Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The Effect of Midwife-led Childbearing Counseling compared to routine care on Fertility Motivation and Empowerment of Women Referring to Health Centers

Protocol summary

Study aim

Determining the Effectiveness of Midwife-led Childbearing Counseling on Fertility Motivation and Empowerment of Women Referring to Selected Health Centers of Kashan City

Design

A randomized controlled clinical trial, with an intervention and a control group (parallel groups) on 130 people. Blinding will not be done in this study. The samples are selected as available and then the people are randomly assigned to two control and intervention groups using blocks of size 4. Random blocks will be generated through the site (www.sealedenvelope.com). For concealment, the randomized sequences are placed in sealed envelopes and numbered sequentially.

Settings and conduct

Four centers out of 14 urban health centers of Kashan city centers (with the most referrals) will form the research environment. All married women referring to urban health centers of Kashan city will form the research population. Blinding will not be done in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Iranian Muslim Couple; Able to Speak Persian Language; Having Minimum Reading and Writing Literacy; Without Previous Marriage of Each Couple; Having a Child at Least Two Years Old. Non-inclusion criteria: Addiction in Each of the Couples; Severe Chronic Physical and Mental Diseases in Each of the Couples; Secondary Infertility Diagnosed in Each of the Couples; Experience of Extreme Stress in Each of the Couples (During the Last Six Months)

Intervention groups

Intervention Group: Including 65 Qualified Women Who Will Receive 4 Face-to-Face Counseling Sessions in 60 Minutes/ One Session Every Week, in Groups of 15-20 People, by a Trained Midwife in addition of Routine Cares. Control Group: Including 65 Qualified Women Who Will Only Receive Routine Cares.

Main outcome variables

Women's Empowerment; Women's Fertility Motivation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230706058685N1**
Registration date: **2023-08-08, 1402/05/17**
Registration timing: **prospective**

Last update: **2023-08-08, 1402/05/17**
Update count: **0**

Registration date

2023-08-08, 1402/05/17

Registrant information

Name

zahra mehdizadeh

Name of organization / entity

Alborz university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 26 3419 7000

Email address

zahramehdizadeh_t@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-21, 1402/05/30

Expected recruitment end date

2023-11-21, 1402/08/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of Midwife-led Childbearing Counseling compared to routine care on Fertility Motivation and Empowerment of Women Referring to Health Centers

Public title
The Effect of midwife-led Childbearing Counseling on Fertility Motivation and Empowerment of Women
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Iranian Muslim Couple Able to Speak Persian Language Having Minimum Reading and Writing Literacy Without Previous Marriage of Each Couple Having a Child at Least Two Years Old
Exclusion criteria:
Addiction in Each of the Couples Severe Chronic Physical and Mental Diseases in Each of the Couples Secondary Infertility Diagnosed in Each of the Couples Experience of Extreme Stress in Each of the Couples (During the Last Six Months)
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **130**
Randomization (investigator's opinion)
Randomized
Randomization description
The Samples Are Selected As Available and Then the People Are Randomly Assigned to Two Control and Intervention Groups in Blocks of size 4 (4 people). Random Blocks Will Be Generated Through the Site (www.sealedenvelope.com). For Concealment, the Randomized Sequences Are Placed in Sealed Envelopes and Numbered Sequentially.
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
Alborz University of Medical Sciences
Street address
North Taleghani Blvd; Taleghani Square
City
Karaj
Province
Alborz
Postal code
3149779453
Approval date
2023-07-02, 1402/04/11
Ethics committee reference number
IR.ABZUMS.REC.1402.095

Health conditions studied

1

Description of health condition studied
Midwife led consuling
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Women's Fertility Motivation
Timepoint
Measuring the Fertility Motivation Score of Women Before and One Month After the Intervention
Method of measurement
Miller's Fertility Motivation Questionnaire with Two Positive Dimensions Including 34 Questions and Negative Including 19 Questions

2

Description
Women's Empowerment
Timepoint
Measuring Women's Empowerment Before and One Month After the Intervention
Method of measurement
Dr. Cohen's Empowerment of Women Questionnaire with 38 Questions in Four Cultural, Individual - Family, Social and Family Planning Dimensions

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group: The Intervention Group With 65 People Who Will Receive the Intervention Include of Face-to-Face Counseling in the Form of 4 One-Hour Sessions (15-20 people). The Content of the Child-Bearing Educational Counseling Sessions Will Be Compiled by the Research Team with an Emphasis on the Contents of the Questionnaires of Fertility Motivations and Women's Empowerment Based on the Guidelines of the Ministry of Health As Well As Reliable Sources and Sites, and Will Include Discussions in the Field of Self-Knowledge, Planning, Factors Affecting the Correct Decision-Making for Fertility and Child-Bearing, and the Importance of Women's Independence to Make Free Decisions on Various Reproductive Health Issues, Including the Aspect of Family Planning. Each Counseling Session Will Include the Presentation of Appropriate Content, Assignments and Feedback to the Participants, As Well As a Review of the Previous Sessions.

Category
Lifestyle

2

Description
Control Group: Including 65 People Who Will Receive Routine Care of the Centers.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Health deputy of Kashan

Full name of responsible person
Mehdi Delavari

Street address
Shamshad 13 St; Kashan Phase 2

City
Kashan

Province
Isfehan

Postal code
8713783976

Phone
+98 31 5542 0001

Email
info@kaums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Alborz University of Medical Sciences

Full name of responsible person
Razieh Lotfi

Street address
Safarian alley; 45 Meteri-e-Gulshahr

City
Karaj

Province
Alborz

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3198764653

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Research@abzums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Alborz 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
Alborz University of Medical Sciences

Full name of responsible person
Zahra Mehdizadeh Tourzani

Position
Instructor of Midwifery

Latest degree
Master

Other areas of specialty/work
Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Alborz University of Medical Sciences

Full name of responsible person
Zahra Mehdizadeh Tourzani

Position
Instructor of Midwifery

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Other areas of specialty/work
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Person responsible for updating data

Contact

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Full name of responsible person
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Position
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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