Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jun 2026

Designing, implementation and evaluating an educational program to improve the postpartum quality of life among nulliparous women based on Salutogenesis theory: An exploratory sequential mixed methods study

Protocol summary

Study aim
Determining the impact of a designed educational intervention in pregnant women on the postpartum quality of life

Design
The clinical trial has a control group, with parallel groups, randomized. In order to carry out the intervention, nulliparous women will be divided into two parallel groups by random allocation method using blocked randomization with 6 blocks. For allocation concealment, the names of the control and intervention groups will be written and placed in numbered identical closed and opaque envelopes by a person who has no information about the research objectives.

Settings and conduct
The educational intervention will be held for at least 30 minutes in groups of at least 4 people in the comprehensive health service centers number 1 East of Ahvaz in Ahvaz by the researcher in person. The intervention sessions will start from the age of 28 weeks of pregnancy. Before each meeting, the time and place of the meeting will be reminded. First, participants will complete demographic and SOC-13 questionnaires.

Participants/Inclusion and exclusion criteria
inclusion criteria: Nulliparous women being at gestational age 28 weeks and above being over 18 years old singleton pregnancy ultrasound confirmation of fetus health willingness to participate in the study Exclusion criteria: Women with a history of infertility pregnancy following ART refusing to complete questionnaires cannot be accessed for unpredictable reasons

Intervention groups
Intervention group: The educational content is prepared based on the determinants effective in improving the quality of life after childbirth in primiparous women, which will be obtained from the qualitative and review phase. control group: Participants in the control group will attend routine childbirth preparation classes.

Main outcome variables
SOC, maternal self-efficacy, postpartum quality of life, breastfeeding self-efficacy, type of delivery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230626058592N1**
Registration date: **2023-07-05, 1402/04/14**
Registration timing: **prospective**

Last update: **2023-07-05, 1402/04/14**
Update count: **0**

Registration date
2023-07-05, 1402/04/14

Registrant information

Name
Maryam shami

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 6692 7171

Email address
shami.m@ajums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-12-22, 1402/10/01

Expected recruitment end date
2025-03-19, 1403/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Designing, implementation and evaluating an educational program to improve the postpartum quality of life among nulliparous women based on Salutogenesis theory: An exploratory sequential mixed methods study

Public title

Salutogenesis theory on the postpartum quality of life

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Nulliparous women Being at gestational age 28 weeks and above Being over 18 years old Singleton pregnancy Ultrasound confirmation of fetus health Having no history of depression or long-term medical illness in the past according to the mother's statement Willingness to participation the study

Exclusion criteria:

Women with a history of infertility Pregnancy following assisted reproductive treatment. Refusing to complete questionnaires Cannot be accessed for unpredictable reasons. The presence of illness in the spouse

Age

From **18 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

First, a list of nulliparous women who met the inclusion criteria will be extracted from all health centers of Ahvaz. The selected women will be contacted through their contact information to be informed briefly about the purpose and method of the research and then invited to participate in the study. Sampling will continue until the predetermined number of participants enter the study. In order to carry out the intervention, nulliparous women will be divided into two parallel group of intervention group (ST based training program along with routine childbirth preparation classes) and control (routine childbirth preparation classes) by random allocation method using blocked randomization with blocks of 6. For allocation concealment, the names of the control and intervention groups will be written and placed in numbered identical closed and opaque envelopes by a person who has no information about the research objectives and when choosing the envelopes, a person who was not involved in the study is asked to choose an envelope.

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

Research Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Ground floor, Ahvaz Academic City

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Approval date

2023-06-03, 1402/03/13

Ethics committee reference number

IR.AJUMS.REC.1402.137

Health conditions studied

1

Description of health condition studied

Postpartum quality of life

ICD-10 code

-

ICD-10 code description

-

Primary outcomes

1

Description

Postpartum quality of life

Timepoint

Immediately after delivery, 4 weeks after delivery and 8 weeks after delivery

Method of measurement

Using the postpartum quality of life questionnaire

2

Description

Type of delivery

Timepoint

After delivery

Method of measurement

Examination of maternity records

Secondary outcomes

1

Description

Sense of coherence

Timepoint

Before the intervention, immediately after delivery, 4 weeks after delivery and 8 weeks after delivery

Method of measurement

SOC-13 questionnaire

2

Description

Maternal self-efficacy

Timepoint

Immediately after delivery, 4 weeks after delivery and 8 weeks after delivery

Method of measurement

Maternal self-efficacy questionnaire

3

Description

Breastfeeding self-efficacy

Timepoint

Immediately after delivery, 4 weeks after delivery and 8 weeks after delivery

Method of measurement

Breastfeeding Self-Efficacy Scale-Short Form

Intervention groups

1

Description

Intervention group: The educational content is prepared based on the determinants effective in improving the quality of life after childbirth in primiparous women, which will be obtained from the qualitative and review phase.

Category

Behavior

2

Description

Control group: Participants in the control group will attend routine childbirth preparation classes.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Center No. 1 in East Ahvaz

Full name of responsible person

Maryam Shami

Street address

Between Rostagari and Vakili, In front of Hoda Middle School, Shahid Gandami St.

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maryamshami1870@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mehrnoosh Zakirkish

Street address

Ground floor, Vice-Chancellor for Research and Technology, Jundishapur University of Medical Sciences and Healthcare Services, Ahvaz, Ahvaz Academic City

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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
Maryam Shami

Position
student

Latest degree
Master

Other areas of specialty/work
Midwifery

Street address
Shahid Kolahdoz St, Koi Saidieh

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Person responsible for scientific inquiries

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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
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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
The demographic characteristics of participants are confidential, but information on other variables will be shareable.

When the data will become available and for how long
12 months after the publication of the final article

To whom data/document is available
Researchers in scientific and academic institutions, health education and health promotion unit of the Ministry of Health and family health unit of the Ministry of Health

Under which criteria data/document could be used
Educational and research use is permitted with the permission of the Ethics Committee of Ahvaz University of Medical Sciences. The application should be sent through the Research Vice-Chancellor of Medical Sciences Universities.

From where data/document is obtainable
Corresponding author: Mojgan Javadnoori javadnoori-m@ajums.ac.ir

What processes are involved for a request to access data/document
Up to three weeks after receiving the request by email to the corresponding author

Comments