Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Oct 2026

Comparing the effect of "Motivational Interviewing" with "Information, Motivation and Behavioural skills" on choosing mode of delivery in pregnant women

Protocol summary

Study aim
To compare the effect of face-to-face motivational interviewing with face-to-face IMB and IMB delivered by mobile App on choosing type of delivery in pregnant women.

Design
In this study, four groups including a face-to-face motivational interviewing intervention group, a face-to-face IMB group, an IMB intervention using mobile App, and a control group will participate in the study. Four public hospitals affiliated to the Tehran University of Medical Sciences will be randomly selected and each selected hospital will be randomly assigned to one of the intervention or control groups. The sample size in each group is 90 pregnant women (Total=360)

Settings and conduct
Four public hospitals affiliated to the Tehran University of Medical Sciences

Participants/Inclusion and exclusion criteria
inclusion criteria: ability to speak Persian; being literate; having single pregnancy; gestational age : 6, 7 and 8 months; no complications in pregnancy; no indications for Cesarean section; have enough time to participate in the study; having smart mobile phone and being able to work with mobile App. Exclusion criteria: having complications during pregnancy and childbirth

Intervention groups
1- face-to-face motivational interviewing 2- face-to-face IMB 3- IMB using mobile App

Main outcome variables
behavioural intention, self-efficacy, mode of delivery, usability of the mobile app

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20151208025431N7**
Registration date: **2018-12-07, 1397/09/16**
Registration timing: **registered_while_recruiting**

Last update: **2018-12-07, 1397/09/16**
Update count: **0**

Registration date
2018-12-07, 1397/09/16

Registrant information

Name
Elham Shakibazadeh

Name of organization / entity
Tehran University of Medical Sciences

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Iran (Islamic Republic of)

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+98 21 4293 3210

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shakib@zums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-11-22, 1397/09/01

Expected recruitment end date
2019-10-21, 1398/07/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the effect of "Motivational Interviewing" with

"Information, Motivation and Behavioural skills" on choosing mode of delivery in pregnant women

Public title
Comparing the effect of "Motivational Interviewing" with "Information, Motivation and Behavioural skills" on choosing mode of delivery in pregnant women
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Ability to speak Farsi literacy Being pregnant Having single pregnancy; Gestational age: 6, 7, and 8 months; No complications in pregnancy; No indication for Cesarean section Having enough time to participate in the study Having smartphone and ability to work with the Mobile App
Exclusion criteria:
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **360**
Randomization (investigator's opinion)
Randomized
Randomization description
\regnant women (GA: 6.7 and 8 months) referred to the four public hospitals affiliated to Tehran University of Medical Sciences will randomly be assigned to one of the intervention or control groups.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of tehran University of Medical Sciences
Street address
Faculty of Health,Tehran University of Medical Sciences, Enghelab ST
City
Tehran
Province
Tehran
Postal code
1417613151
Approval date
2018-10-03, 1397/07/11
Ethics committee reference number
IR.TUMS.SPH.REC.1397.130

Health conditions studied

1

Description of health condition studied
Cesarean Section
ICD-10 code
O75.82
ICD-10 code description
Onset (spontaneous) of labor after 37 completed weeks of gestation but before 39 completed weeks gestation, with delivery by (planned) cesarean section

Primary outcomes

1

Description
Pregnant women's behavioral intention on choosing mode of delivery
Timepoint
Pretest and post-test
Method of measurement
Questionnaire

2

Description
Pregnant women's self-efficacy on choosing mode of delivery
Timepoint
Pretest and post-test
Method of measurement
Questionnaire

3

Description
Mode of delivery
Timepoint
Pretest and post-test
Method of measurement
Questionnaire

4

Description
Usability of the mobile app
Timepoint
3 month
Method of measurement
Questionnaire

Secondary outcomes

1

Description
Mode of Delivery
Timepoint
3 month
Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention Based on Information, Motivation and Behavioral Skills Model: This will be a tailored intervention based on the needs of target group. According to this model, necessary information about the deficiencies in the information, motivation and behavioral skills will be delivered to the participants after a needs assessment through interviews and focus groups discussions. Each group will be consisted of 8-12 participants. The Intervention will have three sections: Information will be provided in 45 minutes using lectures and appropriate teaching aids (PPT slides, educational videos, whiteboards, markers, etc.) to provide better information to pregnant women. For promoting the motivation and behavior, reasons for change will be discussed and feedback will be provided. These three sections will be presented within three sessions for each group. Thus, we will have 18 sessions.
Category
Behavior

2

Description
Intervention based on mobile app; This app will be installed in the phone of the participants. The functions will be trained individually. Patients will work in conjunction with an application-oriented research team and any existing problems will be resolved. The predicted strategies for improving adherence includes reminders that are set up at pop-ups at specified intervals. To monitor adherence, data collected on the server is used. By designing a server, users' activities will be gathered. Items such as the time the application is open and specific parts that are used by the user will be recorded. Each time the user's mobile phone is connected to the Internet, the data will be loaded and stored on the server. This data will be used as a proxy for joining the intervention. In addition, to facilitate women's communication with each other, a chat room will be created in which pregnant women will share their experiences with others. Women can ask questions or contact other pregnant women.
Category
Behavior

3

Description
Intervention based on face-to-face motivational interviews: In this group, pregnant women will be taught face-to-face based on motivational interviews (8-10 individuals in each group). The duration of the sessions will be 45-60 minutes. A brief intervention based on the motivational interview will be conducted by the researcher. During the intervention, women will be acquainted with the purposes in the first session, the norms and processes of the group will be presented. Emotions affecting behaviors will be identified. A homework assignment will be determined. In the second session, discussions will be held on the positive and negative dimensions of behavior. In the third session, values will be identified and prioritized, and the view will be drawn for behavior change.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr Hospital
Full name of responsible person
Mahboube Shirzad
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Keshavarz Blvd, Imam Khomeini Hospital Complex in Valiasr Hospital
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Email
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Ali Sahraeiyan
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Poursina Street, Quds Ave, Keshavarz Boulevard, Tehran, Iran
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Tehran
Postal code
1417653761

Phone
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Email
name@domian.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Tehran University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr Elham Shakibazadeh
Position
Associate Professor
Latest degree
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Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to

make this available	
Data Dictionary	Undecided - It is not yet known if there will be a plan to make this available