

Effect of E-learning programme on increasing physical activity in pregnant women

Submission date 16/01/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/01/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 12/03/2019	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Physical activity during pregnancy is one of the priority issues during this period. Due to the vital role of mothers, their health plays an important role in the health of children. Therefore, in this study, the researchers have tried to evaluate the effectiveness of the e-learning program to increase physical activity in pregnant women referring to health centers.

Objectives will include:

1. Determining the factors affecting physical activity in pregnant women
2. Preparation and development of E-learning software aiming to increase physical activity in pregnant women.
3. Determining the effect of an educational intervention based on E-learning on perceptual factors (knowledge, attitude) and enabling factors in order to increase physical activity in pregnant women referred to health centres.

Who can participate?

All pregnant women aged 18-40 years old with a gestational age of 24-38 weeks who have been referred to health centers in district 5 of Tehran city municipality from 22 areas of the city.

What does the study involve?

Focus groups will be conducted to identify factors that may affect the physical activity of pregnant women. Interviews will then be conducted in order to design a questionnaire and intervention.

Pregnant women in the intervention group will receive content based on E-learning. The E-learning method will integrate current classroom activities with online and mobile learning about physical activity.

What are the possible benefits and risks of participating?

Risks will be minimized to the fullest extent possible. Potential benefits to pregnant women may include reduced risk of blood pressure and diabetes. The risks of pre-term labour and stroke during exercise are reasonable in relation to the benefits to subjects.

Where is the study run from?
Health centers in district 5 of Tehran city municipality.

When is the study starting and how long is it expected to run for?
March 2019 to June 2019.

Who is funding the study?
The Council for Health Research and Development (COHRED) - Department of Science and Technology (DOST).

Who is the main contact?
Leila Kianfard
leila_kf@yahoo.com

Contact information

Type(s)
Scientific

Contact name
Dr Leila Kianfard

ORCID ID
<http://orcid.org/0000-0001-7672-8776>

Contact details
Tarbiat Modares University, No. 7, Jalal Al Ahmad St.14115-116,Tehran,Iran
Tehran
Iran
0098 14115-331

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1412697

Study information

Scientific Title
Effect of E-learning program on increasing physical activity in pregnant women referred to health centers based on the PEN-3 cultural model: a mixed methods study

Acronym
N/A

Study objectives

1. An intervention based on E-learning has a significant effect on perceptive factors (knowledge, attitude) that will increase the physical activity of pregnant women.
2. An intervention based on E-learning has a significant effect on enabling factors that will increase physical activity in pregnant women.
3. An intervention based on E-learning will significantly increase physical activity in pregnant women.
4. An educational intervention based on the cultural model PEN-3 will significantly affect behaviour related to increased physical activity in pregnant women.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The National Research Ethics Committee, Iran, 16/09/2018i, IR.MODARES.REC.1397.091.

Study design

Multicentre randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Internet/virtual

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use the contact details below to request a participant information sheet

Health condition(s) or problem(s) studied

Pregnancy

Interventions

Qualitative Study

Focused group discussions with pregnant women, husbands and individual interviews will be conducted with pregnant women and health care providers (including physicians, nurses and health professionals such as faculty members, researchers, etc.). This will enable us to identify the educational needs, perceptions and enabling factors based on the cultural model PEN-3 that may affect physical activity of pregnant women referred to health centers.

Quantitative study

In the quantitative study a questionnaire will be designed based on the results of focus group discussions and individual interviews (perceptions, enablers, nurtures, educational needs). We will collect the opinions of at least 200 pregnant women referred to health care centers using

this questionnaire. Statistical analysis (essential parametric and non-parametric tests) will be performed using the software Statistical analysis of SPSS 21. Based on these results, the educational content of the E-learning interventions will be designed.

Pregnant women will be randomly divided into intervention and control groups using a computer programme. The educational content based on the E-learning programme will be taught to the intervention group only. The E-learning method will integrate current classroom activities with online and mobile learning. The online component will be delivered via the Tarbiat Modares library website, as well as specifically designed online lectures, made available through YouTube that pregnant women will view prior to attending the respective two hour teaching block. The E- learning component will be delivered when pregnant women are on their ward rounds and interacting with patients during their existing 'bedside teaching' schedule. Pregnant women will present their learning during the next two hour teaching block. Whilst a two-hour block of time will be dedicated to teaching using the E- learning approach, it is anticipated that only one hour of that time will be spent in the tutorial setting, with the other hour available for them to implement their mobile and online learning activities.

In the control group, the content based on E-learning will not be taken and pregnant women will receive their prenatal care according to the past.

Immediately after the end of the intervention, both groups will be followed-up, and then, three months later, both intervention groups will be monitored.

After the study, if the E-learning intervention is found to be effective, it will be delivered to the control group.

Intervention Type

Behavioural

Primary outcome measure

The ability to complete the programme during pregnancy.

Secondary outcome measures

1. Physical activity will be measured objectively and by self-report using the questionnaire MET-PPAQ.
2. Body mass index (BMI).

Overall study start date

20/07/2018

Completion date

10/09/2019

Eligibility

Key inclusion criteria

1. Pregnant women aged 18 to 40 years old
2. Gestational age 24 to 38 weeks of gestation based on the first day of the last menstrual period
3. Resident in Tehran's 5th district.

Participant type(s)

Other

Age group

Other

Sex

Female

Target number of participants

The required sample size per each group (intervention and control group) is 100, for a total sample size of 200 participants.

Total final enrolment

200

Key exclusion criteria

1. Lack of participation in online discussions over 2 sessions
2. High risk pregnancy
3. Had more than three abortions

Date of first enrolment

20/10/2018

Date of final enrolment

20/02/2019

Locations

Countries of recruitment

Iran

Study participating centre

Tarbiat Modares University

Jalal Al Ahmad St.14115-116,Tehran,Iran

Tehran

Iran

0098 14115-331

Sponsor information

Organisation

Tarbiat Modares University

Sponsor details

Tarbiat Modares University, No. 7, Jalal Al Ahmad St.14115-116,Tehran,Iran
Tehran
Iran
0098 14115-331

Sponsor type

University/education

Website

www.tarbiatmodares.ac.ir

ROR

<https://ror.org/03mwgfy56>

Funder(s)

Funder type

University/education

Funder Name

Tarbiat Modares University

Results and Publications

Publication and dissemination plan

There is no program for its release.

Intention to publish date

10/09/2020

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date