

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### Effectiveness of educational intervention using the integration of planning behavior theory and stages of change model on childbearing intention couples without children

#### Protocol summary

##### Study aim

Determining the effectiveness of educational intervention based on the structures of the theory of planned behavior and stages of change on the intention to have children in couples

##### Design

Randomized parallel groups clinical trial with control group, phase 3 on 30 couples, for randomization of quadruple blocks A (intervention group) and B (control group) by randomly choosing one of the blocks AABBBB/BBAA/ABAB/BAAB/ABBA/BBBA will be done.

##### Settings and conduct

This study will be conducted in Farmanfarmaian Health Center, Tehran city, in couples who meet the inclusion criteria. The educational intervention in the intervention group will be in the 5 sessions of 60 minutes, and the control group will not receive any education during the study, and after completing the study, the educational materials will be presented to them in the form of an educational package.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 to 40 years, willing to participate in the study, not having children, in the preconception and conception stages to have children, having been married for 2 years or more, being Iranian, not having any contraindications for pregnancy, no known infertility, Use of contraceptive methods, lack of mental disability that prevents education Exclusion criteria: Reluctance of each couple to continue, lack of participation in more than one training session, diagnosis of couple's infertility during study, diagnosis of chronic diseases during study, severe conflicts in couple

##### Intervention groups

The intervention group consists of 15 couples in the preconception and conception stages of having children who will participate in training sessions. The control group consists of 15 couples in the preconception and

conception stages who will not receive educational intervention.

##### Main outcome variables

Stages of behavior change; Attitude, behavioral control, normative beliefs

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220618055210N2**

Registration date: **2023-10-03, 1402/07/11**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-10-03, 1402/07/11**

Update count: **0**

##### Registration date

2023-10-03, 1402/07/11

##### Registrant information

##### Name

Maryam Moridi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6691 4368

##### Email address

ma.moridi@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-10-02, 1402/07/10

##### Expected recruitment end date

2025-02-28, 1403/12/10

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effectiveness of educational intervention using the integration of planning behavior theory and stages of change model on childbearing intention couples without children

**Public title**

The effectiveness of educational intervention on the intention to have children

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age 18 to 40 years Willing to participate in the study Not having children In the pre-contemplation stage or contemplating the intention to have children Having been married for 2 years or more Being Iranian Not having any contraindications for pregnancy No known infertility Use of contraceptive methods Lack of mental disability that prevents education

**Exclusion criteria:**

Reluctance of each couple to continue lack of participation in more than one training session Diagnosis of a couple's infertility during the study Diagnosis of chronic diseases during the study Severe conflicts in a couple

**Age**From **18 years** old to **40 years** old**Gender**

Both

**Phase**

3

**Groups that have been masked***No information***Sample size**Target sample size: **30****Randomization (investigator's opinion)**

Randomized

**Randomization description**

People will be assigned to one of the intervention or control groups using the block randomization method. In this way, the identified people who volunteer to participate in the research are randomly assigned into two intervention and control groups using the 4 block method. The letter A is for the intervention group and the letter B is for the control group; Then, write down all the alternating combinations of letters AA and BB, which are 6 different combinations (AABB/BBAA/ABAB/BAAB/ABBA/BBBA), and one combination is randomly selected from combinations 1 to 6. For example, if the combination of AABB is chosen, it means that the first and second people will be in the intervention group and the next two people will be in the control group, and this process will continue until the quorum sample size is reached.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Single

**Other design features****Secondary Ids**

empty

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

Research Ethics Committees of School of Nursing and Midwifery & Rehabilitation - Tehran University o

**Street address**

Dr. Mirkhani St. (East Nusrat), Toohid Square, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1419733171

**Approval date**

2023-05-03, 1402/02/13

**Ethics committee reference number**

IR.TUMS.FNM.REC.1402.013

**Health conditions studied****1****Description of health condition studied**

Intention to have children

**ICD-10 code**

Z33.1

**ICD-10 code description**

Pregnant state, incidental

**Primary outcomes****1****Description**

Stages of changing childbearing intention, attitude, normative beliefs and behavioral control

**Timepoint**

Data will be collected before the study, immediately after and six months after the intervention.

**Method of measurement**

Data collection will be done using a questionnaire of demographic characteristics and a questionnaire designed based on the structures of the theory of planned behavior and stages of change of the trans-theoretical theory.

## Secondary outcomes

empty

## Intervention groups

1

### Description

Intervention group: It will be done on childless couples who have been married for at least 2 years and are in the pre-contemplation and contemplation stages about having children. They will receive educational intervention during 5 sessions.

### Category

Behavior

2

### Description

Control group: It will be done on childless couples who have been married for at least 2 years and are in the pre-contemplation and contemplation stages about having children. They will not receive any educational intervention.

### Category

Behavior

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Farmanfarmaian Primary Health Center

#### Full name of responsible person

Maryam Moridi

#### Street address

Dr. Mirkhani St., Nosrat st. Tohid sq. Tehran

#### City

Tehran

#### Province

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#### Postal code

1419733171

#### Phone

+98 21 6105 4221

#### Email

ma.moridi@yahoo.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Vice President of Research and Technology

#### Street address

Dr. Mirkhani St. (East Nusrat), Toohid Square, Tehran

#### City

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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

Tehran 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

Tehran University of Medical Sciences

#### Full name of responsible person

Maryam Moridi

#### Position

Assistant professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Midwifery

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#### Fax

#### Email

ma.moridi@yahoo.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Maryam Moridi

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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**Contact**

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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**

Not applicable

**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