

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 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

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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

Street address

No. 731, 19 East , 2 Sablan St , Rosie Town

City

Semnan

Province

Semnan

Postal code

3519954446

Phone

+98 23 3342 2032

Email

sakineh.zarei.1363@gmail.com

Person responsible for scientific

inquiries

Contact

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Sakineh Zarei

Position

Student

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Bachelor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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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