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: 5sessions 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 Kavoos Health Center
Full name of responsible person
Saeideh Ranjbar
Street address
East Taleghani Street, Gonbad Health Center
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4971767333
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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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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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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
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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