

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 2026

### Clinical trial of comparing effectiveness of "rereading of written scenario" and "theory of planned behavior" with a group without any intervention on selection of delivery method in nulliparous pregnant women

#### Protocol summary

##### Summary

Objective: this study aims to define the effectiveness of rereading of written scenarios on the selection of delivery method. (2) Design: this is a randomized controlled clinical trial, containing 213 nulliparous pregnant women with experimental group1, experimental group 2 and a control group. (3) Setting and conduct: The experimental group 1 went under rereading of written scenario and experimental group 2 went under the theory of planned behavior and the control group received no intervention at all (each one consist of 71 persons). All groups were analyzed with standard questionnaires before the intervention and 37-40th week of pregnancy. (4) Participants including major eligibility criteria: The sample of this study includes 213 nulliparous pregnant women between 28th and 32th week of pregnancy. (5)Interventions: Experimental group 1 received rereading of scenario once a week and 120 minutes per sessions for 3 weeks. Experimental groups 2 received the theory of planned behavior once a week and 120 minutes per sessions for 3 weeks. Control group had received no intervention at all. Main outcome were analyzed using standard questionnaires, once during 32-28week of pregnancy and another time in 37-40th week of pregnancy among all three groups. (6) Main outcome measures (variables): delivery mode and Childbirth Self-Efficacy

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015052020706N2**  
Registration date: **2015-08-29, 1394/06/07**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-08-29, 1394/06/07

##### Registrant information

###### Name

Massome Rasoli

###### Name of organization / entity

Shahroud University of Medical Sciences and Health Services

###### Country

Iran (Islamic Republic of)

###### Phone

+98 11 3453 6767

###### Email address

massomerasoli@shmu.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research ; Shahroud University of Medical sciences and health

##### Expected recruitment start date

2015-05-22, 1394/03/01

##### Expected recruitment end date

2015-12-01, 1394/09/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Clinical trial of comparing effectiveness of "rereading of written scenario" and "theory of planned behavior" with a group without any intervention on selection of delivery method in nulliparous pregnant women

**Public title**

Effect of rereading of written scenario on selection of delivery method

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

Inclusion criteria: Primigravida; pregnancy age:28-32 weeks; age of mother: 18-35 years; singleton pregnancy, having educational degree higher than a fifth grade of primary school, lack of repeated miscarriages, placenta previa and a ban on normal childbirth, lack of history for mental and physical diseases, non- smoking and drug abuse. Exclusion criteria: Those women will be excluded who do not tend to participate in educational classes, are absent in any of sessions of consultation, are not threatened by risk factors such as being conflicted with preeclampsia and preterm 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: **213**

**Randomization (investigator's opinion)**

Randomized

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

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features**

Randomization done through  
(<http://graphpad.com/quickcalcs/randomize1.cfm>)

**Secondary Ids**

empty

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

Ethics committee of Shahroud University of Medical Sciences.

**Street address**

Shahroud University of Medical sciences and Health, 7 Tir Square, Shahroud

**City**

Shahroud

**Postal code**

3614773955

**Approval date**

2015-05-13, 1394/02/23

**Ethics committee reference number**

lr.shmu.rec.1394.32

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

Delivery

**ICD-10 code**

O80, O82

**ICD-10 code description**

Single spontaneous delivery, Single delivery by caesarean section

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

delivery mode

**Timepoint**

After intervention and Immediately after delivery

**Method of measurement**

Percent

**2****Description**

Childbirth Self-Efficacy

**Timepoint**

before the intervention at 28-32 weeks and after the intervention at 37-40 weeks of pregnancy

**Method of measurement**

childbirth self-efficacy questionnaire

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

The score of knowledge

**Timepoint**

before the intervention at 28-32th week of pregnancy and after the intervention at 37-40th week of pregnancy

