

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Comparison of group education with sending health messages and education through CD on knowledge, attitude and practice of male about participation in perinatal care

Protocol summary

Study aim

Determining and comparing the effect of two methods of group training with the sending of SMS messages and CD-ROM training on men's knowledge, attitude and practice about participation in perinatal care

Design

The clinical trial has two intervention groups and one control group, each group based on the lottery and randomly selected from a prenatal clinic. Sample size for each group of 22 and total was calculated to be 66. but considering the chance of sample loss, sample size was increased to 72.

Settings and conduct

The research environment is three prenatal clinics is affiliated Social Security Organization of Tabriz city, each group will be randomly selected from a center. Initially, through pregnancy care records, the list of pregnant women with a gestational age of 20 to 22 weeks was extracted and through Phone will be invited from their husband to participate in the research. Training for group education is conducted in two sessions 2-hours with a weekly interval on Fridays in rooms in the same centers, and then each week 3-4 health messages will be sent to them.

Participants/Inclusion and exclusion criteria

The inclusion criteria are Being literate; not having passed any educational courses; living with spouse; There is no problem in the relationship between couples. The exclusion criteria are unwillingness to continue the study; and not participating in all the conducted educational sessions for the education group.

Intervention groups

The present study is a clinical trial which is conducted on three groups of group education with sending health messages , education using multimedia compact disk (CD) and control group.

Main outcome variables

Knowledge, attitude and practice in all three groups will be measured before and 3 months after intervention through researcher-made questionnaires.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160224026756N4**

Registration date: **2018-05-27, 1397/03/06**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-27, 1397/03/06**

Update count: **0**

Registration date

2018-05-27, 1397/03/06

Registrant information

Name

Mahnaz Noroozi

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3441 1421

Email address

noroozi@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2018-08-23, 1397/06/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of group education with sending health messages and education through CD on knowledge, attitude and practice of male about participation in perinatal care

Public title
Comparison of Two Methods of Education on Men Participation in perinatal care

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Literacy reading and writing Living with spouse
Exclusion criteria:
There is problem in the relationship between couples
Participation of men in any educational intervention or training course on participation in perinatal care

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 72

Randomization (investigator's opinion)
Randomized

Randomization description
Assign three clinics for two intervention groups (education with sending health messages and education through CD) and control group through the lottery. Samples will be selected based on convenience sampling in clinics.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical

Sciences

Street address
School of Nursing and Midwifery, Isfahan University of Medical Sciences, Hezar Jarib Street, Azadi Square

City
Isfahan

Province
Isfahan

Postal code
8174673461

Approval date
2016-11-27, 1395/09/07

Ethics committee reference number
IR.MUI.Rec.1395.3.599

Health conditions studied

1

Description of health condition studied

Men participation in perinatal care

ICD-10 code

094-099

ICD-10 code description

Pregnancy, childbirth and the puerperium

Primary outcomes

1

Description

Knowledge

Timepoint

Before the intervention, three months after the intervention

Method of measurement

Questionnaire

2

Description

Attitude

Timepoint

Before the intervention, three months after the intervention

Method of measurement

Questionnaire

3

Description

Practice

Timepoint

Before the intervention, three months after the intervention

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Group training with classroom training (groups of 8 people) will be conducted in two sessions of two hours a day, one week intervals on Fridays, and then three to four short messages will be sent each week to 3 months after the start of intervention.

Category

Other

2

Description

Intervention group 2: Training by CD

Category

Other

3

Description

Control group: No intervention will be received

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Prenatal Clinic, 29 Bahman Hospital

Full name of responsible person

Dr Lida Heidari

Street address

29 Bahman Blvd

City

Tabriz

Province

East Azarbaijan

Postal code

5166617857

Phone

+98 41 3338 9342

Email

lh1373@yahoo.com5133

2

Recruitment center

Name of recruitment center

Shahid Mokhtari prenatal clinic

Full name of responsible person

Dr Amir Hossein Samimifar

Street address

Before of Monajem Blvd, Shams-e- Tabrizi Street

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Tabriz

Province

East Azarbaijan

Postal code

5139933356

Phone

+98 41 3266 2720

Email

vahidehfirouzan@yahoo.com

3

Recruitment center

Name of recruitment center

Shahid Malekpour Prenatal Clinic

Full name of responsible person

Mohammad Azimi

Street address

Saeb Street, lower than Masjid Station, Zaferanieh Town

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Tabriz

Province

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5166736868

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Email

vahidehfirouzan@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr Shaghayegh Haghjouy Javanmard

Street address

Research & Technology Dept, Isfahan University of Medical Sciences, St Hezar Jarib, Azadi Square

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Phone

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Email

Research@mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

80

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

2**Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Abolghasem Jouyban

Street address

Research Department, Third Floor, Central
Construction Number 2, Tabriz University of Medical
Sciences, Golghast Street, Azadi Avenue, Tabriz

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East Azarbaijan

Postal code

5138947977

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+98 41 3479 6969

Email

Research@tbzmed.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

20

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**

Esfahan University of Medical Sciences

Full name of responsible person

Mahnaz Noroozi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

School of Nursing and Midwifery, Isfahan University of
medical sciences, St. thousand acres, Azadi Square

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 7532

Email

noroozi@nm.mui.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Mahnaz Noroozi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

School of Nursing and Midwifery, Isfahan University of
medical sciences, St. thousand acres, Azadi Square

City

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

Esfahan University of Medical Sciences

Full name of responsible person

Vahideh firoozan

Position

Phd candidate

Latest degree

Master

Other areas of specialty/work

Reproductive Health

Street address

School of Nursing and Midwifery, Isfahan University of
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City

Isfahan

Province

Isfahan

Postal code

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Email

vahidehfirouzan@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Data of participants are privacy

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The result of clinical study will be published as article

When the data will become available and for how long

Immediately after publishing the results.

To whom data/document is available

All researchers

Under which criteria data/document could be used

Scientific using with citation to article.

From where data/document is obtainable

Email: noroozi@nm.mui.ac.ir

What processes are involved for a request to access data/document

Maximum one week after the communication by email.

Comments