

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Aug 2026

### Comparison of the effect of two methods of education including distant education multimedia and Short Message Sending (SMS) on the amount of physical activity in patients with type 2 diabetes: An application of Health Promotion Model

#### Protocol summary

##### Summary

The aim of the study: compare the effect of a distant education, multimedia and SMS, health promotion model based on the amount of physical activity in patients with type II diabetes in Bushehr. Inclusion criteria for this study includes having high school diploma, lack of diabetic foot ulcers, passing at least one year after diabetes, and Exclusion criteria includes functional disability to walk without stick, unable to walk one mile (about 1.6 km) without any rest, having cardiovascular disease and the inability to continue to contribute for at least 3 months. This study is a randomized clinical trial on 180 patients (60 in Multimedia, 60 SMS and 60 in the control group) of patients with type II diabetes in Bushehr city. Two groups of multimedia and SMS receive health promotion model-based education on changing physical activity behavior and the control group receives routine clinical education. Participants in all three groups before starting education fill in all questionnaires which include demographic and health promotion model constructs (perceived benefits and barriers, perceived self-efficacy, perceived health status, perceived social support) and seven-day physical activity recall questionnaire. In addition, two weeks after education, health promotion model constructs questionnaires and three months after finishing the second step, all questionnaires (without demographic) will be filled in by participants. The amount of physical activity before and three months after intervention will be evaluated.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016062928697N1**

Registration date: **2016-07-15, 1395/04/25**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2016-07-15, 1395/04/25

##### Registrant information

###### Name

Hamide Lari

###### Name of organization / entity

Bushehr University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 77 3345 0134

###### Email address

h.lari@bpums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research of Bushehr University of Medical Sciences

##### Expected recruitment start date

2016-07-22, 1395/05/01

##### Expected recruitment end date

2016-11-21, 1395/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effect of two methods of education

including distant education multimedia and Short Message Sending (SMS) on the amount of physical activity in patients with type 2 diabetes: An application of Health Promotion Model

## Public title

The impact of distant education on physical activity in patients with diabetes.

## Purpose

Prevention

## Inclusion/Exclusion criteria

Inclusion criteria: having high school diploma; Not having diabetic foot ulcers; Willingness to participate in the study; Passing at least one year after diabetes; having a computer or CD player for multimedia group. Exclusion criteria: Functional inability to walk without stick; inability to walk one mile (about 1.6 km) without rest according to the individual saying; inability to continue participation for at least 3 months; Having cardiovascular disease.

## Age

From **25 years** old to **65 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **180**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

Randomization is performed using random number table

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Bushehr University of Medical Sciences

##### Street address

Bushehr University of Medical Sciences, Salman Farsi Street, Bahmani, Bushehr, Iran

##### City

Bushehr

##### Postal code

7518759577

## Approval date

2016-06-20, 1395/03/31

## Ethics committee reference number

IR.BPUMS.REC.1395.56

## Health conditions studied

### 1

#### Description of health condition studied

Diabetes

#### ICD-10 code

E11

#### ICD-10 code description

Diabetes mellitus

## Primary outcomes

### 1

#### Description

Doing physical activity

#### Timepoint

Before education and 3 months later.

#### Method of measurement

Seven-day physical activity recall

## Secondary outcomes

### 1

#### Description

Perceived benefits

#### Timepoint

Before, two weeks and three months after education

#### Method of measurement

Standard perceived benefits questionnaire

### 2

#### Description

Perceived barriers

#### Timepoint

Before, two weeks and three months after education

#### Method of measurement

Perceived barriers questionnaire

### 3

#### Description

Perceived Self-efficacy

#### Timepoint

Before, two weeks and three months after education

#### Method of measurement

Perceived self-efficacy questionnaire

### 4

#### Description

Perceived health status

#### Timepoint

Before, two weeks and three months after education

**Method of measurement**

12-Item short form health survey(SF-12)

**5****Description**

Perceived social support

**Timepoint**

Before, two weeks and three months after education

**Method of measurement**

Perceived Social Support Questionnaire

**Intervention groups****1****Description**

Multimedia education group will receive health promotion model-based education in the field of physical activity behavior change. Multimedia educational group receives a CD about the benefits and barriers of physical activity such as issues on physical activity during the periods of high blood sugar and educational materials on the reduction of muscle cramps after the initial increased physical activity, educating based on step by step changing of physical activity and increase it gradually over a period of 3 months, correcting people's views on the usefulness of an increase in heart rate associated with the exercise in order to improve the efficacy. In addition, multimedia Group receives some messages twice a week up to 3 months after the educational program, in order to recall information.

**Category**

Prevention

**2****Description**

SMS education group, receives health promotion model-based education to change physical activity behavior. The SMS group receives multimedia content group gradually in which short messages, daily 2 messages (total per week, 12 messages from Saturday to Thursday) in the fields related to health promotion structures two weeks. In addition SMS group receives message twice on the week to remind information, data structures, the time interval up to 3 months after completing the educating program will be sent.

**Category**

Prevention

**3****Description**

control group receives clinical routine education.

**Category**

Prevention

**Recruitment centers****1****Recruitment center****Name of recruitment center**

7th Tir Diabetes Clinic in Health Center

**Full name of responsible person**

Zinat Sarkhosh

**Street address**

7th Tir Diabetes Clinic in Health Center, alley next to 115 emergency, Stone street

**City**

Bushehr

**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 Street, 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, Bushehr

**Full name of responsible person**

Azita Noroozi

**Position**

Ph.D. of Health Education and Health Promotion

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**Full name of responsible person**

Hamide Lari

**Position**

MSc Student of Health Education

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**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*