

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 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 with T2D

##### 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 (  $k$ ), [ $k = N / n$  ( $1500 \div 166 = 9$ )] 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

##### City

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##### Province

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##### Postal code

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

bandarabbas

#### Province

Hormozgan

#### Postal code

7916613885

#### Phone

+98 76 3371 0393

#### 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

##### City

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##### Province

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**Email**  
nahid.shahabi@hums.ac.ir

## Person responsible for scientific inquiries

### Contact

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nahid.shahabi@hums.ac.ir

## Person responsible for updating data

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**City**  
Bandarabbas

**Province**  
Hormozgan  
**Postal code**  
7919916753  
**Phone**  
+98 76 3333 8583  
**Fax**  
**Email**  
nahid.shahabi@hums.ac.ir

## 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