

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The Effect Of Group Hope Therapy On The Quality Of Life Of Elderly Women With Type 2 Diabetes

Protocol summary

Study aim

Determining the effect of group hope therapy on the quality of life of elderly women with type 2 diabetes in Mostafavian Diabetes Clinic in 1402

Design

According to the inclusion criteria, 40 elderly women with diabetes were selected to participate in the study. Allocation of samples to intervention and control groups was by random block method. Then, through random allocation 2 statistical software, the samples were randomized into 10 blocks of 4 people. The patient number and group name were placed in the envelope and people opened the envelope according to their arrival and the type of group was determined.

Settings and conduct

The researcher explains how hope grows and the necessity of its existence and its effect on despair, depression and feelings of emptiness. Each client tells their own life story. The purpose of this meeting is to help members find hope. It is tried to identify some of the past hopes and successes of the members in order to identify the cause and the paths of these successes. People are encouraged to choose the right goals and bring up the characteristics of the right goals, and the goal in this meeting and the previous two meetings is to increase hope in the members and help the members to increase it after the end of hope.

Participants/Inclusion and exclusion criteria

female Age over 60 years Definitely suffering from type 2 diabetes

Intervention groups

The control group received the center's routine services for 4 weeks, and the intervention group (two groups of ten people) received 8 sessions of 90 minutes (2 sessions per week with an interval of two days) under the supervision of the first project manager (a master's student in psychiatry trained in hope therapy) received the hope therapy program that was designed based on the protocol of Schneider (1999).

Main outcome variables

quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240130060857N1**

Registration date: **2024-03-03, 1402/12/13**

Registration timing: **retrospective**

Last update: **2024-03-03, 1402/12/13**

Update count: **0**

Registration date

2024-03-03, 1402/12/13

Registrant information

Name

Yadollah Jannati

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-15, 1402/05/24

Expected recruitment end date

2023-10-22, 1402/07/30

Actual recruitment start date

2023-08-17, 1402/05/26

Actual recruitment end date

2023-10-22, 1402/07/30

Trial completion date

2023-11-06, 1402/08/15

Scientific title

The Effect Of Group Hope Therapy On The Quality Of Life Of Elderly Women With Type 2 Diabetes

Public title

The Effect Of Group Hope Therapy On The Quality Of Life

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Female Age 60 years and older Definitely suffering from type 2 diabetes At least one year has passed since the diagnosis of the disease Lack of physical consequences related to diabetes such as: amputation, kidney failure, blindness No use of psychoactive drugs Not suffering from cognitive problems (scoring 7 or higher in the AMT test) Ability to communicate Obtaining a score of 15-45 (on a scale of 15-75) from the quality of life tool of Thomas diabetic patients

Exclusion criteria:

Inability to participate in meetings Having an acute physical or mental illness

Age

From **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **40**

More than 1 sample in each individual

Number of samples in each individual: **40**
44

Actual sample size reached: **40**

More than 1 sample in each individual

Actual sample size in each individual: **40**

Description of the sample per participant

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description

Statistical consultant who is responsible for data analysis

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Mazandaran University of Medical Sciences

Street address

Nasiba Sari School of Nursing and Midwifery. Wasal St. Amir Mazandarani Blvd. Mazandaran Sari

City

Sari

Province

Mazandaran

Postal code

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Approval date

2023-08-15, 1402/05/24

Ethics committee reference number

IR.MAZUMS.REC.1402.301

Health conditions studied**1****Description of health condition studied**

diabetes

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes**1****Description**

quality of life

Timepoint

in three stages; Before the intervention, the end of 8 intervention sessions and one month after the end of the intervention

Method of measurement

Thomas quality of life questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: includes group hope therapy training. The researcher explains how hope grows and the necessity of its existence and its effect on despair, depression and feelings of emptiness. Each client tells their own life story. The goal is to help members find hope. An attempt is made to identify some of the members' past hopes and successes in order to identify

the causes and pathways of these successes. People are encouraged to choose appropriate goals and the goal in this intervention is to give hope to the members. Solutions to create and maintain the factor are proposed and people are asked to engage in positive self-talk and mental imagination. In this meeting, the goal is to maintain hope in the members of the group.

Category

Lifestyle

2

Description

Control group: No intervention is done for the control group.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Mostafavian Diabetes Clinic

Full name of responsible person

Dr. Zahra Kashi

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Amir Mazandarani St. Sari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Pedram Ebrahim Nejad

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Vice President of Research and Technology. Teacher's Square Sari, Mazandaran.

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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

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Yadollah Jannati

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

psychiatric nursing

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after de-identifying individuals

When the data will become available and for how long

2024

To whom data/document is available

All university people

Under which criteria data/document could be used

Their membership in a scientific institution should be confirmed and they should have an official request from the institution

From where data/document is obtainable

jannati.yadollah@gmail.com

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

It will be done through email correspondence

Comments