

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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		Secondary Ids	empty
Public title	Impact of training extended parallel process model on adherence to treatment and self-care of type 2 diabetic elderly	Ethics committees	
Purpose	Education/Guidance	1	
Inclusion/Exclusion criteria		Ethics committee	
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.	Name of ethics committee	Ethics Committee of Golestan University of Medical Sciences
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.	Street address	Deputy of Research and Technology- Golestan University of Medical Sciences and Health Services- Hyrkan Blvd-Gorgan
Age	From 60 years old	City	Gorgan
Gender	Both	Province	Golestan
Phase	N/A	Postal code	4918936316
Groups that have been masked	Data analyser	Approval date	2022-05-08, 1401/02/18
Sample size	Target sample size: 70	Ethics committee reference number	IR.GOUMS.REC.1401.046
Randomization (investigator's opinion)	Randomized	Health conditions studied	
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.	1	
Blinding (investigator's opinion)	Single blinded	Description of health condition studied	Type 2 diabetes mellitus
Blinding description	The study will be single blind. The data analyzer who does the data analysis will be blinded to the type of intervention.	ICD-10 code	E11
Placebo	Not used	ICD-10 code description	Type 2 diabetes mellitus
Assignment	Parallel	Primary outcomes	
Other design features		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

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Province

Golestan

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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.

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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

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inquiries

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Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

Malihe Kabusi

Position

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Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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

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