

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Assesing the Effect of Group Counseling on the Pregnancy Experience in Primi Gravida Women

Protocol summary

Study aim

Determining the Effect of Group Counseling on the Pregnancy Experience in Primi Gravida Women Referring to Urmia Health Centers

Design

A clinical trial with a simple random assignment of the list of centers is prepared from the health center and placed inside the bag by drawing lots.

Settings and conduct

40 people with sample loss during 6 two-hour sessions per week, two sessions in pairs in weeks 30 and 31 on attachment and social support and the rest of the sessions were done in groups in the counseling room of health centers and 40 people in the control group received only routine care they do.

Participants/Inclusion and exclusion criteria

Satisfaction for inclusion in the study, Iranian citizenship and resident of Urmia, minimum literacy, no speech problems, gestational age 28 weeks, age between 18-35 years, obtaining a score below 23 of the 28-GHQ questionnaire, abdomen First, no history of underlying diseases (diabetes, hypertension, kidney disease) or taking certain medications, single pregnancy, no history of infertility, wanting to conceive, BMI <25, having regular perinatal care, not having a stressful accident Severe during the last 6 months, having a mobile phone
Exclusion criteria: occurrence of any specific problem or disease in the current pregnancy, having a high-risk pregnancy, occurring a severe stressful event during the intervention, non-participation of mothers in more than two sessions or Reluctance to continue cooperation

Intervention groups

The intervention group received 6 sessions of 2 hours once a week as a group and in pairs (weeks 30 and 31 about attachment and social support) and received routine care, and the control group received only routine care.

Main outcome variables

Increase happiness and reduce discomfort during

pregnancy, reduce stress and anxiety and reduce fear of childbirth in the intervention group after counseling sessions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151004024340N17**

Registration date: **2020-12-26, 1399/10/06**

Registration timing: **retrospective**

Last update: **2020-12-26, 1399/10/06**

Update count: **0**

Registration date

2020-12-26, 1399/10/06

Registrant information

Name

Hamideh Mohaddesi

Name of organization / entity

Urmia University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 44 3275 4963

Email address

mohaddesi.h@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assesing the Effect of Group Counseling on the Pregnancy Experience in Primi Gravida Women

Public title

the Effect of Group Counseling on the Pregnancy Experience in Primi Gravida Women

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Willingness to participation in study Iranian citizenship and living in Urmia At least literacy No speech problems Phone access Gestational age 28 and above Age 18-35 Enjoy general health (cut score 23(GHQ_ 28) Possibility to participate in meetings First pregnancy No underlying disease or special medication Single pregnancy Do not have a history of infertility Wanting to get pregnant BMI<25 Having regular perinatal care No serious stressful events occur in the last 6 months Having a cell phone

Exclusion criteria:

Occurrence of any specific problem or disease in the current pregnancy Having a high-risk pregnancy Occurrence of severe stressful event during the intervention Absence of mothers from attending more than two sessions Reluctance to continue cooperation

Age

From **18 years** old to **35 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

First, the list of all urban health centers in Urmia was prepared from the health center of Urmia city. Then, according to the experts of Urmia Health Center, the above centers are divided into three groups of first, second and third degree based on their social, economic and cultural status. The lottery (simple random) was selected from each group of two centers. By drawing lots in each level, one center was assigned to the control group and one center to the intervention group.

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 Urmia University of Medical Sciences

Street address

Urmia University of Medical Sciences Urmia, Emergency Alley, Resalat Blvd.

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2019-02-27, 1397/12/08

Ethics committee reference number

ir.umsu.REC.1397.479

Health conditions studied**1****Description of health condition studied**

Women's experiences during pregnancy

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Pregnancy experiences

Timepoint

Before the intervention and two weeks after the intervention

Method of measurement

Questionnaire 41 questions of pregnancy experience

Secondary outcomes**1****Description**

Reduce pregnancy anxiety

Timepoint

Before the intervention and two weeks after the intervention

Method of measurement

Beck Anxiety Inventory

Intervention groups

1

Description

Intervention group: In addition to routine care and completing a pre-test questionnaire, enter study counseling sessions that include (providing general information _ stress and anxiety during pregnancy and coping strategies _ mother and fetus attachment and practical implementation of attachment behaviors _ social support and strategies to increase it Especially the support of the spouse _Spiritual support and practical implementation is preparation for childbirth and overcoming the fear of childbirth).The desired intervention will be done in the counseling room of health centers during six two-hour sessions once a week in groups and in pairs (weeks 30 and 31 on attachment and social support) and after two weeks from the end of the intervention of mothers The tools are re-evaluated.

Category

Behavior

2

Description

Control group: No intervention will be performed by the research team and they will only receive the center's routine care.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Health centers of Urmia city

Full name of responsible person

Rasul Entezar mahdi

Street address

West Azerbaijan Province, Urmia, Daneshkadeh street

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<https://phc.umsu.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Iraj Mohebbi

Street address

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Mohebi.i@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Shima Kia

Position

Master student of midwifery counseling

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Hamideh Mohaddesi

Position

Associate professor

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

Midwifery

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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

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

the study result of will be published in the form of an article

When the data will become available and for how long

starts the access period 6 month after article is published

To whom data/document is available

public

Under which criteria data/document could be used

Use for counseling and support program in health centers

From where data/document is obtainable

Ms. Hamideh Mohaddesi-Contact number:

00989143413242-Email address:

hmohadesi.han@gmail.com

What processes are involved for a request to access data/document

Login to Urmia University of Medical Sciences and Search for thesis

Comments