Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jun 2026

Evaluating of the effect of educational intervention based on the developed parallel process model on the adherence to the proper diet, glycemic factors, and lipid profile in middle-aged people with type 2 diabetes

Protocol summary

Study aim
Effect of educational intervention based on the developed parallel process model on the adherence to proper diet, glycemic control, and lipid profile in middle-aged people with type 2 diabetes

Design
A 4-arm randomized, controlled, single-blind,factorial field trial (with control group) on 88 participants was designed. Centers were randomly allocated to the control or intervention groups and in each center, 22 were selected by simple random sampling. Nutrition education including Gain Frame Messages,Loss Frame Messages,or a combination of both types of messages versus usual diabetic nutritional education were conveyed to 88 type 2 diabetic patients aged 30 to 59 years.

Settings and conduct
Nutritional education including Gain Frame Messages,Loss Frame Messages,or their combination versus usual nutritional education were conveyed to diabetic patients in Bowanat city for 3 months to assess their effects on dietary adherence,biochemical,anthropometric,and glycemic control markers.Data analyzer was not informed of study groupings (single-blind).

Participants/Inclusion and exclusion criteria
Age range: 30-59 years old (middle age); having type 2 diabetes and not using insulin (FBS higher than 125 and 2-hr glucose higher than 200 mg/dl); not having chronic diseases including cancer; kidney or liver diseases not using special drugs; not smoking; having no special diet; not being pregnant or lactating; not having sudden disturbances of blood glucose including sudden and dangerous hypo- or hyperglycemia;

Intervention groups
1)Gain Frame Messages(GFM) 2) Loss frame Messages(LFM) 3) Combination of both types of messages(G\LFM) 4) Control(CG)

Main outcome variables
Hb A1C,blood glucose

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230104057040N1**
Registration date: **2023-05-08, 1402/02/18**
Registration timing: **retrospective**

Last update: **2023-05-08, 1402/02/18**
Update count: **0**

Registration date
2023-05-08, 1402/02/18

Registrant information

Name
Tayebe Dehghan

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 917 566 2643

Email address
dehghant89@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-22, 1400/10/01

Expected recruitment end date
2022-05-20, 1401/02/30

Actual recruitment start date
2022-01-21, 1400/11/01
Actual recruitment end date
2022-04-19, 1401/01/30
Trial completion date
2022-08-21, 1401/05/30

Scientific title
Evaluating of the effect of educational intervention based on the developed parallel process model on the adherence to the proper diet, glycemic factors, and lipid profile in middle-aged people with type 2 diabetes

Public title
Nutrition education with extended parallel model in diabetic patients for improving glycemic indices and lipid profile control and adherence to the proper diet
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Age range: 30-59 years old (middle age) Having type 2 diabetes and not using insulin (FBS higher than 125 and 2-hr glucose higher than 200 mg/dl) Not having chronic diseases including cancer, kidney or liver diseases Not using special drugs, not smoking Having no special diet Not being pregnant or lactating
Exclusion criteria:
Incidence of any chronic or acute diseases or incidence of some diseases such as kidney diseases Sudden disturbances of blood glucose including sudden and dangerous hypo- or hyperglycemia Acute or respiratory infections Any surgery Following any special diet or physical activity regiment
Age
From **30 years** old to **59 years** old
Gender
Both

Phase
3
Groups that have been masked

- Data analyser

Sample size
Target sample size: **88**
Actual sample size reached: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
For data gathering, first, name and address of all health centers of Bowanat city were extracted and from 8 centers, four centers were selected by random multi-stage method. After selecting 4 centers, each center was allocated to a group of intervention or control group by lottery, in order not to let the patients visit each other and not to distort the results. Then, from each center, 22 patients were selected from eligible middle-aged diabetic patients with simple random sampling.
Blinding (investigator's opinion)
Single blinded
Blinding description
the study was single blind. Data analyzer was not also informed of groupings.At the time of analysis, the analyzer was informed that 4 groups with the names of A,B,C,D were available and he/she was not informed of group characteristics.
Placebo
Not used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shiraz University of Medical Sciences
Street address
Razi Avenue
City
Shiraz
Province
Fars
Postal code
7134814336
Approval date
2021-07-18, 1400/04/27
Ethics committee reference number
IR.SUMS.SCHEANUT.REC.1400.012

