Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Assessment of effectiveness of telenursing on the awareness and self-care performance of patients with diabetes in the conditions of the COVID-19 pandemic

Protocol summary

Study aim

Determination the effectiveness of telenursing on the awareness and self-care performance of patients with diabetes in the conditions of the COVID-19 pandemic

Design

The clinical trial has a control and intervention group, The sample size is 100 people, patient files will be selected using random numbers obtained from the Excel program and placed in two intervention and control groups using random allocation.

Settings and conduct

Diabetic patients who have files in Bushehr diabetes clinic will be included in the study if they are eligible. After reaching the quorum of the number of patients who are willing to participate in the study, a sequence of 100 people (control group-intervention group) will be produced using the simple randomization method from the Excel program. Numbers that are more than 0.5 are placed in one group and numbers that are less than 0.5 are placed in another group. There will be no blinding in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: having at least literacy, having a smartphone, connecting to the Internet, not having speech and hearing problems, not having a mental disorder, over 18 years Exclusion criteria: Being pregnant

Intervention groups

In the intervention group, the necessary training will be provided to diabetic patients during 8 sessions, in coordination with the patient, two days a week for one month. The duration of each session is on average twenty minutes. Educational content will be sent to patients through social messengers, and they will be asked to ask their questions through phone calls or social messengers. In the control group, they will be just provided with a brochure about Corona pandemic.

Main outcome variables

Awareness; Self-care performance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220815055701N1**
Registration date: **2022-11-15, 1401/08/24**
Registration timing: **prospective**

Last update: **2022-11-15, 1401/08/24**
Update count: **0**

Registration date

2022-11-15, 1401/08/24

Registrant information

Name

Akhtar Dehghani Manesh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 905 455 4439

Email address

adehghani1202@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-06, 1401/09/15

Expected recruitment end date

2022-12-21, 1401/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Assessment of effectiveness of telenursing on the awareness and self-care performance of patients with diabetes in the conditions of the COVID-19 pandemic

Public title
The effectiveness of telenursing on the knowledge and self-care performance of patients with diabetes

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Have an active file in Bushehr diabetes clinic. At least they should be able to read and write. Have a smartphone. Have the possibility to connect to the Internet. Do not have a known mental disorder according to the person's statement. Do not have known speech and hearing problems. The age of the patient should be over 18 years.

Exclusion criteria:
The patient is pregnant.

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
1. The number of files in the diabetes clinic is 1967 files. The researcher will select 320 files by systematic sampling method, in such a way that a number is randomly selected from one to six to determine the first selected file. The researcher moves in the list of files by adding the number six each time until finally 320 files are selected. 2. After identifying the files, the researcher will select the final patients according to the Inclusion and exclusion criteria. Then the selected patients are contacted by phone and invited to participate in the study. 3. The objectives of the study will be explained to the patients who express their desire to participate in the study. The researcher will explain to the patients about the intervention group and the control group, and the patients will be told that they will be randomly assigned to one of these two groups. 4. After reaching the quorum of the number of patients who want to participate in the study, these people will be assigned to two intervention and control groups using random numbers obtained from the Excel program. 5. By using the simple randomization method from the Excel program, a sequence of 100 people (control group-intervention group) of numbers less than one (0_1) will be created. Numbers that are more than 0/5 are placed in one group and numbers that are less than 0/5 are placed in another group. The researcher contacts the patients based on this sequence. 6. The randomization unit in this study is the patients with files that are willing to participate in the study . 7. The randomization tool in this study is the sequence generated by excel program . 8. Allocation concealment will not be done in this study.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Bushehr University of Medical Sciences

Street address
Research Ethics Committee, 1st Floor, Bushehr Medical Sciences Campus, Salman Farsi St. , Bahmani, Bushehr, Iran

City
Bushehr

Province
Boushehr

Postal code
7518759577

Approval date
2022-09-12, 1401/06/21

Ethics committee reference number
IR.BPUMS.REC.1401.098

Health conditions studied

1

Description of health condition studied
Type 1 diabetes mellitus

ICD-10 code
E10

ICD-10 code description
Type 1 diabetes mellitus

2

Description of health condition studied
Type 2 diabetes mellitus

ICD-10 code
E11

ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
awareness
Timepoint
Before the start of the intervention, immediately after the end of the intervention, one month after the end of the intervention.
Method of measurement
A researcher-made questionnaire on awareness and self-care performance of patients with diabetes in the conditions of the coronavirus pandemic, which has 56 items.

2

Description
Self-care performance
Timepoint
Before the start of the intervention, immediately after the end of the intervention, one month after the end of the intervention.
Method of measurement
A researcher-made questionnaire on awareness and self-care performance of patients with diabetes in the conditions of the coronavirus pandemic, which has 56 items.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: During 8 sessions, the necessary training will be provided to patients with diabetes to take care of themselves and how to function in Corona conditions using the phone and social messenger, two days a week for one month. After holding each educational session and teaching the designated topic to the patients, the educational content will be sent to them through social messenger and they are requested to raise their questions through phone call or social messenger in case of any ambiguity and problems. In each session, the patient will be asked questions about the educational topic of the previous session and troubleshooting will be done. The time of each group meeting will be determined by asking the research unit from 8:00 am to 8:00 pm on non-holiday days. The duration of each session is on average twenty minutes .The educational topic of each session is as follows: First session: diabetes - complications of diabetes - foot care in diabetic patients Second session: what diabetic patients should know about Covid-19 Third session: personal hygiene and use of equipment Personal protection during the corona pandemic Session 4: Vaccination against covid 19 Session 5: Factors affecting blood sugar in patients with diabetes during the corona pandemic Session 6: Management of diabetes during covid 19 disease Session 7: Diet in patients with diabetes Especially in the corona pandemic The eighth session: sports activities in patients with diabetes with an emphasis on the corona pandemic.
Category
Behavior

2

Description
Control group: In the control group, no intervention will be done and only to comply with the ethical standards, a pre-prepared brochure will be provided to them regarding the necessary information in the corona pandemic.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Diabetes Clinic, Mellat Clinic
Full name of responsible person
ALI Benhelal
Street address
Diabetes Clinic, 2nd Floor, Mellat Clinic, Sangi St., Bushehr, Iran
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Postal code
7514633341
Phone
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Email
benhelal1732@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Boushehr University of Medical Sciences
Full name of responsible person
Dr. Akram Farhadi
Street address
Research deputy, 1st Floor, Medical Sciences Campus, Salman Farsi St. , Bahmani, Bushehr, Iran
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Email

ak.farhadi@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Boushehr University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Boushehr University of Medical Sciences

Full name of responsible person

Akhtar Dehghani Manesh

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Bushehr School of Nursing and Midwifery, Campus Complex of Bushehr University of Medical Sciences, after Salman Farsi Hospital (Social Security), Salman Farsi Street, Sabzabad Boulevard, Bahmani, Bushehr, Iran

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Boushehr University of Medical Sciences

Full name of responsible person

Akhtar Dehghani Manesh

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

Name of organization / entity

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available