Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effectiveness of counseling on midwifery with a motivational interview approach on men's participation in preconception care

Protocol summary

Study aim
Determining the effectiveness of midwifery counseling with a motivational interview approach on men's participation in pre-pregnancy care

Design
Randomized clinical trial of parallel type with two arms, without blinding, Restricted randomization of block randomization type with blocks of four, allocation sequence is generated by the software.

Settings and conduct
A clinical trial with two control and intervention arms, available sampling method, in the comprehensive health center of Sorkheh city and Semnan Health Center , in order to collect information before assigning people to the control and intervention groups, from the demographic questionnaire and the researcher-made questionnaire of male participation in Women's pre-pregnancy care and the standard questionnaire to evaluate men's knowledge, attitude and performance regarding reproductive health before having children, which will be used by the couple, and the stages of change questionnaire which will be completed by men.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age under 50 years for men and 15-45 years for women and intention to have children in the next year; Exclusion criteria: wife being pregnant.

Intervention groups
Five sessions of motivational interview for couples, one session per week and each session in 45-60 minutes for the intervention group. At the end of the study, a training session with the content of pre-pregnancy health and childbearing for the control group.

Main outcome variables
Couple's knowledge and attitude towards men's prenatal care; Men's participation in women's pre-pregnancy care including wife's companionship, wife's health recommendations, wife's financial and emotional support and man's awareness of women's problems and health in pre-pregnancy care

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231214060361N1**
Registration date: **2024-01-06, 1402/10/16**
Registration timing: **prospective**

Last update: **2025-09-10, 1404/06/19**
Update count: **1**

Registration date
2024-01-06, 1402/10/16

Registrant information

Name
Sakineh Zarei

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 23 3342 2032

Email address
sakineh.zarei.1363@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-03-20, 1403/01/01

Expected recruitment end date
2024-05-21, 1403/03/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of counseling on midwifery with a motivational interview approach on men's participation in preconception care

Public title

Evaluation of the effectiveness of motivational interview approach on men's participation in preconception care

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Literacy for reading and writing Being Iranian Age below 50 years for men and 15-45 years for women Intend to have children in the next year Consent and cooperation to participate in the study

Exclusion criteria:

Staff and students of the University of Medical Sciences Having a history of infertility treatment (according to the person's statement) Having a known chronic disease Wife being pregnant Participation in similar programs Difficulty in communicating such as blindness and deafness and any cognitive impairment Poor health of the child or previous children

Age

From **15 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **102**

Randomization (investigator's opinion)

Randomized

Randomization description

We will use the restricted randomization method of the block randomization type. . The size of all the blocks is equal and we will use 4 blocks in this experiment. We will have 6 blocks in this order (BABA, BBAA, AABB, BAAB, ABBA, ABAB) and the blocks will be numbered. A will be the test group and B will be considered as the control group. In blocks of 4, two allocations to the intervention group and two allocations to the control group are considered.

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 Shahrood University of Medical Sciences

Street address

7 Tir Ave

City

Shahrood

Province

Semnan

Postal code

7395536147

Approval date

2023-11-28, 1402/09/07

Ethics committee reference number

IR.SHMU.REC.1402.138

Health conditions studied

1

Description of health condition studied

Preconception care

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Couple's knowledge and attitude towards men's preconception care

Timepoint

Before the start of the intervention, immediately after the intervention and 3 months after the intervention

Method of measurement

Questionnaire to evaluate the knowledge, attitude and performance of married men regarding pre-pregnancy care.

2

Description

Men's involvement in women's prenatal care

Timepoint

Before the start of the intervention, immediately after the intervention and 3 months after the intervention

Method of measurement

Questionnaire to evaluate the knowledge, attitude and performance of married men regarding pre-pregnancy care

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Five sessions of motivational interview for couples, one session per week and each session lasts 45-60 minutes
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Sorkheh comprehensive health center
Full name of responsible person
Sohrab Yadalhi
Street address
Basij Blvd
City
Sorkhe
Province
Semnan
Postal code
3551785397
Phone
+98 23 3361 3876
Email
sorkhe.behdasht@semums.ac.ir

2

Recruitment center
Name of recruitment center
Semnan health center
Full name of responsible person
Shiraze Maani
Street address
West Shahid Rajaei
City
Semnan
Province
Semnan
Postal code
3513698883
Phone
+98 23 3332 2274
Email
Behdashti@sem-ums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Behzad Garmabi
Street address
7 Tir Ave
City
Shahrood
Province
Semnan
Postal code
3614773943
Phone
+98 23 3239 5054
Fax
+98 23 3239 5009
Email
info@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
Sakineh Zarei
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
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No. 731, 19 East , 2 Sablan St , Rosie Town
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Person responsible for scientific

inquiries

Contact

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Shahroud University of Medical Sciences

Full name of responsible person
Sakineh Zarei

Position
Student

Latest degree
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Other areas of specialty/work
Midwifery

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Person responsible for updating data

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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