Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of couple counseling based on cognitive emotional regulation on the fear of child birth in primigravida women referring to general health service centers in Salmas, 2019-2020

Protocol summary

Study aim

Determining the efficacy of couple counseling based on cognitive emotional regulation on the fear of child birth in primigravida women referring to general health service centers in Salmas, 2019-2020. Determining and comparing the mean score of fear of childbirth between and within the intervention and control groups before and after the intervention.

Design

Clinical trial with simple random assignment with a sealed envelope to the intervention and control groups on 48 couples.

Settings and conduct

Couple counseling will be held in eight sessions, one session per week and each session for 60-75 minutes. Counseling based on emotion regulation training based on the gross protocol Online and using WhatsApp and execution time according to the agreement of the interrogators. 3-8 will be held in the presence of the spouse (couple) and the rest of the group meetings. During the follow-up period, the researcher's telephone number will be provided to the intervention group. The control group will receive routine pregnancy care.

Participants/Inclusion and exclusion criteria

Inclusion criteria: not having pregnancy complications such as preclampsia and placenta previa; scoring below 85 in the Wijma delivery expectancy questionnaire. Exclusion criteria more than twice in the counseling session, the occurrence of any stressful event, termination of pregnancy or fetal death for any reason before the end of the counseling sessions.

Intervention groups

The intervention group will receive 8 sessions couples counseling online which will be held every week for 60-75 minutes and routine pregnancy care, and the control group will receive routine pregnancy care.

Main outcome variables

Decreasing the score of fear of childbirth; increased desire to have a normal delivery; increased social support on a family scale; increased natural delivery in the intervention group after counseling sessions.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151004024340N16**
Registration date: **2020-12-02, 1399/09/12**
Registration timing: **prospective**

Last update: **2020-12-02, 1399/09/12**
Update count: **0**

Registration date

2020-12-02, 1399/09/12

Registrant information

Name
Hamideh Mohaddesi
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-31, 1399/10/11

Expected recruitment end date

2021-01-18, 1399/10/29

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of couple counseling based on cognitive emotional regulation on the fear of child birth in primigravida women referring to general health service centers in Salmas, 2019-2020

Public title
The effect of couple counseling on the fear of child birth in primigravida women
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
First pregnancy Single pregnancy Literacy Fluency in Persian or Azeri Being a resident of Salmas Age 18 to 35 years old mother Wanting to get pregnant Gestational age 20-28 weeks at the beginning of the study Healthy and normal fetus in the first trimester sonographic examinations No indication for cesarean section at the time of sampling No mental illness and psychiatry according to the mother Do not use psychiatric drugs Enjoy general health (cut score 23 (GHQ-28) Lack of experience of an unfortunate accident such as an accident or the death of a loved one in the last 6 months No addiction to cigarettes, drugs and alcohol Monogamy Do not have a history of infertility
Exclusion criteria:
Achieving a score above 85 in the Wijma delivery expectancy questionnaire (W-DEQ) Absence more than twice in the counseling session Occurrence of any stressful incident Relocation and unavailability of couples Dissatisfaction and unwillingness to continue cooperation Termination of pregnancy or fetal death for any reason before the end of counseling sessions
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: **48**
Randomization (investigator's opinion)
Randomized
Randomization description
To randomize an envelope containing the letters A and B, we will have equal numbers. The letter A represents the intervention group and B represents the control group. People will be asked to take a piece of paper from the envelope. People who choose the letter A will be part of the intervention group and people who choose the letter B will form the control 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
2020-08-21, 1399/05/31
Ethics committee reference number
IR.UMSU.REC.1399.154

Health conditions studied

1

Description of health condition studied
Fear of childbirth
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Score of fear of childbirth in Vijma questionnaire
Timepoint
Before intervention - after intervention
Method of measurement
Wijma delivery expectancy questionnaire

Secondary outcomes

1

Description
Score of perceived social support – family score
Timepoint

Before intervention - after intervention
Method of measurement
Perceived social support – family scale

2

Description
Frequency of desire to perform type of delivery
Timepoint
Before intervention - after intervention
Method of measurement
Asking questions

3

Description
Performed type of delivery
Timepoint
Before intervention - after intervention
Method of measurement
Asking questions

Intervention groups

1

Description
Intervention group: They will receive eight sessions of Online couples counseling based on cognitive emotion regulation according to the Gross protocol. sessions will be held once a week for 60-75 minutes. Sessions 1-3-8 The presence of the spouse is necessary and the rest of the sessions will be done in groups. The sessions Content as follows: Session one (acquaintance) - Session two (position assessment) - Session three (position selection) - Session four (position correction) - Session five (attention span) - Session six (assessment Cognitive) - Session Seven (response modification) - Session Eight (evaluation and application).
Category
Lifestyle

2

Description
Control group: This group will receive routine pregnancy care.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
general health service centers in Salmas
Full name of responsible person
Akram Sabourinia
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Salmas Health Center, Chamran St., Shohada Intersection-
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Fax
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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
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Urmia University of Medical Sciences, Emergency St., Resalat Alley
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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
Akram Sabourinia
Position

Master student of midwifery counseling
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
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Person responsible for scientific inquiries

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Master Educated of Midwifery , Assistant Professor,Science Committee Member of Nursing and Midwifery
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Person responsible for updating data

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Latest degree
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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 results 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 months after the 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 Uiversity of Medical Sciences and Search for thesis
Comments