

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2023

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

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2

Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

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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
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
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Other areas of specialty/work
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Razieh Lotfi
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Person responsible for updating data

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Poonehrad73@gmail.com

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