

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### The effect of midwifery-Led childbearing counseling on fertility knowledge; desire and intention among New couple

#### Protocol summary

##### Study aim

Determining the Effect of Midwifery-led childbearing counseling on fertility knowledge, desire and intention among New couple.

##### Design

The study will be conducted on 112 newly married couples who are randomly placed in two intervention and control groups. Block randomization method will be used for randomization using internet tools.

##### Settings and conduct

Sampling is done in two premarital counseling centers in Alborz province. Early sampling will be available at first. In this way, the researcher contacts the eligible people using the phone number listed in their file and after explaining about the objectives and method of conducting the research and the confidentiality of the information obtained, invites the eligible people to complete the questionnaires online. Eligible students are placed in a list with a row number, block randomization is used for random allocation .

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Iranian men and women able to speak Farsi; be literate in reading and writing; aged 18-39 for women, 18-49 for men, without previous marriage; cohabitation within one month. Exclusion criteria: the personnel of medical department; couples who have not lived together after one month for any reason; as well as chronic physical; severe mental illnesses.

##### Intervention groups

First, the participants will be placed in two intervention and control groups. The intervention will be carried out in 4 child-bearing counseling sessions (3 couples and private sessions in virtual space and 1 online Sky Room session in a group of 14 people, men and women separately. And the participants of the control group will only undergo routine pre-marriage counseling.

##### Main outcome variables

The knowledge and desire for fertility; the time of the intention of the first pregnancy

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20161230031662N12**

Registration date: **2022-10-05, 1401/07/13**

Registration timing: **prospective**

Last update: **2022-10-05, 1401/07/13**

Update count: **0**

##### Registration date

2022-10-05, 1401/07/13

##### Registrant information

##### Name

Razieh Lotfi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 26 3430 4433

##### Email address

raziehlutfi@abzums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-10-29, 1401/08/07

##### Expected recruitment end date

2022-12-28, 1401/10/07

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of midwifery-Led childbearing counseling on fertility knowledge; desire and intention among New couple

**Public title**

The effect childbearing counseling By Midwife on fertility intention among New couple

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

Iranian men and women able to speak Farsi. Be literate in reading and writing Aged 18 to 39 for women and 18 to 49 for men Without previous marriage Cohabitation with one month

**Exclusion criteria:**

The personnel of the medical department Couples who have not lived together after one month for any reason Chronic physical and severe mental illnesses

**Age**

From **18 years** old to **49 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **112**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Block randomization method is used in the present study. This will be done using a random block internet tool via <http://www.sealedenvelope.com/simple-randomiser/v1/lists>. Block size is determined 4 and allocation was done upon arrangement of codes in the blocks. Randomization will be concealed in sequentially numbered, sealed, opaque envelopes. After producing randomization sequence, 112 opaque envelopes will be provided and each randomization sequence is recorded on a card, then placed in the envelope in order. To keep concealment, envelopes are numbered too. The envelope is sealed and placed in a box in order. At the beginning of the registration of participants, according to the order of entry of eligible participants to study, one of the envelopes will be opened and the assigned group of the participant will be determined.

**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 Alborz university of medical sciences

**Street address**

Alborz University of Medical Sciences, Shahrake Edari, North Taleghani, Azimieh, Karaj

**City**

Karaj

**Province**

Alborz

**Postal code**

3149779453

**Approval date**

2022-09-26, 1401/07/04

**Ethics committee reference number**

IR.ABZUMS.REC.1401.169

**Health conditions studied****1****Description of health condition studied****ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Average fertility knowledge score in the Cardiff questionnaire

**Timepoint**

Before the start of the study and 4 weeks after the end of the intervention

**Method of measurement**

The Cardiff Psychometric Fertility Knowledge Questionnaire

**2****Description**

The mean fertility tendency score in the questionnaire of Naghibi et al

**Timepoint**

Before the start of the study and 4 weeks after the end of the intervention

**Method of measurement**

Fertility Desire Questionnaire, designed by Naghibi et al. (2019)

**Secondary outcomes****1****Description**

The average time of intention to have the first child, in a question designed by the researcher

#### **Timepoint**

Before the start of the study and 4 weeks after the end of the intervention

#### **Method of measurement**

With a question designed by the researcher, the period of time (months) when they decide to have their first child after marriage is determined.

