Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

Effectiveness of an educational intervention on fertility knowledge, childbearing intention and planned pregnancy among new couples referring to premarital counselling centers: a randomized clinical trial

Protocol summary

Study aim

This study aims to evaluate the effectiveness of an educational intervention program on fertility knowledge, childbearing intention and planned pregnancy rate among 1240 couples referring to premarital counselling centres.

Design

This study is a parallel randomised clinical trial with pre-test/post-test design.

Settings and conduct

This study will be conducted in five metropolitan cities of Iran with a diverse geographical distribution (Tehran, Mashhad, Ahvaz, Tabriz and Shiraz). Data will be collected by questionnaires at baseline and 3, 12 and 18 months after the intervention in each selected city. Participants will respond to a self-administered demographic characteristics questionnaire, the Cardiff Fertility Knowledge Scale (CFKS), the childbearing intention questionnaire and some questions about their pregnancy (planned/unplanned pregnancy). Given the nature of the intervention, it is not possible to blind participants to researchers involved in providing the intervention and data collection.

Participants/Inclusion and exclusion criteria

We plan to recruit new couples (men and women) referring for compulsory premarital counselling.

Intervention groups

The intervention group will receive both the typical premarital counselling training and a fertility knowledge package containing virtual (off-line) educational package at two time episodes with an interval of one month. The intervention includes text messages and short films. The control group will receive only typical premarital counselling.

Main outcome variables

The primary outcomes are fertility knowledge, childbearing intention and the first planned pregnancy rate (positive pregnancy test).

General information

Reason for update

Due to suspension of face-to-face premarital counseling during the COVID-19 pandemic in Iran, we have to change the protocol. In this regard, face-to-face training will not be provided for the intervention group. The intervention group will receive a fertility knowledge package containing only virtual (off-line) educational package at two time episodes with an interval of one month. The intervention includes text messages and short films.

Acronym

IRCT registration information

IRCT registration number: **IRCT20201005048925N1**
Registration date: **2020-10-12, 1399/07/21**
Registration timing: **prospective**

Last update: **2022-01-12, 1400/10/22**
Update count: **1**

Registration date

2020-10-12, 1399/07/21

Registrant information

Name

Fahimeh Ranjbar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8867 1613

Email address

ranjbar.f@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2020-11-21, 1399/09/01
Expected recruitment end date
2022-11-22, 1401/09/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effectiveness of an educational intervention on fertility knowledge, childbearing intention and planned pregnancy among new couples referring to premarital counselling centers: a randomized clinical trial

Public title
Effectiveness of an educational intervention on fertility knowledge, childbearing intention and planned pregnancy among new couples
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Childless couples are about to live together in their new home (under one roof) in the near future having an Iranian nationality Minimum basic literacy Aging from 18 to 35 years, men aging 18-45 Lacking prior marriage history
Exclusion criteria:
Medical students or staff Having any known chronic diseases
Age
From **18 years** old to **35 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **1240**
Randomization (investigator's opinion)
Randomized
Randomization description
Samples will be selected through stratified sampling and random samples are then selected from each stratum. The strata consist of 5 cities and separate randomization lists will be prepared for each city using a block randomization. Then we will use central randomization that is stratified to the cities. The couples will randomly be assigned into 2 groups in each city by a computer-generated random sequence. For randomization, the permuted block randomization will be used (block size=4). According to the sample size of 440 identified, 110 blocks will be produced using the online site (www.sealedenvelope. com) for Tehran. According to the sample size of 200 identified, 50 blocks will be produced using the online site (www.sealedenvelope. com) for other cities. Allocation will be concealed by using sequentially numbered opaque sealed envelopes that contain group assignments determined by computer-generated random sequences.
Blinding (investigator's opinion)
Single blinded
Blinding description
Given the nature of the intervention, it is not possible to blind participants to researchers involved in providing the intervention and data collection. However, allocation to intervention or control groups will be blinded for researchers in the data set available during data analysis. To avoid the potential contamination between two groups, we will provide the educational intervention after the typical premarital counselling.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
National Institute for Medical Research Development (NIMAD)
Street address
No.21, Besat Ave., West Fatemi Ave.
City
Tehran
Province
Tehran
Postal code
۱۴۱۹۶۹۳۱۱۱
Approval date
2020-08-09, 1399/05/19
Ethics committee reference number
IR.NIMAD.REC.1399.123

