

# 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)

##### Phone

+98 21 6692 7171

##### Email address

vaseghrh@tums.ac.ir

##### 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**

Questionnaire

**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**

Questionnaire

**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**

Ghemshahr

### 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

### Contact

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## Person responsible for scientific inquiries

### Contact

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**Postal code**  
**Phone**

## Person responsible for updating data

### Contact

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## 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*