

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

The effect of nutrition-based educational intervention based on Health Action Process Approach (HAPA) on pregnancy outcomes of pregnant mothers covered by nutritional support program

Protocol summary

Study aim

Determining the effect of nutrition-based educational intervention based on HAPA educational model on pregnancy outcomes of pregnant mothers covered by support program

Design

Randomized trial with control group, with parallel groups, without blinding, randomized by simple randomized method using randomizer website, phase 3 on 210 participants.

Settings and conduct

This study will be performed in comprehensive health centers of Qazvin province. Pregnant women covered by the nutritional support program are randomly selected and assigned to intervention or control groups. Due to the nature of the study, blinding is not performed. The intervention group will receive nutrition process training based on health practice.

Participants/Inclusion and exclusion criteria

Inclusion criteria: mother's unfavorable economic status; BMI < 18.5 at the beginning of pregnancy; weight < 45 kg before pregnancy; Hemoglobin < 11 gr/dl; multi fetal gestation; unfavorable weight gain during pregnancy based on the table of weight gain in terms of BMI. Exclusion criteria: lack of regular visits to receive prenatal care; reluctance to participate in the study.

Intervention groups

Intervention group: receiving nutrition-based educational intervention based on HAPA educational model. Control group: no intervention only routine care.

Main outcome variables

Health action process approach constructs; consequences of pregnancy include type of delivery, gestational anemia, gestational diabetes, hypertension in pregnancy, optimal gestational weight gain, birth weight, neonatal hypothyroidism, weight for child age.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180218038789N5**

Registration date: **2020-12-24, 1399/10/04**

Registration timing: **prospective**

Last update: **2020-12-24, 1399/10/04**

Update count: **0**

Registration date

2020-12-24, 1399/10/04

Registrant information

Name

Zainab Alimoradi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3333 6003

Email address

z.alimoradi@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-04, 1399/10/15

Expected recruitment end date

2021-04-19, 1400/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of nutrition-based educational intervention based on Health Action Process Approach (HAPA) on pregnancy outcomes of pregnant mothers covered by nutritional support program

Public title

Nutrition-based educational intervention based on Health Action Process Approach (HAPA) on pregnancy outcomes

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Inadequate economic status of the mother BMI <18.5 before pregnancy weight <45 kg before pregnancy hemoglobin < 11 gr/dl multi fetal gestation Unfavorable weight gain during pregnancy based on the table of weight gain in terms of BMI

Exclusion criteria:

Irregular visits for prenatal care Reluctance to participate in the study

Age

From **18 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **210**

Randomization (investigator's opinion)

Randomized

Randomization description

A simple randomization method was used to assign individuals in study groups. Assignment sequences were generated using the randomizer website. To hide the allocation sequence, 240 matte envelopes were prepared. The type of intervention was written based on the allocation sequence and was placed inside a matte envelope and closed.

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 Qazvin University of Medical Sciences

Street address

Qazvin University of Medical Sciences, Bahonar Boulevard

City

Qazvin

Province

Qazvin

Postal code

59811 -34197

Approval date

2019-11-27, 1398/09/06

Ethics committee reference number

IR.QUMS.REC.1398.209

Health conditions studied

1

Description of health condition studied

Gestational outcomes

ICD-10 code

O99

ICD-10 code description

Other maternal diseases classifiable elsewhere but complicating pregnancy, childbirth and the puerperium

Primary outcomes

1

Description

The constructs of the health action process approach include behavioral intent, outcome expectations, perceived risk, action planning, self-planning, self-efficacy, self-efficacy improvement

Timepoint

Before and 3 months after the intervention

Method of measurement

Questionnaire

2

Description

Consequences of pregnancy include type of delivery, gestational anemia, gestational diabetes, hypertension in pregnancy, optimal gestational weight, birth weight, neonatal hypothyroidism, weight for child age

Timepoint

3 months after the intervention

Method of measurement

Check list

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: receive nutrition training based on

the structures of the health action process approach model in 3 sessions of 45 to 60 minutes, which will be presented by a nutrition expert in the form of a lecture, group discussion with an educational pamphlet. Training will be designed based on the structures of the health action process approach model, including self-efficacy, behavioral intent, outcome expectations, perceived risk, action control, action planning, and nutrition planning related to pregnancy.

Category

Prevention

2

Description

Control group: no intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive health clinics affiliated to Qazvin University of Medical Sciences

Full name of responsible person

Zainab Alimoradi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr MohammadMahdi EmamJomeh

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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

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Zainab Alimoradi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

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Position

Assistant Professor

Latest degree

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Other areas of specialty/work

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Participants' individual data after unidentifiable

When the data will become available and for how long

Start the access period at the same time as printing the results

To whom data/document is available

There are no restrictions on access

Under which criteria data/document could be used

For secondary analysis and by sending an email request

From where data/document is obtainable

Email to the responsible author

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

The request contains the required information

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

Zainab Alimoradi

Position

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Latest degree

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Other areas of specialty/work

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