

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

The Effect of New Technology-Based Consultation on Physical Activity Behavior Modification of Pregnant Women

Protocol summary

Study aim

Determining the effect of Consultation based on new technologies on changing the physical activity behavior of pregnant women

Design

Clinical trial with control group, randomized, simple randomized blocked method is used for randomization.

Settings and conduct

Forty people will be selected from the pregnant women who refer to the health centers of Urmia, taking into account the loss of the sample. Virtual space (creating a virtual channel and group) and using it at home is provided for the comfort of pregnant mothers.

Participants/Inclusion and exclusion criteria

Participation in study - minimum literacy - less than 20 weeks of pregnancy, no chronic diseases (diabetes, high blood pressure, kidney disease), no medical reasons to restrict the movement of mothers, having prenatal care, having a smartphone, Internet access and residents of Urmia; Occurrence of any special forms or diseases in the current pregnancy, frequent bleeding during the intervention, preterm labour, reduced fetal movements, leakage of amniotic fluid, diet for a specific disease and migration from Urmia.

Intervention groups

The control group will only receive routine care and will receive a contact number from the intervention group to send instructional messages. These interventions are providing effective exercises and physical activity during pregnancy in the form of videos and photos and educational texts aimed at weight gain in the appropriate range of pregnancy.

Main outcome variables

physical activity; Body Mass Index; weight

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151004024340N15**

Registration date: **2020-06-05, 1399/03/16**

Registration timing: **retrospective**

Last update: **2020-06-05, 1399/03/16**

Update count: **0**

Registration date

2020-06-05, 1399/03/16

Registrant information

Name

Hamideh Mohaddesi

Name of organization / entity

Urmia University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 44 3275 4963

Email address

mohaddesi.h@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-09-23, 1398/07/01

Actual recruitment start date

2019-01-10, 1397/10/20

Actual recruitment end date

2019-12-01, 1398/09/10

Trial completion date

2020-02-17, 1398/11/28

Scientific title

The Effect of New Technology-Based Consultation on Physical Activity Behavior Modification of Pregnant Women

Public title

The Effect of New Technology-Based Consultation on Physical Activity Behavior Modification of Pregnant Women

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Willingness to Participation in study At least literacy Being under 20 weeks of gestational age Without risk of chronic diseases (diabetes, hypertension, kidney disease) No medical reasons for the restriction of movement during pregnancy No Mental illness and hospitalization (according to the client) No cerclage Having prenatal care The ability to use new technology Having a smartphone Internet access Living in Urmia

Exclusion criteria:

Occurrence of any particular form or disease in the current pregnancy such as pre eclampsia, diabetes, anemia, having a high-risk pregnancy and cerclage surgery repeated bleeding during the intervention preterm labour decreased fetal movements amniotic fluid leakage diet for a specific disease emigrating from Urmia

Age

From **15 years** old to **49 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Actual sample size reached: **71**

Randomization (investigator's opinion)

Randomized

Randomization description

Urmia Health Centers will be classified into three levels 1, 2 and 3 based on economic and social conditions. Then, from each level, 2 centers are randomly selected from all the centers by lottery method. Pregnant women in selective centers by weight groups (normal, overweight, obese), in three groups, independently using randomly assigned allocation method, individuals will be in two groups of control and intervention (according to importance) Weight groups, this process will be performed three times). In this way, first the blocks with AAABBB composition and all possible modes from that list were assigned to each of the exclusive codes, and then according to the sample size of each group, the number of blocks required was selected using the lottery method. will be.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Factorial

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

کمیته اخلاق دانشگاه علوم پزشکی ارومیه

Street address

Orjhans Street, Resalat Blvd, Urmia , Iran

City

Urmia

Province

West Azarbaijan

Postal code

571478334

Approval date

2018-08-15, 1397/05/24

Ethics committee reference number

IR.UMSU.REC.1397.162

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

Pattern of physical activity during pregnancy

ICD-10 code

-

ICD-10 code description

-

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

physical activity behavior

Timepoint

Before the start of the intervention and the end of the intervention

Method of measurement

pregnancy physical activity questionnaire

Secondary outcomes**1****Description**

Maternal weight

Timepoint

Before the start of the intervention and the end of the intervention

Method of measurement

scales

2**Description**

Body Mass Index

Timepoint
Before the start of the intervention and the end of the intervention

Method of measurement
Scales and meters

Intervention groups

1

Description
Intervention group: Providing effective exercises and information about physical activity during pregnancy in the form of videos, photos and educational texts with the aim of changing the behavioral pattern of physical activity of mothers through cyberspace (creating a channel and virtual group) and using it at home for the comfort of pregnant mothers. The unique dietary are prepared by a nutritionist and provided to women. The content will be placed in a virtual group for 8 sessions and will be re-evaluated with the tools immediately after the mothers' intervention.

Category
Behavior

2

Description
Control group: There is no intervention by the research team and they only receive routine care along with a unique diet prepared by a nutritionist.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Health centers of Urmia city

Full name of responsible person
Rasul Entezar mahdi

Street address
West Azerbaijan Province, Urmia, Daneshkadeh str

City
Urmia

Province
West Azarbaijan

Postal code
5714783734

Phone
+98 44 3223 4897

Email
hmohaddesi.han@gmail.com

Web page address
<https://phc.umsu.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Iraj Mohebbi

Street address
Orjhans Street, Resalat Blvd, Urmia , Iran

City
Urmia

Province
West Azarbaijan

Postal code
571478334

Phone
+98 44 3222 9059

Email
hmohaddesi.han@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Oroumia 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
Oroumia University of Medical Sciences

Full name of responsible person
Erfaneh Talebi

Position
midwifery BS student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
Orjhans Street, Resalat Blvd, Urmia , Iran

City
Urmia

Province
West Azarbaijan

Postal code
571478334

Phone
+98 44 3222 9059

Email
erfaneh_talebi_1995@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Hamideh Mohaddesi

Position

Associate professor

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

Orjhans Street, Resalat Blvd, Urmia , Iran

City

Urmia

Province

West Azarbaijan

Postal code

571478334

Phone

+98 44 3222 9059

Email

hmohadesi.han@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Erfaneh Talebi

Position

midwifery B.Sc. student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Urmia University of Medical Sciences, nursing & midwifery Faculty

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3275 4963

Fax**Email**

erfaneh_talebi_1995@yahoo.com

Web page address

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

Undecided - It is not yet known if there will be 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

Not applicable

Title and more details about the data/document

-

When the data will become available and for how long

-

To whom data/document is available

-

Under which criteria data/document could be used

-

From where data/document is obtainable

-

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

-

Comments