Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The impact of a computerized decision aids on the mode of delivery, compared with the conventional care

Protocol summary

Summary

The objective of the project is to evaluate a decision aid system (DAs) on mode of delivery. This computerized DA will help pregnant women in making decision about the mode of delivery, by clarifying the advantages and disadvantages of cesarean delivery without medical reason. 60 healthy pregnant women are recruited from two private and two public prenatal centers in Mashhad, they will be assigned in either an intervention or control group. The intervention group will receive the mode of delivery DAs and the control group will receive the conventional care. The system body of knowledge is extracted from the studies on the predictors of cesarean delivery. The DAs will ask a series of questions and offers appropriate advice based on women's answers. Another part of the system is education. The DAs will be installed on women PCs so they enable to use it frequently at home. The two primary outcomes for the study are decisional conflict, and knowledge. Decisional conflict will be measured by decisional conflict scale and knowledge will be evaluated by true/ false questions which provided by researchers. Actual mode of delivery (normal or cesarean) will be compared in two groups as a secondary outcome. The duration of the intervention is considered from recruitment to the time of delivery. After intervention evaluation will be taken at 38 weeks of gestation. Data on mode of delivery will be obtained from hospital maternity records.

General information

Acronym
decision aids

IRCT registration information
IRCT registration number: **IRCT2013111010777N3**
Registration date: **2013-11-19, 1392/08/28**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date
2013-11-19, 1392/08/28

Registrant information

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Azam Aslani Mamghani

Name of organization / entity
Mashhad University of medical science

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Iran (Islamic Republic of)

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+98 51 1894 2657

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Recruitment status
Recruitment complete

Funding source
Investigator

Expected recruitment start date
2013-12-21, 1392/09/30

Expected recruitment end date
2016-08-21, 1395/05/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The impact of a computerized decision aids on the mode of delivery, compared with the conventional care

Public title
A computer based decision aids for mode of delivery (Natural delivery or Cesarean section)

Purpose
Health service research

Inclusion/Exclusion criteria
Inclusion criteria: Positive pregnancy test, being in good health, Pregnancy above 28 weeks, and Singleton pregnancy; Exclusion criteria: unwanted pregnancy, inability to read and write and working with computer, experience of previous cesarean section
Age
From **16 years** old to **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Pregnant women were used as the unit of randomization.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences
Street address
Ghoreishi building Daneshgah street
City
Mashhad
Postal code
۳۴۵ - ۹۱۳۷۵
Approval date
2013-02-02, 1391/11/14
Ethics committee reference number
511/4404

Health conditions studied

1

Description of health condition studied
Delivery
ICD-10 code
O80.9
ICD-10 code description
Single spontaneous delivery, unspecified

Primary outcomes

1

Description
Decisional Conflict
Timepoint
Before and after of the intervention
Method of measurement
O'Connor's decisional conflict scale - University of Ottawa

2

Description
knowledge
Timepoint
Before and after of the intervention
Method of measurement
true/false questions

Secondary outcomes

1

Description
Mode of delivery
Timepoint
After the intervention
Method of measurement
Data available in the hospital records

Intervention groups

1

Description
Intervention group: they will receive a computer based decision aids on mode of delivery
Category
N/A

2

Description
Control group: they will receive the conventional care
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Public health centers
Full name of responsible person
Fatemeh Tara
Street address
16 Ayatollah Behjat street Zarine Intersection

City
Mashhad

2

Recruitment center
Name of recruitment center
private offices
Full name of responsible person
Azam Aslani
Street address
Department of Medical Informatics School of medicine, Pardis university campus, Park square
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences, Vice chancellor for research
Full name of responsible person
Mohsen Tafaghodi
Street address
Ghoreishi building, Daneshgah street
City
Mashhad
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad University of Medical Sciences, Vice chancellor for research
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
Mashhad University of Medical Sciences, Vice chancellor for research
Full name of responsible person
Mohsen Tafaghodi
Position
Vicar of research
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact
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Mashhad University of Medical Science
Full name of responsible person
Saeid Eslami
Position
Pharm.D.; Ph.D
Other areas of specialty/work
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Person responsible for updating data

Contact
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Mashhad University of Medical Science
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Azam Aslani M.
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PhD candidate of medical informatics
Other areas of specialty/work
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Web page address

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