**Method of measurement**

Questionnaire

**2****Description**

The scores of attitude

**Timepoint**

before the intervention at 28-32th week of pregnancy and after the intervention at 37-40th week of pregnancy

**Method of measurement**

Questionnaire

**3****Description**

The scores of Perceived behavioral control

**Timepoint**

before the intervention at 28-32th week of pregnancy  
and after the intervention at 37-40th week of pregnancy

**Method of measurement**

Questionnaire

**4****Description**

The scores of Subjective norms

**Timepoint**

before the intervention at 28-32th week of pregnancy  
and after the intervention at 37-40th week of pregnancy

**Method of measurement**

Questionnaire

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

The control group received no intervention. This group includes 71 nulliparous pregnant women. The delivery type inventory according to theory of planned behavior and also pregnancy self-efficacy scale questionnaire is completed by them once during 28-32th weeks and for the second time at 37-40th weeks of pregnancy.

**Category**

Behavior

**2****Description**

The first intervening group (rereading of written scenarios based on the theory of planned behavior) comprises of 71 nulliparous pregnant women, who receive 3 sessions of 120 minutes with sequence of once a week during 28-32th week pregnancy with written scenarios and educational aids manual about benefits of normal labor and non-pharmacological methods of pain relief.

**Category**

Behavior

**3****Description**

The second intervening group (theory of planned behavior group) comprises of 71 nulliparous pregnant women, who receive 3 sessions of 120 minutes with sequence of once a week during 28-32th week pregnancy with educational aids manual about benefits of normal labor and non-pharmacological methods of pain relief.

**Category**

Behavior

**Recruitment centers****1****Recruitment center**

**Name of recruitment center**

Shohada women's Hospital of Behshahr

**Full name of responsible person**

Massome Rasoli

**Street address**

Shohada Women's Hospital, Behshahr, Mazandaran,  
Iran

**City**

Behshahr

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor for research, Shahroud University of  
Medical Sciences and Health Services

**Full name of responsible person**

Mohammad Hasan Emamian

**Street address**

Vice chancellor for research, : Shahroud University of  
Medical sciences and Health , 7 Tir Square, Shahroud

**City**

Shahroud

**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, Shahroud University of  
Medical Sciences and Health Services

**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**

Shahroud University of Medical Sciences and Health  
Services

**Full name of responsible person**

Massome Rasoli

**Position**

M.sc student of Consulting in Midwifery

**Other areas of specialty/work****Street address**

Shahroud University of Medical Sciences and Health  
Services , 7 Tir Square, Shahroud

**City**

Shahroud

**Postal code**

3614773955

**Phone**

+98 23 3239 5054

**Fax**

+98 11 3474 1752

**Email**

massomerasoli@shmu.ac.ir  
massomerasoli@gmail.com

**Web page address**

www.shmu.ac.ir

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Shahroud University of Medical Sciences and Health Services

**Full name of responsible person**

Mohammad Mirrezaie

**Position**

Faculty Member of Shahroud University of Medical Sciences and Health Services

**Other areas of specialty/work****Street address**

Shahroud University of Medical sciences and Health, 7 Tir Square, Shahroud

**City**

Shahroud

**Postal code**

3614773955

**Phone**

+98 23 3239 5054

**Fax**

+98 23 3239 5009

**Email**

mirrezaie78@gmail.com

**Web page address**

www.shmu.ac.ir

## Person responsible for updating data

**Contact****Name of organization / entity**

Shahroud University of Medical sciences and Health

**Full name of responsible person**

Massome Rasoli

**Position**

M.sc student of Consulting in Midwifery

**Other areas of specialty/work****Street address**

Shahroud University of Medical sciences and Health, 7 Tir Square, Shahroud

**City**

Shahroud

**Postal code**

3614773955

**Phone**

+98 11 3453 6767

**Fax**

+98 23 3239 5009

**Email**

mirrezaie78@gmail.com

**Web page address**

www.shmu.ac.ir

## 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*