Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

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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 SciencesUrmia, 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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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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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
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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

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Latest degree
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Other areas of specialty/work
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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: hmohaddesi.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