

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 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)

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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

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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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Position

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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