

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Clinical trial to determine the effect of training software on the child birth self efficacy among primiparas women in coping with labor

Protocol summary

Summary

The purpose of this study is to determine the impact of computer training programs on the self-efficacy pregnant women in coping with labor. This study is a randomized clinical trial. Inclusion criteria; age range 35-18 years; primiparas; 28-32 weeks gestational age; access to computer; exclusion criteria; case of infection in any pregnancy complications such as placental abruption; fetal death. For this purpose, 150 pregnant women were enrolled to assign randomly to the intervention or control group. 75 pregnant women in an intervention group received training software developed by researchers at 28-32 weeks gestational age. 75 pregnant women in an control group only received usual care. Self-efficacy expectancy and outcome expectancy also compared between two groups.

General information

Acronym

computer and self-efficacy childbirth

IRCT registration information

IRCT registration number: **IRCT201102275918N1**

Registration date: **2011-04-29, 1390/02/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-04-29, 1390/02/09

Registrant information

Name

Seyed Fatemeh Vasegh Rahimparvar

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Tehran University of Medical Sciences

Expected recruitment start date

2010-10-24, 1389/08/02

Expected recruitment end date

2011-01-27, 1389/11/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial to determine the effect of training software on the child birth self efficacy among primiparas women in coping with labor

Public title

computer training and self-efficacy childbirth

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age range 35-18 years; primiparas women; gestational age 28-32 weeks; access to computer; read and write; absence of known contraindication vaginal delivery (such as placenta previa; previous uterine surgery reconstructive or myomectomy entering the uterine cavity; inappropriate malpresentation; active genital herpes infection; and multiple pregnancy...); having a low risk pregnancy (such as there any known chronic disease; gestational hypertension; infertility history; current cerclage in

pregnancy ...); no history of participating in preparation for childbirth classes; absence of mental illnesses known. Exclusion criteria: any complications in pregnancy (such as placental abruption; fetal death; premature rupture of membrane; preterm labor; gestational hypertension; gestational diabetes and ...) are excluded.

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethical Review Committee of Tehran University of Medical Sciences

Street address

Keshavarz BLD, Ghods street, Central building of Tehran University of Medical Sciences, 6th floor

City

Tehran

Postal code**Approval date**

2010-07-03, 1389/04/12

Ethics committee reference number

130/412/89/3

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

Labour pain

ICD-10 code

O75.0

ICD-10 code description

Complications of labour and delivery

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

Self-Efficacy Childbirth, including individual evaluate of his own ability to deal with stressful situations and implement actions is necessary particularly at childbirth.

Timepoint

6-8 week

Method of measurement

Questionnaire

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

Outcome Expectancy, Belief that a certain behavior will produce a particular outcome.

Timepoint

6-8 week

Method of measurement

Questionnair

2**Description**

Self-efficacy Expectancy, The personal conviction that one can successfully perform those behaviors to produce the desired outcome.

Timepoint

6-8 week

Method of measurement

Questionnair

Intervention groups**1****Description**

In addition to the routine pregnancy care in intervention group, mothers received an educational CD named "easy delivery". Pregnant mothers could run the program at home. This CD provided them an educational preparation for delivery based on Lamaz method including familiarity with the birth canal, starting labor, delivery procedures, selecting delivery, danger signs of labor, real labor pain, and techniques such as relaxation, breathing, massage, music therapy. These materials provided for 6-8 weeks .

Category

Prevention

2**Description**

Pregnant women in the control group only received the usual care in pregnancy.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Care Center NO.3

Full name of responsible person

Maryam khanlarzadeh

Street address

Yards 16, Health Care Center Garden Jahandideh

City

Ghaemshahr

2

Recruitment center

Name of recruitment center

Health Care Center NO.6

Full name of responsible person

Fatemeh Mashmoli

Street address

ValiAsr Street, Sary Street

City

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3

Recruitment center

Name of recruitment center

Health Care Center NO.7

Full name of responsible person

Samira Dehghan

Street address

Next bank Meli, Joibar street

City

Ghemshahr

4

Recruitment center

Name of recruitment center

Health Care Center NO.4

Full name of responsible person

Zinab Anvary

Street address

Edalat Street, Babol Street

City

Ghemshahr

5

Recruitment center

Name of recruitment center

Health Care Center Hafttir

Full name of responsible person

Sima Abdi

Street address

City

Ghemshahr

6

Recruitment center

Name of recruitment center

Health Care Center NO.5

Full name of responsible person

Roya Hosiniyan

Street address

City

Ghemshahr

7

Recruitment center

Name of recruitment center

Health Care Center NO.1

Full name of responsible person

Maryam Salehi

Street address

City

Ghemshahr

8

Recruitment center

Name of recruitment center

Health Care Center NO.2

Full name of responsible person

Lila Olad Azami

Street address

City

Ghemshahr

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Tehran University of Medical Sciences

Full name of responsible person

Abbas Hoshmand Behabadi

Street address

Faculty of Nursing and Midwifery, Tohid SQ, Nosrat ST

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research, Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin
Type of organization providing the funding
empty

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Person responsible for general inquiries

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty