Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect of education based on health belief model on physical activity among nulliparous pregnant women attending clinics in the city of Ilam in 1393

Protocol summary

Study aim

Determining the effect of education based on health belief model on physical activity of pregnant women in the first pregnancy referred to ilam city clinics in 2014.

Design

In this study, 64 pregnant women are eligible to enter the study. Participants were randomly divided into intervention and control groups and assigned to the control and intervention groups A and B to hide the intervention group.

Settings and conduct

This study is based on the educational intervention based on the Health Belief Model on physical activity conducted in health centers in Ilam city.By forming a specialist package, the package will be prepared based on the Health Belief Model.A briefing session is organized for educators who will get acquainted with how they work.We will have a briefing for the questioners in which they will be familiar with how to complete the questionnaire and the sample.Following the adoption of the plan by the Ilam Ethics Committee, the researcher introduced the letter of introduction by the vice chancellor for research of the University of Ilam University of Science to the Health Department of Ilam city.And with the written permission of the health department's officials, Shahlam Health Centers are introduced for sampling.The sampling method is two-step Sampling begins The research units completed the pre-test questionnaire, but they did not know about their group Then taught by educatorsThe teacher writes on the letters of the intervention group and controls the letters a and b and then completes the questionnaire after the testAfter collecting data, the data are analyzed by statistical analyzer using SPSS software version 16 And is not aware of the study groups The researcher is also unaware of which interventions and controls are in groups a and b

Participants/Inclusion and exclusion criteria

Entry criteria: Nomads, 18 to 35, 16 to 20 weeks, single-strike, no restrictions for physical activity. Conditions of non-arrival: termination of confinement before the end of intervention, establishment of medical or obstetric limitation for physical activity, immigration of participants.

Intervention groups

The intervention group saw physical education training based on the Health Belief Model and the control group on nutrition education during pregnancy.

Main outcome variables

Increase physical activity during pregnancy

General information

Reason for update

Acronym

HBM

IRCT registration information

IRCT registration number: **IRCT20150302021290N1**
Registration date: **2018-01-19, 1396/10/29**
Registration timing: **registered_while_recruiting**

Last update: **2018-01-19, 1396/10/29**
Update count: **0**

Registration date

2018-01-19, 1396/10/29

Registrant information

Name

Mahnaz Shafieian

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 84 3224 4260

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sh.mahnaz1@yahoo.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-01-01, 1396/10/11
Expected recruitment end date
2018-07-02, 1397/04/11
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of education based on health belief model on physical activity among nulliparous pregnant women attending clinics in the city of Ilam in 1393

Public title
Effect of education based on health belief model on physical activity
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Pregnancy women nulliparous pregnant women
Exclusion criteria:
Pregnant women are multiple Pregnant women with physical activity restrictions Pregnant women aged over 35 Women with a gestational age below 16 weeks Pregnant women with multiple pregnancies
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **32**
Randomization (investigator's opinion)
Randomized
Randomization description
Sampling method is a randomized cluster so that for selecting the research environment all health centers in Ilam are considered as clusters.Each cluster is assigned a number. Then, by using a random number table, two health centers are selected randomly from the cluster as the research environment.Sampling work begins in the form of random assignment, in such a way that the trainer randomly assigns each day to the training of individuals in the intervention group or control group so that a container containing the sheets on which the control group or intervention group is written Has the right to withdraw one of these sheets every day and depending on whether the intervention group controls the day to that group and continues to do so as long as the samples of each group reach the quid pro quo
Blinding (investigator's opinion)
Triple blinded
Blinding description
Participants in the study are not aware of their group. The researcher does not know that the individuals in groups A and B are either interventions or group crimes. Statistical analyzes were not known from the studied groups.
Placebo
Not used
Assignment
Parallel
Other design features
Educational content is approved in a specialized panel.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Ilam University of Medical Sciences
Street address
Pajuhesh Streets
City
Ilam
Province
Ilam
Postal code
6931946533
Approval date
2015-09-23, 1394/07/01
Ethics committee reference number
ir.medilam.rec.1394.35

Health conditions studied

1

Description of health condition studied
physical activity in pregnancy
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Physical activity
Timepoint
It is measured in two steps before and after the intervention.

Method of measurement
Standard Physical Activity Questionnaire in Pregnancy

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: physical activity based on health belife model
Category
Behavior

2

Description
Control group: Oral Health Education
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Health Centers in Ilam City
Full name of responsible person
Mahnaz Shafieian
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ilam University of Medical Sciences
Full name of responsible person
Dr.Gholamreza Kalvandi
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hematianali@yahoo.com
Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ilam 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

2

Sponsor
Name of organization / entity
Ilam University of Medical Sciences
Full name of responsible person
دکتر غلامرضا کلوندی
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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
Ilam 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
Ilam University of Medical Sciences
Full name of responsible person
Mahnaz shafieian
Position
Faculty member
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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 personal information
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