patients suffering from diabetes will be recruited from the 17 Shahrivar Diabetes Clinics in Borazgan through a simple randomized sampling procedure and a sample size of 126. In this study, 126 eligible patients will be categorized in 3 groups; one group will receive educational booklet with gain-frame messages (N=42); another group will receive educational booklet with loss-frame messages (N=42) and control group will receives routine clinical education (N=42). The patients in three groups will complete the questionnaires in three different intervals, before, one week and three months after training. The outcome of this intervention is Commitment to perform self-care behaviors.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016122931653N1**
Registration date: **2017-01-16, 1395/10/27**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-01-16, 1395/10/27

Registrant information

Name

Elahe Afrazeh

Name of organization / entity

Bushehr University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 77 3483 3272

Email address

e.afrazeh@bpums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Bushehr University of Medical Sciences

Expected recruitment start date

2017-01-20, 1395/11/01

Expected recruitment end date

2017-05-22, 1396/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of two messages frame, gain frame or loss frame on knowledge; self-efficacy and self-care in patients with type 2 diabetes

Public title

The Comparison the effect of messages frame on knowledge; self-efficacy and self-care in diabetic patients

Purpose

Prevention

Inclusion/Exclusion criteria

inclusion criteria: Having diabetes for six months or more, Covered by diabetes control center, Having the ability to read and write. Exclusion criteria: unwillingness

to participate in the study, Not gestational diabetes.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **126**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
The patients will be categorized in three groups by random allocation.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Bushehr University of Medical Science

Street address
Bushehr University of Medical Sciences, Salman Farsi St, Bahmani

City
Bushehr

Postal code
7514633341

Approval date
2016-12-19, 1395/09/29

Ethics committee reference number
IR.BPUMS.REC.1395.129

Health conditions studied

1

Description of health condition studied
Type 2 diabetes

ICD-10 code
E11

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

Primary outcomes

1

Description
Self-care in diabetes

Timepoint
Before, a week and three months after education

Method of measurement
Questionnaire

2

Description
Self-efficacy in diabetes

Timepoint
Before, a week and three months after education

Method of measurement
Questionnaire

3

Description
knowledge in diabetes

Timepoint
Before, a week and three months after education

Method of measurement
Questionnaire

Secondary outcomes

1

Description
-

Timepoint
-

Method of measurement
-

Intervention groups

1

Description
The patients in intervention group will receive gain frame messages about knowledge, self-efficacy and diabetic self-care through booklet.

Category
Prevention

2

Description
The patients in another intervention group will receive loss frame messages about knowledge, self-efficacy and diabetic self-care through booklet.

Category
Prevention

3

Description
The patients in control group will receive routine clinical education.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
17 Shahrivar Diabetes Clinic
Full name of responsible person
Jamileh Moarefi
Street address
17 Shahrivar Diabetes Clinic, Hospital Street.
City
Borazjan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research of Bushehr University of Medical Sciences
Full name of responsible person
Afshin Ostovar
Street address
Bushehr University of Medical Sciences, Salman Farsi St, Bahmani, Bushehr, Iran
City
Bushehr
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research of Bushehr 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

Person responsible for general inquiries

Contact
Name of organization / entity
Bushehr University of Medical Sciences
Full name of responsible person
Azita Noroozi
Position
Ph.D. of Health Education and Health Promotion
Other areas of specialty/work
Street address
Bushehr University of Medical Sciences, Salman Farsi Street, Bahmani
City
Bushehr
Postal code
7514633341
Phone
+98 77 3332 2081
Fax
+98 77 3332 3123
Email
azitanoroozi@yahoo.com
Web page address
www.bpums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Bushehr University of Medical Sciences
Full name of responsible person
Azita Noroozi
Position
Ph.D. of Health Education and Health Promotion
Other areas of specialty/work
Street address
Bushehr University of Medical Sciences, Salman Farsi Street, Bahmani
City
Bushehr
Postal code
7514633341
Phone
+98 77 3332 2081
Fax
+98 77 3332 3123
Email
azitanoroozi@yahoo.com
Web page address
www.bpums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Bushehr University of Medical Sciences
Full name of responsible person
Elahe Afrazeh
Position
MSc Student of Health Education
Other areas of specialty/work
Street address
Bushehr University of Medical Sciences, Salman Farsi Street, Bahmani
City

Bushehr
Postal code
7514633341
Phone
+98 77 3332 2081
Fax
+98 77 3332 3123
Email
67.elahe@gmail.come.afrazeh@bpums.ac.ir
Web page address
www.bpums.ac.ir

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