# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Effect of implementation continuity of team midwifery care model on safe motherhood indicators

### Protocol summary

**Study aim**
Determining the impact of implementing continuous team care of pregnant women on safe motherhood indicators

**Design**
The clinical trial has a control group, with parallel groups, randomized, and the assignment method is randomized permutation blocks with a block size of 4 (using the table related to random permutations) and the ratio of assignment to intervention and control groups is 1. It will be: 1. It will be done on 200 low-risk pregnant women. 100 people are in the control group and 100 people are in the intervention group.

**Settings and conduct**
The study is carried out in the health and treatment centers of Kashan city. In the intervention group, pregnant women receive obstetric care as a team and continuously by a team of 5 midwives with the support of a gynecologist, but in the control group, they receive care routinely and without continuous care.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: 1.Pregnant Women aged 18 to 35 years 2. Iranian 3. Singleton pregnancy 4. First pregnancy visit (less than 12 weeks of pregnancy) 5. Low-risk pregnancy Exclusion criteria:1. Women with a history of infertility 2. A history of anxiety or hospitalization in psychiatric wards

**Intervention groups**
In the intervention group, care is continuously provided to pregnant women by a 5-person midwifery team throughout pregnancy, delivery and after delivery, the midwife of the health department is the responsible midwife for every pregnant woman. If pregnant women need specialized care, the midwife will refer them to a specialist and get feedback. Control group: the provision of care in this group will be non-continuous and non-continuous according to the current state of government centers.

**Main outcome variables**
Safe motherhood indicators

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20171106037279N4**
Registration date: **2023-04-17, 1402/01/28**
Registration timing: **prospective**

Last update: **2023-04-17, 1402/01/28**
Update count: **0**

**Registration date**
2023-04-17, 1402/01/28

**Registrant information**

**Name**
farzaneh nasiri

**Name of organization / entity**
Shahid Beheshti University of Medical Sciences

**Country**
Iran (Islamic Republic of)

**Phone**
+98 919 453 6915

**Email address**
farzanehnasiri@sbmu.ac.ir

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2023-04-19, 1402/01/30

**Expected recruitment end date**
2024-01-21, 1402/11/01

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Effect of implementation continuity of team midwifery care model on safe motherhood indicators

**Public title**
Effect of continuity of team care model on safe motherhood indicators

**Purpose**
Health service research

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Pregnant Women aged 18 to 35 years Iranian Singleton pregnancy First pregnancy visit (less than 12 weeks of pregnancy) Low-risk pregnancy

**Exclusion criteria:**
Women with a history of infertility A history of anxiety or hospitalization in psychiatric wards

**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: **200**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
The study subjects will be assigned to each of the control and intervention groups by random block method using blocks 4 and 6 and will be divided into two groups with a ratio of 1:1. Thus, the number of 10 blocks of 6 and 16 blocks of 4 will be randomly extracted using WIN PEPI software. In each of the blocks of 6, 3 people will be related to the control group and 3 people will be related to the intervention group, also in each of the blocks of 4 people, 2 people will be related to the control group and 2 people will be related to the intervention group. The placement order of each person is random. In order to hide the allocation, the type of intervention will be written on paper and placed inside opaque envelopes numbered consecutively, in this way, the researcher and the participant will not know the type of intervention until the intervention begins. Due to the nature of this study, it will not be possible to blind the researcher and the participant.

