Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effectiveness of Life Style Self-Management Interventions Based on Group Cognitive Behavioral Treatment on Life Style, Quality of Life and Metabolic Syndrome Indexes in Adults 30 years and older with Metabolic Syndrome

Protocol summary

Study aim

Determination the Effectiveness of Self-Management Interventions Based on Group Cognitive Behavioral Treatment on Life Style, Quality of Life and Metabolic Syndrome Indexes in Adults with Metabolic Syndrome

Design

Clinical trial with control group, randomized, phase 2 on 80 patients.table of random numbers was used for randomization.

Settings and conduct

For the intervention group: 8 sessions 90-minute group training based on self-management and self-care of metabolic syndrome based on cognitive-behavioral therapy strategies. For the control group: Routine care and training through booklets and pamphlets Individually and a lecture session.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 30-70 years Having metabolic syndrome based on the criteria specified in the operational definition of metabolic syndrome Do not have a known mental disorder such as depression or dementia Have at least literacy. Have the ability to take care of yourself. Have the readiness and satisfaction to participate in the training course. Output Criteria: Lack of willingness to continue working together Absence in more than two sessions of training sessions Need to change the medical treatment plan. He should be hospitalized during the research. Die during research.

Intervention groups

For the intervention group: 8 sessions 90-minute group training based on self-management and self-care of metabolic syndrome based on cognitive-behavioral therapy strategies in observing a healthy diet, mobility, stress control, attention to symptoms and regular screening, self-control, Self-encouragement, self-punishment, self-talk and encouragement by others by example. For the control group: Routine care and training through booklets and pamphlets and a lecture session.

Main outcome variables

Lifestyle; Quality of Life; Metabolic Syndrome Indexes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200507047343N1**
Registration date: **2020-05-28, 1399/03/08**
Registration timing: **retrospective**

Last update: **2020-05-28, 1399/03/08**
Update count: **0**

Registration date

2020-05-28, 1399/03/08

Registrant information

Name

Ali Delshad Noghabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5722 7611

Email address

delshad@gmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-30, 1398/11/10

Expected recruitment end date
2020-03-10, 1398/12/20
Actual recruitment start date
2020-01-30, 1398/11/10
Actual recruitment end date
2020-04-29, 1399/02/10
Trial completion date
2020-07-20, 1399/04/30

Scientific title
Effectiveness of Life Style Self-Management Interventions Based on Group Cognitive Behavioral Treatment on Life Style, Quality of Life and Metabolic Syndrome Indexes in Adults 30 years and older with Metabolic Syndrome

Public title
Effectiveness of Self-Management Interventions Based on Group Cognitive Behavioral Treatment on Life Style, Quality of Life and Metabolic Syndrome Indexes in Adults with Metabolic Syndrome
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Age 70-30 years with metabolic syndrome, based on the criteria set out in the operational definition of metabolic syndrome, not suffering from a known mental disorder such as depression and dementia at least literate have the necessary ability to take care of themselves be prepared and satisfied to participate in the training course
Exclusion criteria:
Lack of willingness to continue working together Absence in more than two sessions of training sessions Need to change the medical treatment plan He should be hospitalized during the research Die during research
Age
From **30 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **100**
Actual sample size reached: **88**
Randomization (investigator's opinion)
Randomized
Randomization description
The sampling method will initially be connivance that first of all adults aged 30 years and older who refer to the comprehensive health service centers of Gonabad city who have the criteria to enter the study based on Specifications Registered in the Integrated Health System First, using the easy sampling method from three comprehensive health service centers in Gonabad, out of 290 adult clients with active care records, 88 people who are eligible to study are selected. Random allocation of the research sample will be done to two intervention and control groups based on quadruple block blocks, so that in each block of 4, two allocations will be allocated to the intervention group and two allocations to the control group. Different ones are created and each block is numbered with one number. The 4 blocks are selected based on a random number table until the sample size reaches 88. In the end, 44 people will be in the control group and 44 people will be in the intervention group.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants themselves did not know the type of educational intervention, and the data analyst did not know the group due to the data encoding.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Gonabad University of Medical Sciences
Street address
Nurse Street
City
Gonabad
Province
Razavi Khorasan
Postal code
9691793718
Approval date
2020-01-27, 1398/11/07
Ethics committee reference number
IR.GMU.REC.1398.160

Health conditions studied

1

Description of health condition studied
Metabolic Syndrome
ICD-10 code
E88.81
ICD-10 code description
Metabolic syndrome

2

Description of health condition studied
Hypertension
ICD-10 code

I10
ICD-10 code description
Essential (primary) hypertension

3

Description of health condition studied
obesity
ICD-10 code
E66.0
ICD-10 code description
Obesity due to excess calories

Primary outcomes

1

Description
Lifestyle refers to the score a person receives from the Walker Lifestyle Questionnaire.
Timepoint
At the beginning of the study, three months after the end of the intervention
Method of measurement
Health-Promoting Lifestyle questionnaire

2

Description
Quality of life in this study refers to the score obtained before and three months after the intervention with the WHO Quality of Life Questionnaire (WHOQOL-BREF).
Timepoint
At the beginning of the study, three months after the end of the intervention
Method of measurement
WHO Quality of Life Questionnaire (WHOQOL-BREF)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group: In this study, lifestyle modification training based on the guidelines of therapeutic strategies in metabolic syndrome: lifestyle interventions to reduce metabolic syndrome and heart disease at Oxford University will be performed in 8 sessions for the Intervention group. In line with the objectives of the study, the self-management intervention training program for lifestyle modification based on group cognitive-behavioral therapy for one month for 8 sessions 90 minutes as two sessions per week as follows for adults 30 years and older with intervention group metabolic syndrome Will be provided.
Category
Behavior

2

Description
Control group: Control group: In the control group, routine care and individual training including booklet, pamphlet and face-to-face training will be provided in connection with the self care of metabolic syndrome and a general magic session.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Gonabad Comprehensive Urban Health Services Centers
Full name of responsible person
Ali Delshad Noghabi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Shahla Khosravan
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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
Gonabad 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
Gonabad University of Medical Sciences
Full name of responsible person
Ali Delshad Noghabi
Position
Associate professor
Latest degree
Master
Other areas of specialty/work
Psychology
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Person responsible for scientific inquiries

Contact
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Gonabad University of Medical Sciences
Full name of responsible person
Reza Esmaeili
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Chief of Social Development and Health Promotion Research Center
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Person responsible for updating data

Contact
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delshad@gmu.ac.ir

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
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
Yes - There is 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
General information and data analysis
When the data will become available and for how long

At any time

To whom data/document is available

University researchers

Under which criteria data/document could be used

General data analysis

From where data/document is obtainable

Gonabad University of Medical Sciences

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

Written request from

Comments