

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 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 educators The teacher writes on the letters of the intervention group and controls the letters a and b and then completes the questionnaire after the test After 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

Email address

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 belief 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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Pajuhesh street

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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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pazhohesh,Ave

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sh.mahnaz1@yahoo.com

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

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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

Latest degree

Master

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

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