Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of education based on the extended parallel process model (EPPM) on eating behavior and increasing physical activity of overweight pregnant women

Protocol summary

Study aim
Determining effect of education based on the extended parallel process model on eating behavior and increasing physical activity of overweight pregnant women

Design
Randomized control clinical trial on100 overweight pregnant women,using R software for randomization

Settings and conduct
overweight pregnant women referring to Shohada Tajrish Clinic/Control:routine care,intervention:training based on extended parallel process model in18-20 , 26-30 and 37-38weeks/Data collection:demographic,midwifery and fertility questionnaire,Eating Behavior Pattern Questionnaire,Pregnancy physical activity questionnaire and perinatal outcome checklist in18-20, 26-30, 38-37weeks and first visit after delivery

Participants/Inclusion and exclusion criteria
Inclusion:Iranian and living in Tehran,age range: 20-40years, basic literacy for reading & writing, Being at the gestational age of18-20weeks, Having a body mass index of 29.9-25 at the beginning of pregnancy,Having a singleton pregnancy,Low-risk pregnancies:lack of medical & midwifery restrictions for moderate physical activity,lack of known systemic physical or mental illness & not using special diet and medication
Exclusion:Consumption of any chemical or herbal medicine(except nutritional supplements recommended during pregnancy)that interferes with normal weight gain during pregnancy,The unwillingness of the mother to continue participating in the study or her simultaneous participation in another research with similar educational interventions,The occurrence of any medical or obstetric disorder that requires the special care for the mother that interferes with the interventions of the present study,Delivery before 37weeks of pregnancy(Reported as perinatal complications)

Intervention groups
Control:routine care/Intervention:training based on the extended parallel process model

Main outcome variables
Eating behavior,Pregnancy physical activity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211207053310N1**
Registration date: **2021-12-17, 1400/09/26**
Registration timing: **prospective**

Last update: **2021-12-17, 1400/09/26**
Update count: **0**

Registration date
2021-12-17, 1400/09/26

Registrant information

Name
Atena Hakimzadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 0000 0000

Email address
hakimzadeh.atena@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-01-21, 1400/11/01

Expected recruitment end date
2022-04-20, 1401/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of education based on the extended parallel process model (EPPM) on eating behavior and increasing physical activity of overweight pregnant women

Public title

The effect of education based on the extended parallel process model (EPPM) on eating behavior and increasing physical activity of overweight pregnant women

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Being Iranian and living in Tehran Being in the age range of 20-40 years Possessing basic literacy for reading and writing Being at the gestational age of 18-20 weeks Having a body mass index of 25- 29/9 at the beginning of pregnancy Having a singleton pregnancy Low-risk pregnancies, including, lack of medical and midwifery restrictions for moderate physical activity, lack of known systemic physical or mental illness, and not using special diet and medication

Exclusion criteria:

Consumption of any chemical or herbal medicine(except for the recommended nutritional supplements during pregnancy)which interferes with normal weight gain during pregnancy The unwillingness of the mother to continue participating in the study or her simultaneous participation in another research with similar educational interventions The occurrence of any medical or obstetric disorder or disease that requires the intervention and special care for the mother that interferes with the interventions of the present study. Delivery before 37 weeks of pregnancy (in this case, it is reported as adverse perinatal complications)

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

After obtaining the relevant permits, the researcher selected eligible pregnant women daily in the present study environment and based on the inclusion criteria, after explaining the objectives of the study and obtaining written consent, and then randomly assigning them to two groups of educational intervention. And divides standard care and enters the study. Purpose-based sampling will be performed at the same time as the samples meet the inclusion criteria until the required sample size is completed. In this study, we will use the limited randomization method of block randomization. In this two-group experiment, we will have 4 blocks (including 2 participants in the intervention group and 2 participants in the control group). Randomization is performed by a statistician using R (Random Allocation Software) software and the randomization list is provided to the researcher before the start of the study (50 people for the intervention group with code A and 50 people for the control group with code B). Due to the use of this software, the researcher can not play a role in predicting group members.

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

Research Ethics Committees of School of Pharmacy and Nursing & Midwifery- Shahid Beheshti University

Street address

Valie Asr St., Niayesh Intersection, School of Nursing & Midwifery Shahid Beheshti University of Medical Science

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2021-12-14, 1400/09/23

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1400.239

Health conditions studied

1

Description of health condition studied

Overweight

ICD-10 code

E66.3

ICD-10 code description

Overweight

Primary outcomes

1

Description
Eating Behavior Pattern
Timepoint
(20-18 weeks, 30-26 weeks, 38-37 weeks)
Method of measurement
Eating Behavior Pattern Questionnaire (EBPQ)

2

Description
Physical activity during pregnancy
Timepoint
(20-18 weeks, 30-26 weeks, 38-37 weeks)
Method of measurement
Pregnancy physical activity questionnaire (PPAQ)

Secondary outcomes

1

Description
Perinatal Outcomes
Timepoint
The first visit after childbirth
Method of measurement
Perinatal Outcome Checklist

Intervention groups

1

Description
Intervention group: The intervention group will receive trainings based on the extended parallel process model , in three shifts (18-20 weeks, 26-30 weeks and 37-38 weeks) in the form of face-to-face training, presentation of educational booklets and pamphlets, as well as educational messages and daily reminders through messages. Virtual media will be provided to them from the time of enrollment until the time of delivery. The educational content includes increasing sensitivity to overweight and its side effects, understanding the benefits of following a proper diet and physical activity during pregnancy, and providing practical solutions to increase self-efficacy.
Category
Other

2

Description
Control group: The control group will receive standard care based on routine care protocols at the training center.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohadaye Tajrish Educational Hospital
Full name of responsible person
Maryam Afrakhteh
Street address
Tajrish Square, Shohada Tajrish Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Shahid Arabi St., Yemen St., Next to Ayatollah Taleghani Hospital, Shahid Chamran Highway
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zarghi@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
Sepideh Hajian

Position
Associate Professor of Reproductive Health

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
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Position
Associate Professor of Reproductive Health

Latest degree
Ph.D.

Other areas of specialty/work
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Person responsible for updating data

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student

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Bachelor

Other areas of specialty/work
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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
Participants' data remain confidential with the researcher at the beginning of the study.

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Not applicable

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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
In relation to the intervention protocol, a diagram has been designed which will be completed and shared after the completion of the project. The informed consent form will be completed by the samples before the start of the research. The final study report will be presented in the form of an article.

When the data will become available and for how long
Available in the journal after publication.

To whom data/document is available
All people interested in the subject of the study

Under which criteria data/document could be used
In order to improve eating patterns and increase physical activity in overweight pregnant women

From where data/document is obtainable
Send email to the responsible author

What processes are involved for a request to access data/document
Reasons for request should be provided in the email.

Comments