

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effects of web-based program training compared to face-to-face training on nutritional literacy and physical activity of Tehrani women with gestational diabetes: a randomized controlled clinical trial

Protocol summary

Study aim

Determining the effect of web-based program training compared to face-to-face training on nutritional literacy and physical activity of women with gestational diabetes in Tehran

Design

A clinical trial with a control group, with parallel groups, on 160 pregnant women from Tehran with gestational diabetes.

Settings and conduct

This study will be conducted as a parallel clinical trial on pregnant women with gestational diabetes from Tehran. Sampling will be done in health centers in Tehran in 2024. After explaining the objectives of the study and its implementation method, informed written consent is obtained from the participants, then they will be randomly assigned to one of the two intervention groups based on the permuted block randomization method in the form of online or face-to-face training. The study period will be 2 months. At the beginning and end of the study, information related to food intake, nutritional literacy, physical activity, and anthropometric evaluations are collected.

Participants/Inclusion and exclusion criteria

Adult pregnant woman over 18 years old, suffering from gestational diabetes, pre-pregnancy body mass index between 18.5-35 kg/m², singleton pregnancy between 12 and 28 weeks of pregnancy, literate to read and write, use the internet regularly Daily and willing to cooperate.

Intervention groups

Intervention group: Tehrani pregnant women with gestational diabetes will receive nutrition and physical activity training online for 2 months. Control group: Tehrani pregnant women with gestational diabetes will receive face-to-face nutrition and physical activity training for 2 months.

Main outcome variables

nutritional literacy; The amount of physical activity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230217057441N2**

Registration date: **2024-02-02, 1402/11/13**

Registration timing: **prospective**

Last update: **2024-02-02, 1402/11/13**

Update count: **0**

Registration date

2024-02-02, 1402/11/13

Registrant information

Name

mahsa ranjbar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 4223 9415

Email address

mahsa.rnjb99@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date

2024-10-22, 1403/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of web-based program training compared to face-to-face training on nutritional literacy and physical activity of Tehrani women with gestational diabetes: a randomized controlled clinical trial

Public title

Evaluation of online training compared to face-to-face training on nutritional literacy and physical activity of Tehrani women with gestational diabetes

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Adult pregnant women over 18 years of age referring to health care centers under the supervision of Tehran University of Medical Sciences for prenatal care in Tehran, Suffering from gestational diabetes, Body mass index before pregnancy between 18.5-35 kg/m², Singleton pregnancy in the 12th to 28th weeks of pregnancy, Literate to read and write, Use the Internet on a daily basis, Willingness to cooperate.

Exclusion criteria:

Having a history of malabsorption diseases, eating disorders, HIV infection, diabetes, high blood pressure
Current smoking Lack of literacy

Age

From **18 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **144**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the permuted block technique using 2 blocks will be based on the BMI variable and will be assigned to one of the two intervention groups with web-based program training or the face-to-face training control group. Participants will be randomised using stratified permuted blocks. A block size of 2 will be used, and stratification factors are the participant's BMI. People will be allocated to one of the two groups of intervention and control. Random allocation will be based on a random number list, the letters A, and B will be assigned to an equal number of random number lists.

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 in Research Institute of Neuroscience "Neurological Rehabilitation" - Tehran Univer

Street address

Keshavarz street

City

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Province

Tehran

Postal code

۱۴۱۹۷۳۳۱۳۹

Approval date

2023-09-27, 1402/07/05

Ethics committee reference number

IR.TUMS.NI.REC.1402.024

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

Gestational Diabetes

ICD-10 code

O24.4

ICD-10 code description

Gestational diabetes mellitus

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

Nutritional literacy

Timepoint

Evaluation of nutritional literacy at the beginning of the study (before the start of the intervention) and 2 months after the start of the nutrition education of Tehrani women with gestational diabetes.

Method of measurement

Nutrition literacy questionnaire of pregnant women with gestational diabetes

2**Description**

Physical activity

Timepoint

Examination of physical activity at the beginning of the study (before the start of the intervention) and 2 months after the start of nutrition education of Tehrani women with gestational diabetes

Method of measurement

Secondary outcomes

1

Description

Gaining weight during pregnancy

Timepoint

Examining the mother's weight at the beginning of the study (before the intervention) and 2 months after the start of nutrition education for Tehrani women with gestational diabetes

Method of measurement

Scale

Intervention groups

1

Description

Intervention group: Tehrani pregnant women with gestational diabetes will receive nutrition and physical activity training online for 2 months.

Category

Lifestyle

2

Description

Control group: Tehrani pregnant women suffering from gestational diabetes will receive face-to-face nutrition and physical activity training for 2 months.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Research Institute of Neurosciences "Neural Rehabilitation"

Full name of responsible person

Kurosh Djafarian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Tehran Province, Tehran, Keshavarz Blvd., corner of Quds St., Central Organization of the University, 6th floor

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Grant name

Research assistant of Tehran University of Medical Sciences

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Kurosh Djafarian

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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Person responsible for updating data

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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