

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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

Name of organization / entity

Urmia University of Medical Science

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Iran (Islamic Republic of)

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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

AgeFrom **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 Sciences Urmia, Emergency Alley, Resalat Blvd.

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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 Wijma 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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

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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

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

Contact

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Full name of responsible person

Hamideh Mohaddesi

Position

Master Educated of Midwifery , Assistant
Professor, Science Committee Member of Nursing and
Midwifery

Latest degree

Master

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

Login to Urmia University of Medical Sciences and Search
for thesis

Comments