# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## Comparison of the effect of educational software and educational booklet on pain and anxiety during labor: a randomised controlled trial

## Protocol summary

**Summary**

Objectives: Comparison of the effect of educational software and educational booklet on pain and anxiety during labor. Design: Randomized Controlled Trial with three parallel arms. Setting and conduct: This study will be carried out in health centers of Miandoab city. Eligible women will be selected with convenience sampling and will be randomly assigned into 3 groups of 51 subjects with block sizes of 3 and 6. A person from research team not involved in the recruitment and assigning participants will generate allocation sequence using a computerized program. Opaque sealed sequentially numbered envelops will be used for allocation concealment. Participants: 153 pregnant women aged 18 to 35 years with gestational age of 30 to 36 weeks. Interventions: After completing the baseline questionnaires, one intervention group will receive educational software and the other intervention group will receive educational booklet. The control group will receive routine care. The participants will be taught how to use educational tools by the researcher. Participants will study software and booklet until they have mastered. Participants will be followed up in the hospital until the end of delivery. Main outcome measures include anxiety that will be evaluated before and after the admission in hospital and also severity of pain that will be evaluated during labor. Secondary outcomes include knowledge rate and labor self-efficacy that will evaluated before and after the admission in hospital and also duration of the active phase of labor and second stage of delivery.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2015072110324N24**
Registration date: **2015-08-22, 1394/05/31**
Registration timing: **prospective**
Last update:
Update count: **0**

**Registration date**

2015-08-22, 1394/05/31

**Registrant information**

**Name**
Mojgan Mirghafourvand
**Name of organization / entity**
Tabriz University of Medical Sciences
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**Recruitment status**

**Recruitment complete**

**Funding source**

Vice chancellor for research, Tabriz University of Medical Sciences

**Expected recruitment start date**

2015-08-23, 1394/06/01

**Expected recruitment end date**

2015-11-21, 1394/08/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the effect of educational software and educational booklet on pain and anxiety during labor: a randomised controlled trial

**Public title**

Comparison of the effect of educational software and educational booklet on pain and anxiety during labor

**Purpose**
Supportive
**Inclusion/Exclusion criteria**
Inclusion criteria: Aged 18 to 35 years; 30 to 36 weeks of pregnancy; Primigravida; Singleton pregnancy; Access to the computer; Knowledge of how to use a computer or access to a person who assist her in the use of computer; Having no visual problem; Having secondary education or more. Exclusion Criteria: Suffering of any pregnancy complications (such as placental abruption, fetal death, premature rupture of membranes, preterm labor, pregnancy induced hypertension and gestational diabetes); High-risk pregnancy (such as the presence of known underlying disease including heart disease, lung disease, hypertension, diabetes, history of infertility, cervical cerclage in current pregnancy and abortion history); Existence of known contraindication for vaginal delivery (abnormal presentation of fetus, placenta and umbilical cord problems, cephalopelvic disproportion, medical-surgical problem, fetal distress, etc.); Participation in preparation classes for childbirth; Woman willingness to perform cesarean delivery.
**Age**
From **18 years** old to **35 years** old
**Gender**
Female

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **153**
**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**
Ethics Committee of Tabriz University of Medical Sciences
**Street address**
Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz, and East Azerbaijan
**City**
Tabriz
**Postal code**
**Approval date**
2015-08-12, 1394/05/21
**Ethics committee reference number**
TBZMED.REC.1394.414

## Health conditions studied

**1**

**Description of health condition studied**
Pain, Anxiety
**ICD-10 code**
R10, F41.1
**ICD-10 code description**
Abdominal and pelvic pain, Generalized anxiety disorder

## Primary outcomes

**1**

**Description**
Pain
**Timepoint**
Active phase of labor per hour
**Method of measurement**
Visual Analogue Scale

**2**

**Description**
Anxiety
**Timepoint**
Before intervention and after the admission in hospital for delivery
**Method of measurement**
Spielberger's Questionnaire

## Secondary outcomes

**1**

**Description**
Labor self-efficacy
**Timepoint**
Before intervention and after the admission in hospital for delivery
**Method of measurement**
Labor self-efficacy questionnaire

**2**

**Description**
Knowledge
**Timepoint**
Before intervention and after the admission in hospital for delivery
**Method of measurement**
Knowledge questionnaire

**3**

**Description**
Duration of the active phase of labor
**Timepoint**
From dilatation of 4 cm until full dilatation
**Method of measurement**
Partograph form in terms of minute

**4**

**Description**
Second delivery phase
**Timepoint**
From full dilation until the newborn expulsion
**Method of measurement**
Partograph form in terms of minute

## Intervention groups

**1**

**Description**
First intervention group will receive educational software.
**Category**
Prevention

**2**

**Description**
The second intervention group will receive educational booklet.
**Category**
Prevention

**3**

**Description**
The control group will receive routine care.
**Category**
Prevention

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Health centers of Miandoab city
**Full name of responsible person**
Parastoo Abbasi
**Street address**
Miandoab city, West Azerbaijan province
**City**
Miandoab

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Vice chancellor for research, Tabriz University of Medical Sciences
**Full name of responsible person**
Rashidi Mohammad Reza
**Street address**
Research department, third floor, central construction number 2, Tabriz medical science university, Golgasht Street, Azadi Avenue, Tabriz
**City**
Tabriz
**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, Tabriz 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*

## Person responsible for general inquiries

**Contact**
**Name of organization / entity**
Tabriz University of Medical Sciences, Nursing & Midwifery Faculty
**Full name of responsible person**
Parastoo Abbasi
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MSc student in Midwifery
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## Person responsible for scientific inquiries

**Contact**
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Tabriz University of Medical Sciences
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Dr. Mojgan Mirghafourvand
**Position**

PhD of Reproductive Health

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## Person responsible for updating data

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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*