

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Aug 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

AgeFrom **18 years** old to **35 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample sizeTarget 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

Street address

Monjem Ave, Naser Cross road

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Recruitment center

Name of recruitment center

Asad Abadi Health Center

Full name of responsible person

Nahid Azimzadeh

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Recruitment center

Name of recruitment center

Farmanfarmayan Ave,

Full name of responsible person

Roghieh Varmazyari

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Between Golshan and Bastan, Azarbaijan Ave.

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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

Abbas Soltani

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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

Mehran Ahmadi Balootaki

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Ahvaz

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Recruitment center

Name of recruitment center

17 Shahrivar Health Center

Full name of responsible person

Amrollah Mardani

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**National Institute for Medical Research Development
(NIMAD)**Full name of responsible person**

Reza Malekzadeh

Street address

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Fax**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 sourceNational Institute 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

Assistant professor

Latest degree

Medical doctor

Other areas of specialty/work

Reproductive Health

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

Iran University of Medical Sciences

Full name of responsible person

Fahimeh Ranjbar

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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

Iran University of Medical Sciences

Full name of responsible person

Fahimeh Ranjbar

Position

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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>