Health conditions studied

1

Description of health condition studied
Type 2 Diabetes
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Glycosylated hemoglobin
Timepoint
At baseline and after 3 months
Method of measurement
High performance liquid chromatography (HPLC)

2

Description
Fasting blood glucose
Timepoint
At baseline and after 3 months
Method of measurement
Calorimetric method by using auto-analyzer

3

Description
2 hour- blood glucose
Timepoint
At baseline and after 3 months
Method of measurement
Calorimetric method by using auto-analyzer

Secondary outcomes

1

Description
Low density lipoprotein-cholestrol
Timepoint
At baseline and after 3 months
Method of measurement
Calorimetric method by using auto-analyzer

2

Description
High density lipoprotein-cholestrol
Timepoint
At baseline and after 3 months
Method of measurement
Calorimetric method by using auto-analyzer

3

Description
Total cholestrol
Timepoint
At baseline and after 3 months
Method of measurement
Calorimetric method by using auto-analyzer

4

Description
Triglyceride
Timepoint
At baseline and after 3 months
Method of measurement
Calorimetric method by using auto-analyzer

5

Description
Weight
Timepoint
At baseline and after 3 months
Method of measurement
With scale

6

Description
Height
Timepoint
At baseline and after 3 months
Method of measurement
With tape meter

7

Description
Body mass index
Timepoint
At baseline and after 3 months
Method of measurement
With calculation from weight and height

8

Description
Waist circumference
Timepoint
At baseline and after 3 months
Method of measurement
With tape meter

9

Description
Hip circumference
Timepoint
At baseline and after 3 months
Method of measurement
With tape meter

10

Description
Waist to hip ratio
Timepoint
At baseline and after 3 months
Method of measurement
Calculate form waist and hip measurements

11

Description
Physical activity
Timepoint
At baseline and after 3 months
Method of measurement
With questionnaire

12

Description
Knowledge level
Timepoint
At baseline and after 3 months
Method of measurement
With questionnaire

13

Description
Perceived sensitivity
Timepoint
At baseline and after 3 months
Method of measurement
With questionnaire

14

Description
Perceived severity
Timepoint
At baseline and after 3 months
Method of measurement
With questionnaire

15

Description
Perceived effectiveness
Timepoint
At baseline and after 3 months
Method of measurement
With questionnaire

16

Description
Self-efficacy
Timepoint
At baseline and after 3 months
Method of measurement
With questionnaire

17

Description
Intention
Timepoint
At baseline and after 3 months
Method of measurement
With questionnaire

18

Description
Food intake of macro nutrients and calorie
Timepoint
3-day dietary recall
Method of measurement
With questionnaire

Intervention groups

1

Description
1- Control group:routine educations for 3 months (82 messages in the form of images and clips, almost 5 messages per day via virtual media such as messengers and by formation of virtual groups)
Category
Prevention

2

Description
1- Intervention group: gain-frame messages group for 3 months (82 messages in the form of images and clips, almost 5 messages per day via virtual media such as messengers and by formation of virtual groups)
Category
Prevention

3

Description
2- Intervention group:loss-frame messages group for 3 months(78 messages in the form of images and clips, almost 5 messages per day via virtual media such as messengers and by formation of virtual groups)
Category
Prevention

4

Description
3- Intervention group: combined messages group for 3 months (157 messages in the form of images and clips, almost 5 messages per day via virtual media such as messengers and by formation of virtual groups)
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Bowanat city health centers
Full name of responsible person
Tayebe Dehghan
Street address
Razi avenue
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Postal code
۱۴۳۳۶۷۱۳۴۸
Phone
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Email
dehghant89@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Zahra Sohrabi
Street address
Razi avenue
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+98 917 711 3086

Email
Zahra_2043@yahoo.com

Grant name

Grant code / Reference number

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

Title of funding source
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Tayebe Dehghan

Position
Msc Student

Latest degree
Bachelor

Other areas of specialty/work
Nutrition

Street address
Razi avenue

City
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Person responsible for scientific inquiries

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Zahra Sohrabi

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Person responsible for updating data

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Position
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Latest degree
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Email
dehghant89@yahoo.com

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
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
The final results will be shared.

When the data will become available and for how long
After publishing the article.

To whom data/document is available

Now it is available for the analyzer and the main investigators.

Under which criteria data/document could be used

Only with permission from the investigator

From where data/document is obtainable

By contacting the investigator

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

By asking from e-mail (email address: Sohrabi@sums.ac.ir)

Comments