Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Determining the Effectiveness of an Educational Program Based on Health Action process Approach on Lifestyle of Women with history of Gestational Diabetes

Protocol summary

Study aim

The effect of educational intervention based on health action process approach on lifestyle of women with gestational diabetes

Design

This study is a randomized controlled clinical trial, and 70 women with history of gestational diabetes will be randomly assigned into two intervention and control groups.

Settings and conduct

In this study, 70 women referred to Tonekabon health centers who had a history of gestational diabetes in their recent pregnancy were randomly divided into intervention and control groups after obtaining informed consent.in Intervention group will present 3 sessions Training Program based on Health Action Approach to Prevent Type 2 Diabetes. The control group will not receive any training.

Participants/Inclusion and exclusion criteria

All women with a history of gestational diabetes in their recent pregnancy that they have Iranian nationality who are able to read and write in Persian can participate in this study if they have given birth at least 6 months up to two years ago. But if they have type one or two diabetes, chronic diseases such as heart disease, hypertension, thyroid disease and ... mental illness and cancer as well as having a physical disability that impedes physical activity and also pregnancy or pregnancy planning In the next 6 months, smoking, drinking and drug use will not be eligible.

Intervention groups

In the intervention group, the training program will be conducted in 3 sessions of 90 minutes in lecture, group discussion, question and answer and slide show at the health center.The content of the curriculum is designed based on the results of a cross-sectional study, a literature review and the opinion of nutritionists, physical education and health educators and based on a health action process approach theory.The control group will receive routine care.

Main outcome variables

Physical Activity Score and Food Group Score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200108046051N1**
Registration date: **2020-01-16, 1398/10/26**
Registration timing: **prospective**

Last update: **2020-01-16, 1398/10/26**
Update count: **0**

Registration date

2020-01-16, 1398/10/26

Registrant information

Name

Banafshe Mohamadi zeidi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8820 2512

Email address

mohamadi23@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2020-07-22, 1399/05/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Determining the Effectiveness of an Educational Program Based on Health Action process Approach on Lifestyle of Women with history of Gestational Diabetes

Public title
Determining the Effectiveness of an Educational Program on Lifestyle of Women with history of Gestational Diabetes
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
They have a history of gestational diabetes in their recent pregnancy. Passing at least 6 months to a maximum of 2 years after delivery. Able to read and write Persian.
Exclusion criteria:
She has type one or two diabetes. Chronic diseases such as heart and respiratory diseases. She has mental illness. She has Cancer. Any physical disability that impedes physical activity. Is pregnant or planning to become pregnant in the next six months. Consume cigarettes, alcohol and other drugs.
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be done by using random numbers in Excel software (Rand function)
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
Shahid Beheshti University of Medical Sciences., Arabi Ave., Daneshjoo Blvd., Velenjak., Tehran., Iran.
City
Tehran
Province
Tehran
Postal code
1983963113
Approval date
2019-01-08, 1397/10/18
Ethics committee reference number
IR.SBMU.RETECH.REC.1397.831

Health conditions studied

1

Description of health condition studied
lifestyle
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Physical activity score
Timepoint
Food subgroups score
Method of measurement
International Physical Activity Questionnaire (IPAQ)

2

Description
Food subgroups score
Timepoint
Food subgroups score
Method of measurement
Food Frequency Questionnaire (FFQ)

Secondary outcomes

1

Description
weight
Timepoint
Before the intervention and 3 months after the intervention
Method of measurement
balance scale

Intervention groups

1

Description

The intervention group will receive 3 sessions of counseling and education based on a health action process approach theory in the areas of nutrition and physical activity to prevent type 2 diabetes. The first session will cover the long-term consequences of gestational diabetes and type 2 diabetes, groups at risk for type 2 diabetes, and ways to prevent or delay type 2 diabetes. These are ways to lose weight, reduce calories, reduce harmful fats, increase fiber and increase physical activity. The positive consequences of healthy eating and physical activity will also be discussed. The interval time of each session with the next session will be a week, each session will take 90 minutes that includes fifteen minutes for a review of past session content, forty-five minute for presentation and individual counseling as required references will be thirty minutes and also a booklet about nutrition and physical activity will given to them. This booklet develop based on review of document and comment of expert.

Category

Lifestyle

2

Description

The control group will receive the routine cares.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Urban Health Care Centres

Full name of responsible person

Banafshe Mohamadi Zeidi

Street address

Urban Health Care Centres., Tonekabom., Mazandaran.,

City

Tonekabon

Province

Mazandaran

Postal code

-

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Mohamadi23@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyyed Ali Ziaei

Street address

Shahid Beheshti University of Medical Sciences., Arabi Ave., Daneshjoo Blvd., Velenjak.,

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Intl_office@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Banafshe Mohamadi Zeidi

Position

PhD student

Latest degree

Master

Other areas of specialty/work

Reproductive Health

Street address

School of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences, Niayesh intersection, Vali-e-Asr street,.

City

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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr. Noroussadat Kariman

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

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Person responsible for updating data

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Name of organization / entity
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Full name of responsible person
Banafshe Mohamadi Zeidi

Position
PhD student

Latest degree
Master

Other areas of specialty/work
Reproductive Health

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1985717443

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Email
Mohamadi23@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is 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

Title and more details about the data/document
We can share information about the main outcome. The data will spread unknown.

When the data will become available and for how long
The data will be an accessible 6-12 month after publishing the results.

To whom data/document is available
Researchers in academic institutes were allowed to access data.

Under which criteria data/document could be used
With stating the reference.

From where data/document is obtainable
Sending email to corresponding author through: n_kariman@yahoo.com

What processes are involved for a request to access data/document
An application letter must include the name of the applicant, used item, the scientific title of the research project or article.

Comments