

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

The effect of educational escape room on health literacy and self-efficacy of patients with type II diabetes

Protocol summary

Study aim

Determining the effect of using the educational escape room on health literacy and self-efficacy of patients with type 2 diabetes

Design

Randomized controlled clinical trial with time block on about 60 patients

Settings and conduct

The research environment is a specialized parsian diabetes clinic in Mashhad. The content used in the study is diabetes education and self-care training, and at the end, the effect of education on patients' health literacy and self-efficacy is measured by a questionnaire.

Participants/Inclusion and exclusion criteria

Inclusion criteria: willingness and satisfaction to participate in the study; age 18 to 63 years old; participation in educational programs; diagnosis of type 2 diabetes by a specialist; literacy. Criteria for non-inclusion: dissatisfaction with continuing to participate in the study; occurrence of acute problems such as severe stress or illness.

Intervention groups

In the intervention group, for each group, first a training session is held by lecturing on diabetes control and self-care, then in the educational escape room, they solve problems and puzzles with the participation of each other and using the given trainings. The control group will hold two training sessions by lecturer and in groups with an interval of half an hour by the researcher.

Main outcome variables

Self-efficacy score with questionnaire (CIDS) and health literacy with questionnaire (DHLS) will be measured at the beginning of the study, immediately and two weeks after the intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200713048090N1**

Registration date: **2021-10-29, 1400/08/07**

Registration timing: **prospective**

Last update: **2021-10-29, 1400/08/07**

Update count: **0**

Registration date

2021-10-29, 1400/08/07

Registrant information

Name

Faezeh Mardani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4224 3320

Email address

mardanif971@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of educational escape room on health literacy and self-efficacy of patients with type II diabetes

Public title

Effect of educational escape room on diabetes

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness and satisfaction to participate in the study
Living in Mashhad at the time of research
Age 18 to 63 years
Ability to participate in the training program
Diagnosis of type 2 diabetes by a specialist doctor
At least 3 months have passed since the diagnosis of diabetes
Have a minimum literacy rate
No severe complications (nephropathy, retinopathy, vasculopathy and neuropathy)
History of drug treatment of diabetes
Be alert and able to communicate verbally and non-verbally.

Exclusion criteria:

Dissatisfaction with continuing to participate in the study
Absence from any training sessions
Acute problems such as severe stress or illness

Age

From **18 years** old to **63 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The time block method is used to allocate research units. Random sequence is pre-determined by SPSS software for at least 20 days and stored in a package. Every morning, the door of the envelope is opened and based on the relevant code, it will be determined in which group all the patients will be in that day.

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 the School of Nursing and Midwifery - Mashhad University of Medical Sciences

Street address

Central Building Mashhad University of Medical Sciences, Daneshgah Avenue, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2020-07-12, 1399/04/22

Ethics committee reference number

IR.MUMS.NURSE.REC.1399.029

Health conditions studied

1

Description of health condition studied

Diabete

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Health literacy score in the comprehensive diabetes health literacy Scale

Timepoint

Before the training session, immediately and two weeks later

Method of measurement

Comprehensive Diabetes Health Literacy Scale

2

Description

Self-efficacy score on the diabetes self-efficacy scale

Timepoint

Before the training session, immediately and two weeks later

Method of measurement

Confidence in Diabetes self-Care Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: to design an educational escape room based on the frameworks presented in the articles, first the educational needs of patients will be examined by reviewing texts, oral questions from officials and patients at the time of completing the personal information questionnaire, and after extracting items and Preparing a checklist, their validity will also be checked and approved. Then learning goals are planned. Based

on the needs, educational goals and the level of knowledge and skills of the participants, the subject of education, narration, game structure and puzzles and their level of difficulty are designed. These puzzles will be narrative-based challenges with a linear structure so that all members of the group can work together to solve each problem at the same time. The physical space in a room at the Parsian Diabetes Center in Mashhad is designed based on learning objectives, puzzles and their narration with appropriate visual effects. In order to evaluate the room before the main meetings, the two groups enter the escape room on a trial and consecutive basis, which is ready for the main intervention after making the necessary corrections. In the intervention group, individuals are divided into groups of 4-6 people based on the same age category and by gender. For each group, a training session with a lecture method with slides and questions and answers for 60 minutes on the topic of diabetes control and self-care is held by the researcher. Before entering the educational escape room, explanations about the rules, scenarios and instructions will be given orally in 5 minutes, which are also available in writing in the room. They then work together to solve problems and puzzles in the room for a maximum of 60 minutes using the instructions given to get the final key to leave the room. The observer (the researcher himself, who also teaches the lecture session) is present with the participants in the room to monitor the performance, provide guidance and measure time, and if he sees a performance error, he will not allow progress until it is corrected. Whenever they need help or clues, they can ask the game supervisor, who will be provided with a minute to add time. Also, if they do not make progress in the first 30 minutes, the game supervisor will guide them. After reaching the final key and leaving the meeting room for 20 minutes to provide feedback, explain mistakes, fix problems, express learning experiences and satisfaction of participants in a group discussion and using the evaluation checklist of the escape room, along with The reception will be held and the relevant questionnaires will be completed.

Category

Other

2

Description

Control group: in the control group, two training sessions (45-60 minutes) will be held by the researcher in the form of lectures by presenting slides and questions and answers during a day with an interval of half an hour (for rest and reception) in groups of 8-12 people. The content and educational objectives will be similar to the intervention group. Finally, people's opinions and learning experiences are checked with a checklist

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Parsian Diabetes Clinic in Mashhad

Full name of responsible person

Seyed Reza Mazloum

Street address

Lashgar Intersection, Bahar Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

mohsen tafaghodi

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Central Building Mashhad University of Medical Sciences, Daneshgah Avenue, Mashhad

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Faeze Mardani

Position

MSc student in Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Seyed Reza Mazloum

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Other areas of specialty/work

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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

Yes - There is 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

Title and more details about the data/document

Study protocol that contains questionnaire and study method. Statistical analysis and study results will be shared in general and no decision has yet been made regarding the participants' data file sharing.

When the data will become available and for how long

Access starts 6 months after the results are published

To whom data/document is available

All researchers and students in the private and public sectors

Under which criteria data/document could be used

For use in research and teaching at universities

From where data/document is obtainable

Seyed Reza Maloum mazlomr@mums.ac.ir

What processes are involved for a request to access data/document

Applying using an official email is sufficient.

Comments