Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The impact of midwife empowerment based on the REDI model in promoting childbearing motivation among women with one child

Protocol summary

Study aim
The impact of midwife empowerment in childbearing counseling based on the REDI model on the fertility motivation of women with one child.

Design
Study Type: A multicenter clinical trial with intervention and control groups, conducted without blinding, utilizing block randomization in sets of four, involving 120 eligible women aged 18 to 35 years.

Settings and conduct
The study will be conducted at Hazrat Raqiyeh, Bahar, and Tadbir health centers in Semnan. Midwives at these centers will receive training on counseling techniques in a workshop and will then provide counseling to eligible women in the intervention group. Counseling sessions will be held weekly for four weeks and will cover topics related to childbearing, including encouraging childbearing, dissuading induced abortion, and providing pre-conception counseling.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Women with one child and aged between 18 and 35 years, with the existing child being under 6 years old. Exclusion Criteria:Pregnant women or those with specific medical conditions will be excluded from the study.

Intervention groups
Intervention Group: This group includes eligible women from the healthcare centers of Hazrat Rouhollah, Bahar, and Tadbir in Semnan who receive REDI-based counseling. Control Group: This group consists of eligible women from the same healthcare centers who do not receive REDI-based counseling but rather receive routine counseling.

Main outcome variables
Fertility Motivation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20241101063556N1**
Registration date: **2024-12-30, 1403/10/10**
Registration timing: **prospective**

Last update: **2024-12-30, 1403/10/10**
Update count: **0**

Registration date
2024-12-30, 1403/10/10

Registrant information

Name
Leila Eskandari

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 23 3334 6290

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leilaeskandari4454@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-01-04, 1403/10/15

Expected recruitment end date
2025-03-10, 1403/12/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The impact of midwife empowerment based on the REDI model in promoting childbearing motivation among women with one child

Public title
The impact of midwife empowerment in promoting childbearing motivation among women with one child
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Written consent to participate in the study Women aged between 18 and 35 years Iranian nationality Living with a spouse under the same roof Full consciousness and acceptable hearing and speaking ability to receive training and respond to questions Literacy in reading and writing. Resident of Semnan city.
Exclusion criteria:
One partner has infertility-related issues. Women who have undergone hysterectomy or tubectomy.
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
In this multicenter randomized controlled trial (RCT), eligible women from Hazrat Raqiyeh, Bahar, and Tadbir centers in Semnan will be enrolled sequentially upon providing informed consent and will be randomly assigned to either the intervention or control group. Randomization method: A block randomization method with a block size of four will be used to allocate eligible women to the intervention or control groups. Unit of randomization: The individual participant. Randomization tool: A randomization sequence will be generated using the website https://www.sealedenvelope.com/simple-randomiser/v1/lists for a sample size of 120, with a block size of four in two groups. Sequence generation: The generated randomization sequence will be provided to the central site. To conceal allocation, group assignments will be placed in sealed, numbered envelopes. After midwives at the participating centers contact the central site, researcher will sequentially open envelopes for eligible participants and allocate them to the corresponding 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
No.37, Yaser street., Valiasr blvd. semnan
City
Semnan
Province
Semnan
Postal code
3519693117
Approval date
2024-12-01, 1403/09/11
Ethics committee reference number
IR.SHMU.REC.1401.153

Health conditions studied

1

Description of health condition studied
childbearing
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Fertility Motivation of Only-Child Women
Timepoint
Before the intervention and one month after the intervention
Method of measurement
Miller's Fertility Motivation Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
All midwives and health caregivers from the healthcare centers of Hazrat Rouhollah, Bahar, and Tadbir in Semnan are invited to participate in training classes aimed at empowering midwives. The educational content of these classes is based on in-depth qualitative interviews and a systematic review derived from the results of a doctoral thesis with the code IR.SHMU.REC.1401.153. The training will be conducted in the form of a two-day workshop totaling 12 hours. Workshop Topics: Day 1:Communication skillsCounseling skills in pre-pregnancy services Childbearing counseling.

Day 2:Infertility counselingPersuasion against abortionConsequences of having a single childTrained midwives, after completing the educational courses, will seek eligible women for study participation and obtain consent to assign them to either the intervention or control group. Those placed in the intervention group will receive face-to-face childbearing counseling sessions lasting 20 minutes, once a week for four weeks.

Category
Other

2

Description
Control Group: Eligible women at health centers will be invited to receive routine counseling until the required sample size is reached, and fertility intention will also be assessed in this group.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Health Centers of Hazrat Ruqyeh, Bahar and Tadbir Semnan City

Full name of responsible person
Leila Eskandari

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Shahid rajaee street, Ghods blvd. semnan

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Web page address
http://www.semums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahroud University of Medical Sciences

Full name of responsible person
Afsaneh Keramat

Street address
Haft-e Tir Square - Shahroud University of Medical Sciences

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Province
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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
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
Other

Person responsible for general inquiries

Contact

Name of organization / entity
Shahroud University of Medical Sciences

Full name of responsible person
Afsaneh Keramat

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Health Reproductive

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Haft-e Tir Square - Shahroud University of Medical Sciences and Health Services"

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Person responsible for scientific inquiries

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Position
Ph.D Candidate

Latest degree
Master

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is 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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
After anonymizing the individuals' information, the main outcomes will be reported.

When the data will become available and for how long
Access will begin six months after the publication of the results

To whom data/document is available
The data and documentation of this study will primarily be accessible to researchers working in academic and scientific institutions, while ensuring the privacy of participants. This includes faculty members, graduate students, and independent researchers who are engaged in fields relevant to this research.

Under which criteria data/document could be used
All requests must be submitted in writing and should include clear explanations regarding the purpose of using the data. Applicants may be required to sign an agreement that includes a commitment to adhere to ethical principles and maintain the privacy of participants.

From where data/document is obtainable
Applicants for obtaining the documents or data related to this study can refer to the following address: Leila Eskandari Email: Leilaeskandari4454@gmail.com"

What processes are involved for a request to access data/document
Applicants must submit an official request that includes personal information, the purpose of the request, and the type of data required. Upon receiving the request, the research team will conduct an initial review. After the necessary evaluations, a final decision will be made regarding the approval or rejection of the request. Applicants will be informed of the outcome via email or phone contact.

Comments