Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Nov 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

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Name of organization / entity

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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 reducion 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
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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