

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of group counseling based on Health Belief Model on nutritional behavior of Pregnant women with overweight:Randomized clinical trial

Protocol summary

Study aim

Determinate the effect of group counseling based on Health Belief Model on nutritional behavior of Pregnant women with overweight

Design

This is a randomized clinical trial in which 90 eligible pregnant women were randomly assigned into two groups of intervention and control.

Settings and conduct

Overweight pregnant women who go to Kermanshah Comprehensive Health Centers during the study will enter the study if they are eligible.

Participants/Inclusion and exclusion criteria

All pregnant women overweight; Twin pregnancy; Gestational age 6 to 10 weeks; Reading and writing literacy; lack of underlying diseases and addiction; Pregnancy wanted Withdrawal conditions: any medical or midwifery problems during the study; Failure to attend more than one consultation session; Occurrence of adverse events during the study

Intervention groups

Routine pregnancy care and group counseling base on health belief model 60-45 minutes per week for 4 weeks

Main outcome variables

Initial outcome: Investigate nutritional behavior before and 4 weeks after the intervention using a researcher-made questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200523047548N1**
Registration date: **2020-05-26, 1399/03/06**
Registration timing: **retrospective**

Last update: **2020-05-26, 1399/03/06**

Update count: **0**

Registration date

2020-05-26, 1399/03/06

Registrant information

Name

sahar saadatnia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3839 2625

Email address

saharsaadatnia@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-05, 1397/10/15

Expected recruitment end date

2020-01-05, 1398/10/15

Actual recruitment start date

2019-01-05, 1397/10/15

Actual recruitment end date

2020-01-05, 1398/10/15

Trial completion date

2020-01-05, 1398/10/15

Scientific title

The effect of group counseling based on Health Belief Model on nutritional behavior of Pregnant women with overweight:Randomized clinical trial

Public title

The effect of group counseling based on Health Belief Model on nutritional behavior of Pregnant women with overweight

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Single pregnancy Gestational age 6 to 10 weeks Body mass index 25 to 29/9 Reading and writing literacy Lack of other disease Wanted pregnancy

Exclusion criteria:

any medical or midwifery problems during the study
Failure to attend more than one consultation session
Occurrence of adverse events during the study

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 90

Actual sample size reached: 90

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the total global health centers of the eight centers were randomly selected using the draw-up of the sealed envelopes, among which 8 Center 4 center was randomly selected by the application of the sealed envelopes and the experimental group was considered 4 other centers of the control group. Using the available information in the comprehensive health centers system among individuals with inclusion criteria, samples were selected using random numbers. The method of allocation of subjects to experimental and control groups was simple randomly with sealed envelopes.

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 Hamadan University of Medical Sciences

Street address

Shahid Fahmideh St., Hamadan University of Medical Sciences, Vice Chancellor for Research and Technology

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hamadan

Province

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Postal code

6517838695

Approval date

2018-12-01, 1397/09/10

Ethics committee reference number

IR.UMSHA.REC.1397.617

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

Nutritional behavior

ICD-10 code

Z71.3

ICD-10 code description

Dietary counseling and surveillance

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

Investigating Nutritional Behavior

Timepoint

Before the intervention and 4 weeks later

Method of measurement

Using a researcher-made questionnaire Based on health belief model

Secondary outcomes

empty

Intervention groups**1****Description**

The intervention group: routine care of pregnancy and group counseling of 60-45 minutes per week for 4 weeks based on health belief model by presenting pamphlets and educational pamphlets

Category

Other

2**Description**

Control group: There was no intervention and only prenatal care was performed. After the end of the study, the consultations provided to the case group, will also be placed in pamphlet and pamphlets at the discretion of the control group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive health centers in Kermanshah

Full name of responsible person

Sahar Saadatnia

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeed Bashirian

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Sahar Saadatnia

Position

دانشجوی کارشناسی ارشد مشاوره در مامایی

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Farzaneh Soltani

Position

Reproductive health specialist

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

MSC Student in midwifery counseling

Latest degree

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Other areas of specialty/work

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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