

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### Comparing the effectiveness of midwifery counseling with a motivational interview approach on the decision of Single child couples and Single child women in having children

#### Protocol summary

##### Study aim

Comparing the effectiveness of midwifery counseling with a motivational interview approach on the decision of Single child couples and Single child women in having children

##### Design

The study is carried out as a parallel clinical trial with a control group on 126 married women with one child and using the allocation sequence which is produced based on the block method in volume 6, the participants are randomly assigned to 3 groups

##### Settings and conduct

Gonbad health centers are socio-economically divided into three floors. From each floor, one center is randomly selected. A total of 126 women with inclusion criteria were selected from among the clients and randomly placed in three groups. Intervention group 1 receives five sessions of individual or group motivational counseling and intervention group 2 receives five sessions of motivational counseling with a spouse and control group. Before the intervention, after the intervention and one month after the intervention, the amount of decision-making for childbearing is collected using a standard questionnaire.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria; Iranian, Gonbad citizen, Tendency to participate in the study and fill out the informed consent form, Married women, Being at reproductive age, No contraindications for pregnancy, Have a child two years or older, Literate, Ability to participate in virtual classes, Individuals who received low and average scores from the decision-making questionnaire for childbearing. Exclusion criteria; Positive pregnancy test before intervention

##### Intervention groups

Intervention 1: 5 sessions of motivational interview are held once a week individually or in groups. Intervention

2: 5 sessions of motivational interview are held once a week, in pairs and the control group receives routine training.

##### Main outcome variables

Deciding to have children

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210223050473N1**

Registration date: **2021-09-09, 1400/06/18**

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

Last update: **2021-09-09, 1400/06/18**

Update count: **0**

##### Registration date

2021-09-09, 1400/06/18

##### Registrant information

##### Name

Saeideh Ranjbar

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 17 3323 7203

##### Email address

ranjbarsaide@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-09-06, 1400/06/15

##### Expected recruitment end date

2021-12-06, 1400/09/15

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparing the effectiveness of midwifery counseling with a motivational interview approach on the decision of Single child couples and Single child women in having children

**Public title**

Comparing the effectiveness of midwifery counseling with a motivational interview approach on the decision of Single child couples and Single child women in having children

**Purpose**

Education/Guidance

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

Iranian Gonbad Citizen Tendency to participate in the study and fill out the informed consent form Married women Being at reproductive age No contraindications for pregnancy Have a child two years or older Literate Ability to participate in virtual classes Individuals who received low and average scores from the decision-making questionnaire for childbearing

**Exclusion criteria:**

Positive pregnancy test before intervention

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 126

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The allocation sequence is generated using the block method with a volume of 6. These blocks are randomly designed in the software and then groups equal to a are assigned to the first intervention group, b to the second intervention group and c to the control group. As participants gradually enter the study, the 6-volume block method is used to assign participants to groups. To hide the assignment sequence, we give it to someone outside the research team. In each center, the expert, after registering the participants in the study, contacts the person with the test sequence and assigns the person to the desired group.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

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

empty

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

Ethics Committee of Shahroud University of Medical Sciences

**Street address**

Shahroud, Haftam Tir Square - Shahroud University of Medical Sciences and Health Services

**City**

Shahroud

**Province**

Semnan

**Postal code**

3614773947

**Approval date**

2021-05-08, 1400/02/18

**Ethics committee reference number**

IR.SHMU.REC.1400.042

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

Fertility

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Deciding to have children

**Timepoint**

Before the intervention, immediately after the intervention and one month after the intervention

**Method of measurement**

Questionnaire for decision to have children

**Secondary outcomes**

empty

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

Intervention group 1: Participants in counseling with a motivational interview approach, which is one of the new methods of counseling and has a specific protocol, will

receive an individual session of 60 to 90 minutes to 5 weeks per week based on the content prepared by the researcher.

**Category**

N/A

**2**

**Description**

Intervention group 2: Participants in counseling with the approach of motivational interviewing, which is one of the new methods of counseling and has a specific protocol, will receive a weekly session of 60 to 90 minutes to 5 weeks based on the content prepared by the researcher.

**Category**

N/A

**3**

**Description**

Control group: Routine training during the intervention and after the intervention will receive a counseling session with a motivational approach

**Category**

N/A

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Gonbad Kavoods Health Center

**Full name of responsible person**

Saeideh Ranjbar

**Street address**

East Taleghani Street, Gonbad Health Center

**City**

Gonbad Kavoods

**Province**

Golestan

**Postal code**

4971767333

**Phone**

+98 17 3323 7203

**Email**

ranjbarsaide@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Shahroud University of Medical Sciences

**Full name of responsible person**

Mohammad Hassan Emamian

**Street address**

Shahroud, Haftam Tir Square - Shahroud University of Medical Sciences and Health Services

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**Province**

Semnan

**Postal code**

3614773955

**Phone**

+98 23 3239 6714

**Fax**

+98 23 3239 4852

**Email**

emamian@shmu.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Shahroud 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**

Shahroud University of Medical Sciences

**Full name of responsible person**

Saeideh Ranjbar

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

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**Contact**

**Name of organization / entity**

Shahroud University of Medical Sciences

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**Position**

Student

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Yes - There is 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**

Regarding the sharing of participants' personal data, information about the initial outcome is shared

**When the data will become available and for how long**

Start time of access period 6 months after printing the results

**To whom data/document is available**

Researchers are allowed to access the data

**Under which criteria data/document could be used**

Use of available data to advance the objectives of the study is permitted

**From where data/document is obtainable**

To receive information, they can be contacted via the following email ranjbarsaide@gmail.com

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

The applicant's request will be answered within a period of one week

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

Shahroud University of Medical Sciences

**Full name of responsible person**

Saeideh Ranjbar

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

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