

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

The effect of integrated educational intervention from Pender's health promotion model and self-regulation theory in insulin injection skill in patients with type 2 diabetes

Protocol summary

Study aim

Determining the effect of integrated educational intervention from Pender's health promotion model and self-regulation theory on insulin injection skill in patients with type 2 diabetes

Design

From the list of patients in endocrinology and metabolism clinic of Firouzgar hospital, patients will be selected and randomly assigned to the control and the intervention group. Will be use block size 4 to randomization.

Settings and conduct

Setting: Endocrinology and Metabolism Clinic, Firouzgar Hospital. Conduct: Seventy eight patients will be selected and randomly assigned to the control and the intervention group. The groups completed the questionnaires and a checklist. Educational sessions will be developed based on the pretest results and will be conducted for the participants in the intervention group. Three months after the intervention, the two groups will be followed and completed the questionnaires and checklist. Finally, the data will be analyzed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: History of diagnosis of type 2 diabetes for at least one year, history of insulin injection for at least 3 months and age 18 to 70 years. Exclusion criteria: History of diagnosed psychological and cognitive problems, history of diagnosed gestational diabetes and discontinuation of insulin (or medication change) by the doctor

Intervention groups

Intervention group: Educational intervention based on the structures of the Pender's health promotion model and self-regulation theory will be designed to address Insulin injection skill and will be done for patients in the intervention group. Control group: No intervention.

Main outcome variables

Primary outcomes: Increasing skill of study participants on Insulin injection. Secondary outcomes: Modifying the attitude and beliefs of participants in terms of Insulin injection.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110727007132N22**

Registration date: **2023-04-04, 1402/01/15**

Registration timing: **prospective**

Last update: **2023-04-04, 1402/01/15**

Update count: **0**

Registration date

2023-04-04, 1402/01/15

Registrant information

Name

Tahereh Dehdari

Name of organization / entity

Iran University of Medical Sciences and Health Services

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-22, 1402/03/01

Expected recruitment end date

2024-12-21, 1403/10/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of integrated educational intervention from Pender's health promotion model and self-regulation theory in insulin injection skill in patients with type 2 diabetes

Public title
The effect of integrated educational intervention from Pender's health promotion model and self-regulation theory in insulin injection skill in patients with type 2 diabetes

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
History of diagnosed type 2 diabetes for at least one year
History of insulin injection for at least 3 months
Age 18 to 70 years
Living in Tehran province
Having reading and writing literacy in Persian
Exclusion criteria:
History of psychological and cognitive problems
History of diagnosed gestational diabetes
Discontinuation of insulin (or medication change) by the doctor during the study

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **78**

Randomization (investigator's opinion)
Randomized

Randomization description
The list of patients who refer to the endocrinology and metabolism clinic of Firouzgar hospital is available to researchers. We will select 78 patients from this list at random and then randomly assign these individuals to the experimental and control groups. For randomization we will use block size 4. With a sample size of 78, 19 blocks of size 4 will be produced based on this online software: www.sealedenvelope.com.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
There is no special characteristic in this study.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

کمیته اخلاق دانشگاه علوم پزشکی و خدمات بهداشتی-درمانی
ایران

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Iran University of Medical Sciences, Shahid Hemmat
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1449614535

Approval date

2023-01-25, 1401/11/05

Ethics committee reference number

IR.IUMS.REC.1401.867

Health conditions studied

1

Description of health condition studied

diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Insulin injection skill

Timepoint

Before and three months after the intervention

Method of measurement

Checklist

Secondary outcomes

1

Description

Increasing the perceived benefits of study participants in terms of insulin injection

Timepoint

Before and three months after the intervention

Method of measurement

Questionnaire

2

Description

Reducing the perceived barriers of study participants in terms of insulin injection

Timepoint

Before and three months after the intervention

Method of measurement

Questionnaire

3

Description

Increasing the perceived self-efficacy of study participants in terms of insulin injection

Timepoint

Before and three months after the intervention

Method of measurement

Questionnaire

4

Description

Increasing the activity-related affect of study participants in terms of insulin injection

Timepoint

Before and three months after the intervention

Method of measurement

Questionnaire

5

Description

Increasing the interpersonal influences of study participants in terms of insulin injection

Timepoint

Before and three months after the intervention

Method of measurement

Questionnaire

6

Description

Increasing the situational influences of study participants in terms of insulin injection

Timepoint

Before and three months after the intervention

Method of measurement

Questionnaire

7

Description

Increasing the preferences and decreasing the immediate competing demands of study participants in terms of insulin injection

Timepoint

Before and three months after the intervention

Method of measurement

Questionnaire

8

Description

Increasing the commitment to a plan of action of study participants in terms of insulin injection

Timepoint

Before and three months after the intervention

Method of measurement

Questionnaire

9

Description

Reducing the HbA1c

Timepoint

Before and three months after the intervention

Method of measurement

It is extracted from recorded patients' files

Intervention groups

1

Description

Control group: No intervention.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Endocrinology and Metabolism Iran
University of Medical Sciences

Full name of responsible person

ramin malboos baf

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Dr. Tahereh Dehdari

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The results only will be published in the article.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not 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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable