Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Designing and Implementing an Educational Intervention for Preventing Gestational Obesity : The Application of the Health Belief Model

Protocol summary

Study aim

The present study was conducted to design and explore the effectiveness of an educational intervention based on some constructs of the Health Belief Model (HBM) in preventing excessive gestational weight gain (GWG) among pregnant women in Isfahan, Iran.

Design

This study is a single blind, randomized controlled clinical trial with parallel group design

Settings and conduct

This survey was done in Isfahan health care centers. 100 pregnant women were randomly selected and allocated to intervention and control groups with the use of random number table. Then, intervention group members have participated in four educational sessions.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Consent for participation in the study;The pregnant women aged 18-35 years old referred to Isfahan health care centers; Pre- pregnancy BMI between 18.5 and higher; Gestational age of 15 weeks; Singleton pregnancy. Exclusion criteria: Diagnosed mental health problems such as anxiety, depression and Obsessive-Compulsive Disorder (OCD); BMI higher than 30 kg/m².

Intervention groups

Intervention group: four educational sessions were designed and conducted for intervention group members based on Health Belief Model Constructs. Control group: There was not any educational session for the control group and they have received only the routine cares from health care centers.

Main outcome variables

Gestational Obesity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180703040325N1**
Registration date: **2018-08-20, 1397/05/29**
Registration timing: **retrospective**

Last update: **2018-08-20, 1397/05/29**
Update count: **0**

Registration date

2018-08-20, 1397/05/29

Registrant information

Name

Hossein Shahnazi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2016-08-22, 1395/06/01

Actual recruitment start date

2016-04-20, 1395/02/01

Actual recruitment end date

2016-09-10, 1395/06/20

Trial completion date

empty

Scientific title

Designing and Implementing an Educational Intervention for Preventing Gestational Obesity : The Application of the Health Belief Model

Public title

The effect of educational intervention based on Health Belief Model on Gestational Obesity

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Consent for participation in the study The pregnant women at the age of 18-35 years old referred to Isfahan health care centers Pre- pregnancy BMI between 18.5 and higher Gestational age 15 weeks Singleton pregnancy

Exclusion criteria:

Diagnosed mental health problem such as anxiety, depression, and Obsessive-Compulsive Disorder (OCD) BMI higher than 30 kg/m²

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, participants were selected by multi-stage sampling. At first, all districts in Isfahan were categorized into five sections, namely north, south, west, east, and central. Two health centers were selected randomly from each district to organize the intervention and control groups. Next, medical records of 100 pregnant women were randomly selected and allocated to intervention and control groups using random number table.

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 Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezarjerib street

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8174673461

Approval date

2015-07-06, 1394/04/15

Ethics committee reference number

IR.MUI.REC.1394.3.350

Health conditions studied

1

Description of health condition studied

Excessive Gestational Weight Gain

ICD-10 code

E66.9

ICD-10 code description

Simple obesity NOS

Primary outcomes

1

Description

The mean score of Health Belief Model constructs

Timepoint

Before intervention, Two and four months after intervention

Method of measurement

The questionnaire of Health Belief Model

2

Description

Excessive Gestational Weight Gain

Timepoint

Two and four months after intervention

Method of measurement

Balance (Seca) scale (precision = 0.1 kg)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The subjects of the intervention group were assigned to four 10- to 15-member groups and attended the training sessions once a week for four weeks. An outlook of educational sessions are:Increasing knowledge about the usefulness of healthy diet and physical activity, severity and duration of physical activity, to become familiar with the changes of nutritional needs and advised weight gain in pregnancy. Perceived susceptibility: Referring to the statistics of overweight problems during pregnancy for the mother and the fetus using the figure and related images. Self-

efficacy: Breaking down the overall goals into smaller goals for making implementation easier and using a role model and verbal encouragement to promote the self-confidence of pregnant women. Perceived barriers: Discussion of possible solutions to solving negative attitudes to improve nutritional status and physical activity in them. Cues to action: Getting help from other family members to improve the healthy lifestyle of pregnant women.

Category

Prevention

2

Description

Control group: The control group has received only the routine education from health care centers.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Dastgerd health center

Full name of responsible person

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Sponsors / Funding sources

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Hossein Shahnazi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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Person responsible for scientific inquiries

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Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information is available

Study Protocol

No - There is not 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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable