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

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**
- None

**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

**Primary outcomes**

1. **Description**
   - Doing physical activity

2. **Timepoint**
   - Before education and 3 months later.

3. **Method of measurement**
   - Seven-day physical activity recall

**Secondary outcomes**

1. **Description**
   - Perceived benefits

2. **Timepoint**
   - Before, two weeks and three months after education

3. **Method of measurement**
   - Standard perceived benefits questionnaire

4. **Description**
   - Perceived health status

5. **Timepoint**
   - Before, two weeks and three months after education

6. **Method of measurement**
   - 12-Item short form health survey (SF-12)

**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
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
Street address
Bushehr University of Medical Sciences, Salman Farsi Street, Bahmani, Bushehr, Iran
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, Bushehr, Iran
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, Bushehr, Iran
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, Bushehr, Iran
Full name of responsible person
Hamide Lari
Position
MSc Student of Health Education
Other areas of specialty/work
Street address
Bushehr University of Medical Sciences, Salman Farsi Street, Bahmani, Bushehr, Iran
City
Bushehr
Postal code
7514633341
Phone
+98 77 3332 2081
Fax
+98 77 3332 3123
Email
hamide.lari27@gmail.com
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