

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### The effect of education based on the extended parallel process model (EPPM) on adherence to treatment and self-care of type 2 diabetic elderly

#### Protocol summary

##### Study aim

Determining effect of education based on the extended parallel process model on adherence to treatment and self-care of type 2 diabetic elderly

##### Design

Clinical trial with control group, with parallel groups, single blind, Random Allocation on 70 patients, random number table was used for randomization.

##### Settings and conduct

Sampling will begin among the type 2 diabetic elderly referred to the diabetes clinic who have the conditions to participate in the study. First, randomization will be performed and then individuals will be randomly divided into 2 groups. The study will be single blind. Adherence to treatment and Self-care is measured by questionnaire, in both groups before the intervention. The intervention group will receive 5 training sessions based on the extended parallel process model and the control group will receive routine training. Four weeks after training, the level of adherence to treatment and self-care is assessed by a questionnaire.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria : Type 2 diabetic Elderly over the age of 60 who have not a known psychiatric illness based on a medical record . Be aware of the time and place and have the ability to understand educational content. Have a minimum literacy rate. Exclusion criteria: The patient's unwillingness to participate in the research. Participate in a similar training program that coincides with the intervention.

##### Intervention groups

The intervention group consisting of 35 patients, based on the extended parallel process model, will receive training in 5 sessions, each session lasting 45 minutes. There will be 1 training session every week. The control group of 35 patients will receive the usual training in these 5 weeks.

##### Main outcome variables

Adherence to treatment, self-care

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220522054962N1**

Registration date: **2022-06-09, 1401/03/19**

Registration timing: **prospective**

Last update: **2022-06-09, 1401/03/19**

Update count: **0**

##### Registration date

2022-06-09, 1401/03/19

##### Registrant information

##### Name

Malihe Kabusi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 17 3232 3662

##### Email address

kabusi.m@goums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-07-27, 1401/05/05

##### Expected recruitment end date

2022-08-10, 1401/05/19

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of education based on the extended parallel process model (EPPM) on adherence to treatment and self-care of type 2 diabetic elderly

#### **Public title**

Impact of training extended parallel process model on adherence to treatment and self-care of type 2 diabetic elderly

#### **Purpose**

Education/Guidance

#### **Inclusion/Exclusion criteria**

##### **Inclusion criteria:**

Type 2 diabetic elderly over 60 years of age who are diagnosed with no psychiatric illness based on medical records. All units participating in this study should be aware of the time and place and have the ability to understand the educational content. Have a minimum literacy.

##### **Exclusion criteria:**

The patient's unwillingness to participate in the research. Participating in a similar educational program that coincides with the implementation of the intervention.

#### **Age**

From **60 years** old

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

- Data analyster

#### **Sample size**

Target sample size: **70**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

The names of the type 2 diabetic elderly who are eligible for the study will be received from the diabetes clinic and will be numbered based on the medical record number and placed in an envelope. We will use a random number table for randomization. In order to use a random number table, it will first be pre-set to read the table numbers. Then odd numbers are assigned to group A and even numbers are assigned to group B. Hand will be on one of the numbers and move in the predetermined direction and the numbers are recorded in one of the groups A and B according to being even and odd. The intervention and control groups are then randomly assigned.

#### **Blinding (investigator's opinion)**

Single blinded

#### **Blinding description**

The study will be single blind. The data analyzer who does the data analysis will be blinded to the type of intervention.

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Ethics Committee of Golestan University of Medical Sciences

##### **Street address**

Deputy of Research and Technology- Golestan University of Medical Sciences and Health Services- Hyrkan Blvd-Gorgan

##### **City**

Gorgan

##### **Province**

Golestan

##### **Postal code**

4918936316

#### **Approval date**

2022-05-08, 1401/02/18

#### **Ethics committee reference number**

IR.GOUMS.REC.1401.046

## **Health conditions studied**

### **1**

#### **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**

Adherence to treatment

#### **Timepoint**

Before training, 4 weeks after training

#### **Method of measurement**

Questionnaire of adherence to the treatment of chronic diseases

### **2**

#### **Description**

Self-care

#### **Timepoint**

Before training, 4 weeks after training

#### **Method of measurement**

Elderly self-care questionnaire

## **Secondary outcomes**

empty

## Intervention groups

### 1

#### Description

Intervention group: The intervention group will receive trainings based on the extended parallel process model , in 5 sessions By Lectures, questions and answers, educational booklets and pamphlets. The educational content includes Familiarity with diabetes and its complications, Complications of non-adherence to treatment and lack of self-care, Benefits of self-care and adherence to treatment in diabetes control and prevention of complications of this disease, removing the wrong barriers in the field of diabetes and Diabetes control methods. One session per week, each session will be 45 minutes and the duration of the training course will be 5 weeks.

#### Category

Lifestyle

### 2

#### Description

Control group: The control group does not receive any intervention, they are only under normal treatment and training.

#### Category

Lifestyle

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Dezyani Specialized and Sub-Specialized Clinic

##### Full name of responsible person

Fateme Maghsodlo

##### Street address

Dezyani Specialized and Sub-Specialized Clinic.,in front of Behesht 17., Shahid Beheshti St.,Gorgan

##### City

Gorgan

##### Province

Golestan

##### Postal code

4916694667

##### Phone

+98 17 3224 2714

##### Email

fateme\_maghsodlo\_51@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Gorgan University of Medical Sciences

##### Full name of responsible person

Mohammad Reza Honarvar

#### Street address

Deputy of research and technology, Golestan University of Medical Sciences, Hyrkan Blvd.,Gorgan.

#### City

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#### Province

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#### Phone

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#### Email

mrhonarvar@goums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Gorgan 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

Gorgan University of Medical Sciences

##### Full name of responsible person

Gholamreza Mahmoudi Shan

##### Position

Associate Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Nursery

##### Street address

School of Nursing and Midwifery, Golestan University of Medical Sciences, Hyrkan Blvd., Gorgan.

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4918936316

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mahmoodigh@yahoo.com

## Person responsible for scientific

## **inquiries**

### **Contact**

**Name of organization / entity**

Gorgan University of Medical Sciences

**Full name of responsible person**

Gholamreza Mahmoudi Shan

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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## **Person responsible for updating data**

### **Contact**

**Name of organization / entity**

Gorgan University of Medical Sciences

**Full name of responsible person**

Malihe Kabusi

**Position**

Master of Nursing student

**Latest degree**

Bachelor

### **Other areas of specialty/work**

Nursery

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Mirfanderski One, Azar One, 5 Azar Street, Gorgan

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**Postal code**

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**Phone**

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**Email**

malihekabusi987@gmail.com

## **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