**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 Ahvaz University of Medical Sciences

**Street address**
No. 45, 15 Muftah St

**City**
Qom

**Province**
Ghoum

**Postal code**
1985717443

**Approval date**
2023-04-08, 1402/01/19

**Ethics committee reference number**
IR.AJUMS.REC.1402.010

## Health conditions studied

### 1

**Description of health condition studied**
Low-risk pregnant Women

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

**Description**
The level of satisfaction with childbirth in the McKay questionnaire

**Timepoint**
After delivery

**Method of measurement**
Mackey childbirth satisfaction rating scale

### 2

**Description**
Score of depression, anxiety and stress in the questionnaire

**Timepoint**
Third trimester of pregnancy and 6 weeks after delivery

**Method of measurement**
Depression anxiety and Stress Scale

### 3

**Description**
Antenatal care quality score in pregnancy care quality questionnaire

**Timepoint**

After delivery

**Method of measurement**

The Quality Prenatal Care Questionnaire

**4**

**Description**

Consequences of pregnancy

**Timepoint**

End of intervention

**Method of measurement**

View the hospital record

**5**

**Description**

Neonatal consequences

**Timepoint**

End of intervention

**Method of measurement**

View the hospital record

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**

Intervention group: Hiring a responsible midwife for every pregnant woman. This midwife is a member of the management team and provides direct care during the prenatal, delivery, and postpartum stages. If pregnant women need special care, the midwife will refer them to the specialist and will take feedback. The responsible midwife will continuously be available for pregnant women in different settings of homes, health centers, and hospitals.

**Category**

Other

**2**

**Description**

Control group: They will receive routine care. In a routine way, pregnant women refer to the health center. There is no responsible midwife or continuous communication with the caregiver. The majority of women are under the supervision of specialists, regardless of whether they are high-risk or low-risk. Caregivers are frequently changed during pregnancy, delivery and after delivery, and care is received by unfamiliar caregivers

**Category**

N/A

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

health centers affiliated to Kashan university

**Full name of responsible person**

Farzane Nhnasiri

**Street address**

No. 45, West Arghavan Ave., Farahzadi Blvd., Qods Town

**City**

Qom

**Province**

Ghoum

**Postal code**

1523647859

**Phone**

+98 25 3423 1395

**Email**

nasiri.f@ajums.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Mehrnoosh Zakir Kish

**Street address**

Ahawaz Academic City - Vice President of Research and Technology, Jundishapur University of Medical Sciences and Healthcare Services, Ahvaz - ground floor

**City**

Ahvaz

**Province**

Ghoum

**Postal code**

15791 61357

**Phone**

+98 61 3336 2414

**Email**

itc@ajums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Ahvaz 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**
Ahvaz University of Medical Sciences
**Full name of responsible person**
Farzaneh Nasiri
**Position**
Student
**Latest degree**
Master
**Other areas of specialty/work**
Midwifery
**Street address**
No. 45, 15 Muftah St
**City**
QOM
**Province**
Ghoum
**Postal code**
1985717443
**Phone**
+98 919 453 6915
**Fax**
**Email**
farzanehnasiri@sbmu.ac.ir

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Ahvaz University of Medical Sciences
**Full name of responsible person**
Farzaneh Nasiri
**Position**
student
**Latest degree**
Master
**Other areas of specialty/work**
Midwifery
**Street address**
No. 45, 15 Muftah St
**City**
QOM
**Province**
Ghoum
**Postal code**
0375314855
**Phone**
+98 25 3423 1395
**Email**
farzanehnasiri@sbmu.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**
Ahvaz University of Medical Sciences
**Full name of responsible person**
Farzaneh Nasiri
**Position**
student
**Latest degree**
Master
**Other areas of specialty/work**
Midwifery
**Street address**
No. 45, 15 Mofatteh St
**City**
QOM
**Province**
Ghoum
**Postal code**
0123456789
**Phone**
+98 25 3423 1395
**Email**
farzanehnasiri100@gmail.com

## 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**
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
**Title and more details about the data/document**
Demographic information and information obtained from the used questionnaire can be shared
**When the data will become available and for how long**
After publishing the article in the journal
**To whom data/document is available**
Researchers, Department of Medical Sciences
**Under which criteria data/document could be used**
Use to treat other patients
**From where data/document is obtainable**
Email farzanehnasiri100@ gmail.com farzaneh nasiri
**What processes are involved for a request to access data/document**
Send message via email
**Comments**