

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Country

Iran (Islamic Republic of)

Phone

+98 21 4293 3210

Email address

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

Pregnant 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

Street address

Keshavarz Blvd, Imam Khomeini Hospital Complex in Valiasr Hospital

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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

Street address

Poursina Street, Quds Ave, Keshavarz Boulevard, Tehran, Iran

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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

Ph.D.

Other areas of specialty/work

Health Promotion

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Person responsible for updating data**Contact****Name of organization / entity**

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Other areas of specialty/work

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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