

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 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)

Phone

+98 17 3358 6822

Email address

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.

City

Shahrood

Province

Semnan

Postal code

۳۶۱۴۷۷۳۹۴۳

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

Pregnancy 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.

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

Street address

Imam Khomeini Square

City

Gonbad e kavoos

Province

Golestan

Postal code

4971613111

Phone

+98 17 3322 8827

Email

Mosadegh_agh@yahoo.com

2

Recruitment center

Name of recruitment center

Urban health base number 1

Full name of responsible person

Dr reza rezazade

Street address

Eleventh alley, east arash

City

Gonbad e kavoos

Province

Golestan

Postal code

4971613111

Phone

+98 933 547 1138

Email

Drrezarezazade@gmail.com

3

Recruitment center

Name of recruitment center

Urban health base number 2

Full name of responsible person

Dr bahare rostaminezhad

Street address

Alavi street

City

Gonbad e kavoos

Province

Golestan

Postal code

4971783651

Phone

+98 17 3322 7178

Email

Bahare_rostaminezhad@gmail.com

4

Recruitment center

Name of recruitment center

Urban health base number 3

Full name of responsible person

Akram amini

Street address

East shohada Street

City

Gonbad e kavoos

Province

Golestan

Postal code

4971888418

Phone

+98 17 3323 4446

Email

5

Recruitment center

Name of recruitment center

Urban health base number 5

Full name of responsible person

Dr maryam changizi

Street address

South Imam Khomeini Street

City

Gonbad e kavoos

Province

Golestan

Postal code

4971954793

Phone

+98 17 3334 4608

Email

Drmariamchangizi24@gmail.com

6

Recruitment center

Name of recruitment center

Urban health base number 6

Full name of responsible person

Dr najmeldin khoshkam

Street address

Shahid dastjerdi Street

City

Gonbad e kavoos

Province

Golestan

Postal code

4971135164

Phone

+98 17 3334 7077

Email

Khoshkamnajmeldin@gmail.com

7

Recruitment center

Name of recruitment center

Urban health base number 7

Full name of responsible person

Dr mahmod behroz

Street address

Sarabi Street

City

Gonbad e kavoos

Province

Golestan

Postal code

4971715988

Phone

+98 17 3328 7485

Email

Behrooz_mahmod@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Dr mohamadhasan emamian

Street address

Hafte tir Square

City

Shahrood

Province

Semnan

Postal code

۳۶۱۴۷۷۳۹۴۳

Phone

+98 23 3239 5054

Email

emamian@shmu.ac.ir

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

Midwifery

Street address

Yousefi building, shaghayegh street

City

Gonbad kavoos

Province

Golestan

Postal code

4979139543

Phone

+98 17 3358 6822

Email

Reihane.anvari@gmail.com

Person responsible for scientific 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

Midwifery

Street address

Yousefi building, shaghayegh street

City

Gonbad kavoos

Province

Golestan

Postal code

4979139543

Phone

+98 17 3358 6822

Email

Reihane.anvari@gmail.com

Person responsible for updating data

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

Midwifery

Street address

Yousefi building, shaghayegh street

City

Gonbad kavoos

Province

Golestan

Postal code

4979139544

Phone

+98 17 3358 6822

Email

Reihane.anvari@gmail.com

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