

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 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 envelopes 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 be 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

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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

Position

MSc student in Midwifery

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Person responsible for scientific inquiries

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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