

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

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Phone

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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.com.afraze@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