Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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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
Ir.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 during28-32th 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 during28-32th 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
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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
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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

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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