Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Oct 2026

Design, implementation and evaluation of an intervention based on the Pender health promotion model to improve the medication adherence of type 2 diabetes patients

Protocol summary

Study aim
Design, implementation and evaluation of an intervention based on the Pender health promotion model to improve medication adherence of patients withT2D

Design
the sample size is 166 people in a total of two groups (83 people in each group). For randomization with systematic sampling method, the selection of individuals according to the list of 1500 people registered in the diabetes clinic from the participants who meet the inclusion criteria through systematic random sampling from the list using the sampling distance (k), [k = N / n = 1500/166 = 9] are selected. From 1 to 9, the number 2 is randomly selected as the first sample and the list of 166 people is completed by adding the number 9 in each step. To randomize this final list, by drawing lots, the first name out of these 166 people will be selected as the second intervention group, and so on.

Settings and conduct
The intervention is designed and implemented based on Pender's health promotion model in face-to-face and online training sessions in Hormoz Diabetes Clinic. Blinding will not be performed in this study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: willingness to participate in research, file registration in diabetes clinic as a patient with type 2 diabetes, living in Bandar Abbas Non-entry condition: Alzheimer's disease based on patient records

Intervention groups
The intervention will be based on the constructs of Pender's health promotion model (Suitable tools for any structure, such as: video clips or posters) for the intervention group and the control group will use the normal services of the clinic.

Main outcome variables
medication adherence score ; hemoglobin A1C test

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211228053558N1**
Registration date: **2022-03-17, 1400/12/26**
Registration timing: **prospective**

Last update: **2022-03-17, 1400/12/26**
Update count: **0**

Registration date
2022-03-17, 1400/12/26

Registrant information

Name
nahid shahabi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 76 3333 8583

Email address
nahid.shahabi@hums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-17, 1401/01/28

Expected recruitment end date
2022-07-24, 1401/05/02

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Design, implementation and evaluation of an intervention based on the Pender health promotion model to improve the medication adherence of type 2 diabetes patients

Public title
Pender's health promotion model on medication adherence of type 2 diabetes patients

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
The desire to participate in research Registration of a case in the diabetes clinic of Shahid Mohammadi hospital as a type 2 diabetic patient Living in Bandar Abbas

Exclusion criteria:
Not participating in regular training sessions (absence of more than 2 sessions) Not going to the diabetes clinic of Shahid Mohammadi Hospital

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **166**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible samples are selected through systematic random sampling from Hormoz Diabetes Clinic (Bandar Abbas Diabetes Reference Clinic). Based on the information recorded in the center files (taking into account the inclusion criteria) to achieve the required sample size of 83 people in the intervention group and 83 control people, individuals through systematic random sampling from the list using sampling distance (k), [k = N / n (1500 ÷ 166 = 9)] will be selected. From 1 to 9, a number will be randomly selected as the first sample and then the second sample will be selected by adding the number 9 to the first patient and this process will continue until the end. After identifying the samples, a lottery will be drawn between the two intervention and control groups. The first lottery will be called the intervention group and then the next names will be placed one by one in the control and intervention group.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
This study is performed in three phases: qualitative, cross-sectional and intervention, and the effect can be measured through a questionnaire and a1c test.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of hormozgan University of Medical Sciences

Street address
Iran, Hormozgan, Bandar Abbas, Shahid Chamran Boulevard

City
bandarabbas

Province
Hormozgan

Postal code
7916613885

Approval date
2022-01-22, 1400/11/02

Ethics committee reference number
IR.HUMS.REC.1400.377

Health conditions studied

1

Description of health condition studied
Type 2 diabetes

ICD-10 code
E11

ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
medication adherence score

Timepoint
At the beginning of the study and 3 months after the intervention

Method of measurement
medication adherence questionnaire

2

Description
Hemoglobin A1C test

Timepoint
At the beginning of the study (before the intervention) and 3 months after the end of the intervention

Method of measurement
The hemoglobin A1C listed in the test result

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Hormoz Diabetes Clinic of Shahid Mohammadi Hospital in Bandar Abbas as the place of intervention and using educational services will be 10-12 sessions in person or online or a combination of both depending on the university conditions during the Covid-19 epidemic. The use of educational clips, posters and pamphlets will be in the training process and the main content of the sessions on promoting and improving adherence to treatment in the areas of drug therapy, physical activity and nutrition (content according to Pender's health promotion model to promote self-efficacy, related emotions By adhering to and reducing benefits, etc.) it will be that face-to-face meetings will be set with an average time of 45 minutes and online meetings of 15 minutes. The control group will not receive training and will receive the clinic's routine care services. Then the changes in the results of the hemoglobin A1C test in both groups will be examined.

Category
Behavior

2

Description
Control group: does not receive any intervention and uses the normal services of the clinic.

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Hormoz Clinic of Shahid Mohammadi Hospital

Full name of responsible person
Mohammad Tamaddondar

Street address
Bandar Abbas - Islamic Republic of Iran Boulevard

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7919916753

Phone
+98 76 3334 7000

Email
tamaddondar491@hums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Bandare-abbas University of Medical Sciences

Full name of responsible person
دکتر تیمور آقا ملایی

Street address
Bandar Abbas - Imam Hossein Boulevard - in front of Kargaran Sports Club - Nabout Town - Campus of University of Medical Sciences

City
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Province
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Phone
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Email
teaghamolaei@gmail.com

Grant name

Grant code / Reference number
4000362

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

Title of funding source
Bandare-abbas 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
Bandare-abbas University of Medical Sciences

Full name of responsible person
Nahid Shahabi

Position
Student

Latest degree
Ph.D.

Other areas of specialty/work
Health Promotion

Street address
Bandar Abbas, Jomhuri Eslami Blvd., Bustan Alley 10, Faculty of Health

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Position
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Latest degree
Ph.D.

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Person responsible for updating data

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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
Yes - There is 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
Yes - There is 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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
All data is potentially shareable after unidentifiable individuals

When the data will become available and for how long
Access period starts 6 months after the results are published

To whom data/document is available
The data will be available to researchers working in academic and scientific institutions

Under which criteria data/document could be used
If the request is kept confidential and reasonable

From where data/document is obtainable
Nahid Shahabi Student nahid.shahabi@hotmail.com Zahra Hosseini First Supervisor hosseinishirin@ymail.com Teamur Aghamolaei Second Supervisor teaghamolaei@gmail.com

What processes are involved for a request to access data/document
After sending the request via email and obtaining permission from the professors, information will be sent to the applicant.

Comments