

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Feb 2023

### 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)

##### Phone

+98 25 3774 3871

##### Email address

m.farshidmoghadam95@arakmu.ac.ir

##### 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

**Age**

From **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**

۳۸۱۹۶۹۳۳۴۵

**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

qom

##### Province

Ghous

##### Postal code

3719965654

##### Phone

+98 25 3670 0427

##### Email

qomoh1@yahoo.com

##### 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

##### Street address

Basij Square - Arak University of Medical Sciences Complex

##### City

arak

##### Province

Markazi

##### Postal code

3848176341

##### Phone

+98 86 3417 3639

##### Fax

##### Email

research@arakmu.ac.ir

##### 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

##### Street address

Golestan Cove, Building No. 2 of Medical Sciences

##### City

arak

##### Province

Markazi

##### Postal code

38181-4-6851

##### Phone

+98 86 3366 4615

##### Email

khorsandi@arakmu.ac.ir

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Arak University of Medical Sciences

##### Full name of responsible person

Mahboubeh Khorsandi

##### Position

Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Health Promotion

##### Street address

Golestan Cove, Building No. 2 of Medical Sciences

##### City

arak

##### Province

Markazi

##### Postal code

6851-4-38181

**Phone**

+98 86 3366 4615

**Email**

khorsandi@arakmu.ac.ir

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

maasumeh farshid moghadam

**Position**

student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Health Promotion

**Street address**

Golestan Cove, Building No. 2 of Medical Sciences

**City**

arak

**Province**

Markazi

**Postal code**

6851438181

**Phone**

+98 86 3366 4615

**Email**

maasumeh\_123@yahoo.com

**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