

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of e-learning pregnancy care training for husbands on self-care and perceived stress in nulliparous pregnant women

Protocol summary

Study aim

Determining the effect of e-learning of prenatal care to husbands on self-care and perceived stress of nulliparous pregnant women

Design

Control group clinical trial with parallel groups, one-sided (researcher), block randomization, on 68 samples, the website <https://www.Randomization.com> was used for randomization of blocks

Settings and conduct

Regarding the effect of e-learning on prenatal care (supportive, counseling and empowerment) of pregnant women's spouses is primiparous on the health of their pregnant women. From the researcher, dark envelopes will be used at the time of sampling

Participants/Inclusion and exclusion criteria

Inclusion criteria for primiparous pregnant women who want to become pregnant and live with their husbands, and for inclusion criteria for wives, have access to a smartphone and have the ability to use it and both are satisfied to participate in the study.

Intervention groups

Intervention group: Wives of nulliparous pregnant women who receive prenatal care training electronically
Control group: Wives of nulliparous pregnant women who receive routine prenatal care training

Main outcome variables

self-care score of pregnant women, Perceived stress rate of pregnant women, Weight gain of pregnant women

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210315050718N1**

Registration date: **2021-04-25, 1400/02/05**

Registration timing: **registered_while_recruiting**

Last update: **2021-04-25, 1400/02/05**

Update count: **0**

Registration date

2021-04-25, 1400/02/05

Registrant information

Name

fariba abbaszadeh nezam abad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6625 1327

Email address

fariba.abbaszadehnezamabad2017@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-21, 1400/01/01

Expected recruitment end date

2021-06-22, 1400/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of e-learning pregnancy care training for husbands on self-care and perceived stress in nulliparous pregnant women

Public title

The effect of e-learning pregnancy care training for husbands on self-care and perceived stress in nulliparous pregnant women

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria for nulliparous pregnant women: Age between 18-45 years (reproductive ages) Have a minimum gestational age of 8 weeks (based on the first ultrasound performed or the first day of the last menstrual period) First pregnancy Single pregnancy Living with a spouse Inclusion criteria for wives of nulliparous women: Monogamy Smartphone access

Exclusion criteria:

Criteria for not including nulliparous pregnant women: Inability to read and write unwanted pregnancy Having a history of infertility Dissatisfaction with participating in the study Having symptoms threatening abortion (spotting, not hearing the sound of the fetal heart, back pain, etc.) Having a mental illness according to the individual's own expression Having a specific disease such as diabetes and ... Criteria for not including the wives of nulliparous women: Inability to read and write Dissatisfaction with participating in the study Having a mental illness according to the individual's own expression Lack of ability to use social networks

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

68 samples are selected by available sampling method and list of apple system of each center and are allocated in two groups of control and intervention using block random allocation method. Due to the sample size, 17 blocks of 4 are required for random block allocation. The intervention group will be displayed with A and the control group with B. Pregnant women 's husbands are placed in quadruple blocks with two AAs each for intervention and two BBs for control. Samples can be placed in blocks in 6 different ways as follows: 1-AABB 2-ABAB 3-ABBA 4-BABA 5-BBAA 6-BAAB Then we roll the dice, for example 4 comes, BABA rolls the dice again, for example 5 comes BBAA and ... we repeat so much and We roll the dice to complete 68 samples or use the website <https://www.Randomization.com> to determine the random sequence of blocks. In order to hide the random allocation from the researcher, a dark envelope sample size is prepared and each of the random sequences created is recorded on a card and placed inside the envelope, and finally the envelope lid is pasted. At the beginning of the registration of individuals, according to the order of arrival of the samples, one of the envelopes is opened in order and the assigned group of that sample is specified.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants: People in the control group also receive routine care at the health center, so they also receive training, and it is not the case that they do not receive any training, and in the intervention group, we teach them. Thus, participants do not know which group (intervention or control) they are in. Data Analyzer: Also does not know if this is the data of the intervention group or the control group that is analyzing its data

Placebo

Not used

Assignment

Parallel

Other design features

In this study, education is given to the wives of pregnant women and the health consequences of the wives of their nulliparous women are measured to show the extent to which training, support and empowerment of the wives of nulliparous pregnant women can affect the health of their pregnant women.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Research, School of Nursing and Midwifery, Rehabilitation, Tehran University of

Street address

Tohid Square, Dr. Mirkhani St. (Eastern Nusrat)

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2021-02-20, 1399/12/02

Ethics committee reference number

IR.TUMS.FNM.REC.1399.222

Health conditions studied

1

Description of health condition studied

Perceived stress in nulliparous pregnant women, self-care in nulliparous pregnant women, weight gain in nulliparous pregnant women

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

self-care score

Timepoint

At the beginning of the study (before the intervention), 8 weeks after the intervention

Method of measurement

Momeni Pregnant Women Self-Care Questionnaire

2

Description

perceived stress score

Timepoint

At the beginning of the study (before the intervention), 8 weeks after the intervention

Method of measurement

Cohen Perceived Stress Questionnaire

Secondary outcomes

1

Description

Weight gain of pregnant women (the closer the weight gain in the apple system is to the balance line, the more desirable)

Timepoint

At the beginning of the study (before the intervention), 8 weeks after the intervention

Method of measurement

Calibrated with digital scales and comparing the weight of pregnant women with the optimal weighting line of pregnant women in the apple system

Intervention groups

1

Description

Intervention group: Wives of nulliparous pregnant women who receive prenatal care training electronically

Category

N/A

2

Description

Control group: Wives of nulliparous pregnant women receiving routine prenatal care training

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

All comprehensive health service centers in the south of Tehran

Full name of responsible person

Fariba Abbaszadehnezhad

Street address

No. 5, Unit 2, 30 Jahangir Khani Alley, Sina Town, Khalij St., Fatah Highway, Tehran

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fariba.abbaszadehnezhad2017@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraian

Street address

Keshavarz Boulevard, corner of Quds Street, Central University Organization, sixth floor, Vice Chancellor for Research and Technology

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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

Tehran University of Medical Sciences

Proportion provided by this source

50

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

Tehran University of Medical Sciences
Full name of responsible person
Fariba.Abbaszadehnezamabad
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
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No. 5, Unit 2, Jahangir Khani Alley, Sina Town, Khalij
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Person responsible for scientific inquiries

Contact

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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

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

Only part of the data, such as information about its main and secondary consequences, can be shared.

When the data will become available and for how long

Start of access period one year after printing results

To whom data/document is available

It will be available to researchers working in academic and scientific institutions, and people in industry can also apply for it.

Under which criteria data/document could be used

Properly documented and referenced to the study

From where data/document is obtainable

fariba.abbaszadehnezamabad.09331277418,
fariba.abbaszadehnezamabad2017@gmail.com

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

The applicant must fully state the purpose of the study and how to cite and use the material. This request will be sent to the tutor. If the tutor approves, the study data will be provided to the person. This process lasts for 10 days and at the end, the applicant will be asked to Cite it correctly

Comments