## **Intervention groups**

### **1**

#### **Description**

Intervention group: All couples eligible to enter the study will complete the personal profile form, fertility and fertility knowledge if they agree to participate in the initial study. Both groups will intervene and control the center's routine counseling services. Then a 60-minute intervention session of childbearing counseling in the form of a speech and group discussion will be held online for groups of 14 people in the intervention group (women and men in the sessions they want to be). Except for one session in the Sky Room, the rest of the sessions will be conducted as a (private) couple counseling on the appropriate virtual messenger network. Virtualization by phone, SMS;Text file, audio, online meetings (Skyroom) will be designed and implemented through suitable platforms and messaging systems. The time of the meetings will be adjusted with the coordination of the participants so that the maximum participation is held with the least obstacles. A meeting may be held in the morning and the next meeting in the evening. The participant's phone, email address and phone number connected to the virtual network will be collected from him to enable the exchange of information, interaction (participants are asked to view and study the contents) to inform the researcher to record in a sheet), complete the questionnaires and send the contents as well as the necessary reminders. Educational and advisory content about fertility knowledge will be compiled by the research team based on the guidelines of the Ministry of Health and the reliable sources and sites. After the end of the intervention, both groups will complete the questionnaires online again after one month. After the end of the intervention and completion of the questionnaires, a session of sex education and parenting in the form of a podcast and text file will be held for the control group. Contents in the field of anatomy and physiology in brief, the rate of fertility and infertility, the risks of delay in fertility, the safe time to wait until childbearing, the effect of age on women's fertility, the definition of infertility and the factors affecting infertility, the benefits of childbearing and its impact on health. family), fertility time during the monthly cycle, the impact of various and important factors in pregnancy such as obesity and smoking, sexually transmitted infections and information on infertility treatments and costs, etc.

#### **Category**

Other

### **2**

#### **Description**

Control group:56 number of control group will receive only routine counseling.

#### **Category**

N/A

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Rastravesh premarital counseling center

##### **Full name of responsible person**

Shamsolmolok Faramarzi

##### **Street address**

Blv south taleghane ;vahdat street

##### **City**

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### **2**

#### **Recruitment center**

##### **Name of recruitment center**

Shohadae Fardis permarital counseling center

##### **Full name of responsible person**

Shamsolmolok Faramarzi

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## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Karaj University of Medical Sciences

##### **Full name of responsible person**

Dr.mohamad Noore Sepehr

##### **Street address**

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Dr.noorisepehr@abzums.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Karaj 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**  
Karaj University of Medical Sciences  
**Full name of responsible person**  
Shamsolmolok Faramarzi  
**Position**  
BCs in midwifery  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Midwifery  
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School of Medicine, University of Medical Sciences  
Campus, University of Art, End of West Bou Ali Street,  
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## Person responsible for scientific inquiries

**Contact**  
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Karaj University of Medical Sciences  
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Razieh Lotfi  
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Associate professor  
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## Person responsible for updating data

**Contact**  
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Karaj University of Medical Sciences  
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Shamsolmolok Faramarzi  
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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**  
Yes - There is a plan to make this available  
**Study Protocol**  
Yes - There is a plan to make this available  
**Statistical Analysis Plan**  
Yes - There is a plan to make this available  
**Informed Consent Form**  
Yes - There is a plan to make this available  
**Clinical Study Report**  
Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Total potential data can be shared after unidentifiable people.

**When the data will become available and for how long**

Date will be in access 6 months after publishing the results.

**To whom data/document is available**

only for researchers working in academic and scientific institution.

**Under which criteria data/document could be used**

scientific studies

**From where data/document is obtainable**

using Email address:poonehrad73@gmail.com

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

up to a week after sending the Email address

**Comments**