

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 Jul 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](http://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](http://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

Isfahan

#### 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

#### Postal code

3198764653

#### Phone

+98 26 3464 3705

#### Email

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

#### Street address

North Taleghani Blvd; Taleghani Square, Alborz University of Medical Sciences

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Karaj

#### Province

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3149779453

#### Phone

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#### Email

zahramehdizadeh\_t@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Alborz University of Medical Sciences

**Full name of responsible person**

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**Position**

Instructor of Midwifery

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Master

**Other areas of specialty/work**

Midwifery

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## Person responsible for updating data

### Contact

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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