

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

The effect of educational intervention based on planned behavioral theory in Fertility intention of women with one child

Protocol summary

Study aim

The effect of educational intervention based on planned behavioral theory in Fertility intention of women with one child in Qom City

Design

After random selection of 10 health center , using the names registered in the electronic system of the household case and random selection of 20 women in each center, which has a single child in random conditions, randomly Simple in both experimental and control groups (each group is 10)

Settings and conduct

After sampling in health centers of Qom province and evaluating the validity and reliability of the questionnaire, 52 completed researcher-made questions were completed for both the experimental and control groups. After initial need assessment, at least 4 training sessions were conducted for the control group and the effective people in their decision making and after Three months later, the intention of women's pregnancy and changes in the theory of planned behavior have been investigated .

Participants/Inclusion and exclusion criteria

women between 18 to 40 years old with one child, who is at least 24 months old; having a healthcare record in health centers and having no pregnancy plans for the next three years.Exclusion criteria: secondary infertility, women who have absolute or contraindications Relative prevention for pregnancy. women who have problems with their husbands or suffering from social pathological, or women who do not use permanent contraception methods,

Intervention groups

At least, four training sessions in groups of five are held for 50 women in the intervention group and those affecting their intention of pregnancy based on initial needs assessment. Moreover, the instructional medium is given to them. The routine training will be conducted in 50 control groups.

Main outcome variables

Frequency of fertility intent Knowledge score about one-child consequences Motivation Score Against Childbirth

General information

Reason for update

Acronym

tpb

IRCT registration information

IRCT registration number: **IRCT20181105041558N1**

Registration date: **2019-03-26, 1398/01/06**

Registration timing: **retrospective**

Last update: **2019-03-26, 1398/01/06**

Update count: **0**

Registration date

2019-03-26, 1398/01/06

Registrant information

Name

masumeh farshid moghadam

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 25 3774 3871

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-30, 1397/11/10

Expected recruitment end date

2019-02-09, 1397/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of educational intervention based on planned behavioral theory in Fertility intention of women with one child

Public title

effect of education intervention in Fertility intention of women with one child

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

women between 18 to 40 years old with one child, who is at least 24 months old consenting for participation in study having a healthcare record in community centers having no pregnancy plans for the next three years

Exclusion criteria:

secondary infertility women who have absolute contraindications to pregnancy they are not to get pregnant till further notice women who have problems with their husbands, suffering from social pathological, women who do not use permanent contraception methods lack of consent to participate in the study and lack of continuous presence in education sessions (more than one session of absence). widows or divorced women

AgeFrom **18 years** old to **40 years** old**Gender**

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **100****Randomization (investigator's opinion)**

Randomized

Randomization description

In each health center, the names of the women who have only one child are listed using electronic health record (HER), and ten names are selected using systematic random sampling. Then five names are assigned to the intervention group and five names to the control group using coin tossing.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features

One of the advisory professors from Australia

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Arak University of Medical Sciences

Street address

A'lam-Al-Hoda Street, Shahid Shiroodi Street

City

arak

Province

Markazi

Postal code

۳۸۱۹۶۹۳۳۴۰

Approval date

2018-09-16, 1397/06/25

Ethics committee reference number

IR.ARAKMU.REC.1397.141

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

Fertility intention of women(18-40year) with one child

Timepoint

Three months after the last EDUCATIONAL session

Method of measurement

questionnaire was designed by the researcher

Secondary outcomes

empty

Intervention groups**1****Description**

At least, four training sessions in groups of five are held for 50 women in the intervention group and those affecting their intention of pregnancy based on initial needs assessment. Moreover, the instructional medium including the book and pamphlet of the consequences of having one-child, advanced age pregnancy complications, and the video of the effect of having one-child on the family health is given to them. The members of the intervention group have access to their instructor's telephone counseling whenever they wish.

Category

Behavior

2

Description

Control group: For 50 ONE-CHILD MOTHER in the control group, only routine training is provided

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Qom Health Center

Full name of responsible person

Masoumeh Farshid Moghadam

Street address

20 m Shahid Beheshti

City

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Ghous

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3719965654

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Web page address

<http://oh.muq.ac.ir/index.aspx?fkeyid=&siteid=125&pageid=6637>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

mohammad argomanzadegan

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Web page address

<https://arakmu.ac.ir/vcr/fa/page/3876/>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Dr. Mahboubeh Khorsandi

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Full name of responsible person

maasumeh farshid moghadam

Position

student

Latest degree

Bachelor

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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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available