Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effectiveness of counseling solution on common complaints of pregnancy and quality of life of nulliparous mothers.

Protocol summary

Study aim

Determining the effectiveness of solution-oriented counseling on common pregnancy complaints and the quality of life of primiparous mothers.

Design

The clinical trial has a control and intervention group, with parallel groups، blinding in such a way that the information analyst is unaware of the group of people and the participants are aware of their group، randomized in a block method، allocated to the volume of 4 sequences، on 94 patients.

Settings and conduct

In Gonbad kavus، it will be done in health centers، and 4 solution oriented counseling sessions will be offered to the intervention group، and the control group will receive routine pregnancy care.

Participants/Inclusion and exclusion criteria

Inclusion criteria: first pregnancy، Age 18 to 35 years، gestational age between 12 weeks and 28 weeks، Iranian nationality satisfaction and willingness to participate in study and cooperation at least reading and writing literacy، Single pregnancy، living in Gonbad kavos city. Exclusion criteria: History of infertility، current high risk pregnancy، history of divorce، ectopic pregnancy، hydatidiform mole، suffering from proven systemic diseases، musculoskeletal disorders، psychiatric disorders.

Intervention groups

The intervention group will receive four solution-focused Midwifery counseling sessions and the questionnaires will be filled in at designated intervals، and the control group will receive routine pregnancy care and the questionnaires will be filled in at designated intervals.

Main outcome variables

Quality of life and common complaints in pregnancy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230909059384N1**
Registration date: **2023-11-14, 1402/08/23**
Registration timing: **prospective**

Last update: **2023-11-14, 1402/08/23**
Update count: **0**

Registration date

2023-11-14, 1402/08/23

Registrant information

Name
Reyhane Anvari
Name of organization / entity
Country
Iran (Islamic Republic of)
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reihane.anvari@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-20, 1402/10/30

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of counseling solution on common complaints of pregnancy and quality of life of nulliparous mothers.

Public title
Effect of solution-focused counseling on common complaints of pregnancy and quality of life
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Primiparous and first pregnancy experience Age 18 to 35 years Gestational age between 12 weeks and 28 weeks Satisfaction and willingness to participate in study and cooperation Iranian nationality At least reading and writing literacy Single pregnancy Living in Gonbadkavos city
Exclusion criteria:
History of infertility Current high-risk pregnancy (such as multiple pregnancies, use of certain drugs, physical disorders and diseases such as: hepatitis or gastrointestinal diseases causing nausea and vomiting, mental retardation, smoking, pregnancy in progress Infertility, occurrence of accidents major and unfavorable in the past 2 months, such as severe differences with spouse, death of father and spouse or mother) History of divorce Ectopic pregnancy Hydatidiform mole Suffering from proven systemic diseases, musculoskeletal disorders, psychiatric disorders
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: **94**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple block randomization. Using white envelopes، the allocation sequence is hidden. Each sequence is placed inside a white envelope and the envelopes are stacked together in a box. Envelopes are numbered. When every eligible patient enters the study, an envelope is opened and the person is assigned to the desired group. Participants are registered by the main presenter (student). If they are eligible, they will enter the study. Based on their entry into the study, the participants will open the desired white envelope and be assigned to the specified group.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Blinding is such that the person who is sampling or receiving the questionnaires at each stage and gives them to the groups, and the person who analyzes the data and enters the results is unaware of the groups and does not know that each questionnaire To which group does he give the data and from which group does he receive it, or which group is he analyzing the data and results of now.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahrod University of Medical Sciences
Street address
Research and Technology Vice Chancellor, Shahrud University of Medical Sciences and Health Services، 7 Tir Square،
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Shahrood
Province
Semnan
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Approval date
2023-10-16, 1402/07/24
Ethics committee reference number
IR.SHMU.REC.1402.114

Health conditions studied

1

Description of health condition studied
Quality of life
ICD-10 code
ICD-10 code description

2

Description of health condition studied
Common Complaints of pregnancy
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Quality of life
Timepoint
Before the start of the intervention, immediately after the intervention mean at the last session of the intervention, and one month after the last session of the intervention.
Method of measurement
Short form 36 health survey questionnaire

2

Description
Quality of life in pregnancy
Timepoint
Before the start of the intervention, immediately after the intervention mean at the last session of the intervention, and one month after the last session of the intervention
Method of measurement
Quality of life gravidarum questionnaire

3

Description
Common complaints in pregnancy
Timepoint
Before the start of the intervention, immediately after the intervention mean at the last session of the intervention, and one month after the last session of the intervention
Method of measurement
Peregnancy related syndrome inventory

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 4 group counseling sessions will be held for the intervention group in a solution-oriented way.١
Category
Lifestyle

2

Description
Control group: only routine prenatal cares
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Urban health base number 4
Full name of responsible person
Mosadegh agh
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2

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5

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Reyhane anvari
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
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Person responsible for updating data

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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