Health conditions studied

1

Description of health condition studied
Fertility knowledge
ICD-10 code
ICD-10 code description

2

Description of health condition studied
Childbearing intention
ICD-10 code
ICD-10 code description

3

Description of health condition studied
Planned pregnancy
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Fertility knowledge
Timepoint
Data will be collected by at baseline and 3, 12 and 18 months after the intervention.
Method of measurement
Cardiff Fertility Knowledge Scale (CFKS)

2

Description
Childbearing intention
Timepoint
Data will be collected by at baseline and 3, 12 and 18 months after the intervention.
Method of measurement
The childbearing intention questionnaire

3

Description
Planned pregnancy (positive pregnancy test)
Timepoint
Data will be collected by at baseline and 3, 12 and 18 months after the intervention.
Method of measurement
Demographic and fertility characteristics questionnaire

Secondary outcomes

1

Description
Contraception method
Timepoint
Baseline, 3, 12 and 18 month after intervention
Method of measurement
Demographic and reproductive characteristic questionnaire

2

Description
Miscarriage
Timepoint
Baseline, 3, 12 and 18 month after intervention
Method of measurement
Demographic and reproductive characteristic questionnaire

3

Description
Unplanned pregnancy
Timepoint
Baseline, 3, 12 and 18 month after intervention
Method of measurement
Demographic and reproductive characteristic questionnaire

Intervention groups

1

Description
Intervention group: The intervention group will receive both the typical premarital counselling training and a fertility knowledge package containing virtual (off-line) educational package at two time episodes with an interval of one month. The intervention includes text messages and short films. The content of educational or counselling program will be based on the most updated literature on fertility knowledge. The fertility knowledge package will consist of information on fertility rates, infertility rates, risks of delay in childbearing, safe waiting period for parenting, Impact of age on female fertility, limited fertility period for women, fertility window and how to optimize fertility, impact of weight and lifestyle on fertility, definition of infertility, infertility risk factors, impact of STD on fertility, the need for earlier evaluation and treatment of infertility, success rate and financial costs of infertility treatments, assisted conception and fertility preservation.
Category
Other

2

Description
Control group: The control group will receive only typical premarital counselling in public health centers.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Haft Tir Health Center
Full name of responsible person
Ziba Najafipour
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Recruitment center

Name of recruitment center

Asad Abadi Health Center

Full name of responsible person

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Recruitment center

Name of recruitment center

Farmanfarmayan Ave,

Full name of responsible person

Roghieh Varmazyari

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Recruitment center

Name of recruitment center

Ershad Health center

Full name of responsible person

Nematollah Mohammadinia

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Recruitment center

Name of recruitment center

Baharneko

Full name of responsible person

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Recruitment center

Name of recruitment center

Can health Center

Full name of responsible person

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Recruitment center

Name of recruitment center

West Health Center of Ahvaz

Full name of responsible person

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Khouzestan

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Recruitment center

Name of recruitment center
17 Shahrivar Health Center
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Reza Malekzadeh
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Email
NIMAD@RESEARCH.AC.IR
Grant name
Young Researcher Grant 2020
Grant code / Reference number
۹۸۸۵۲۳
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
National Institue for Medical Research Development (NIMAD)
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
Iran University of Medical Sciences
Full name of responsible person
Fahimeh Ranjbar
Position
Asistant professor
Latest degree
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Other areas of specialty/work
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Fahimeh Ranjbar
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Latest degree

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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

Yes - There is 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

No - There is not 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

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

Study protocol

When the data will become available and for how long

One year after starting the study

To whom data/document is available

The study protocol will be available to everyone in the form of a paper after its publication.

Under which criteria data/document could be used

The study protocol can be used to design the similar studies.

From where data/document is obtainable

The protocol will be available through the journal website.

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

The study protocol will be available immediately after the article is published.

Comments

protocol link: https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-020-10029-4