

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Sep 2026

The effect of midwifery led counseling based on gamble's Approach on childbirth fear and self-efficacy in nulligravida women

Protocol summary

Study aim

Set the effect of midwifery led counseling based on gamble's Approach on childbirth fear and self-efficacy in nulligravida women Compare the type of preferential maternity pregnant women between the experimental and control group before and after intervention

Design

The statistical society of present research will be all nulligravida women who referred to health and treatment centers of Zanjan city in 2018. The sampling method of this research will be in random cluster way in two stages from all health and treatment centers of Zanjan city. In a way that all these centers are being categorized in three social conditions of weak, average and good districts. Then, from each district's health and treatment centers, two of them will be selected randomly. From 80 women with high childbirth fear rate, 40 women are going to be selected in block randomized method as research's control and experimental groups.

Settings and conduct

Health centers of Zanjan city. Facial and phone call consulting sessions for experimental group during 24 and 34 weeks of pregnancy. The questionnaires will be completed in 36 week of pregnancy in both groups by another researchers help who is unaware of group's sampling method. The person who will analyze the data have no information about the experimental and control groups.

Participants/Inclusion and exclusion criteria

Nulligravida, Earning the score of 66 or more from Wijma's childbirth fear questionnaire

Intervention groups

The researcher will present a consult session with pregnant women during 24 to 34 weeks of pregnancy. In addition, during these weeks (24 to 34), each week one consultancy session will be held through phone calls. The control group will receive standardized cares.

Main outcome variables

Reduce the fear of childbirth; Enhance self-efficacy for

pregnant women

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101219005417N3**

Registration date: **2018-12-19, 1397/09/28**

Registration timing: **retrospective**

Last update: **2018-12-19, 1397/09/28**

Update count: **0**

Registration date

2018-12-19, 1397/09/28

Registrant information

Name

Elham Jafari

Name of organization / entity

Zanjan university of medical sciences

Country

Iran (Islamic Republic of)

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+98 72725130241

Email address

ejafari@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-06, 1397/04/15

Expected recruitment end date

2018-11-06, 1397/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of midwifery led counseling based on gamble's Approach on childbirth fear and self-efficacy in nulligravida women

Public title

The effect of midwifery led counseling on childbirth fear and self-efficacy

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 18-35 years old The first pregnancy Monogamous fetus There is no history of infertility Not having a history of chronic illness, medical or obstetrical The lack of a history of mental health disorders and taking psychedelic drugs The desire to participate in the study Having at least cycle education Earning a score equal to or higher than 66 wijma fear questionnaire Earning a score of less than or equal to the 51 of Toronto's questionnaire The current mental health score the mother include lack of depression less or equal to 13; anxiety score less than or equal 9; lack of stress less than or equal to 18

Exclusion criteria:

Fetal death before birth in the domain of research time Ultrasound of the abnormal embryo

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

in this research the groups are selected in block randomized method into two experimental and control groups (each group will contain 40 members). In a way that at first 6 block may put together according to group`s layout and will be identified and numbered in both group A (experimental) and B (control). Then, block`s numbers will be selected through randomized numbers` table until we achieve the sample size. Written testimonial of sample`s cooperation will be received in advance.

Blinding (investigator's opinion)

Double blinded

Blinding description

By employing an expert researcher, who does not have any information about experimental and control groups, we will gather the data in 36 week of pregnancy. Also the data will be analyzed without any information about group selection, .

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Zanjan University of medical sciences

Street address

Zanjan University of medical sciences, Central Headquarters, The beginning of the Islamic Republic Blvd., Azadi square

City

Zanjan

Province

Zanjan

Postal code

4515613191

Approval date

2018-05-29, 1397/03/08

Ethics committee reference number

IR.ZUMS.REC.1397.025

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

The fear of childbirth and self-efficacy for pregnant women

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

- nulligravida women`s childbirth fear

Timepoint

20-24 weeks of pregnancy (before starting the intervention) and twelve weeks after the start of the intervention

Method of measurement

Wijma fear questionnaire (Version A W-DEQ)

2**Description**

nulligravida women`s self- efficacy

Timepoint

Twenty-four weeks of pregnancy (before the start of the

intervention) and twelve weeks after the start of the intervention

Method of measurement

The questionnaire and the scale of the expected outcome of the delivery and efficacy of Louie

Secondary outcomes

1

Description

The preferred method of delivery

Timepoint

Twenty four weeks of pregnancy (before the start of the intervention) And thirty-six weeks of pregnancy

Method of measurement

The preferred method of delivery of the questionnaire a question

Intervention groups

1

Description

Control Group: This group will receive their special standard care.

Category

Other

2

Description

Intervention group: Based on Gamble`s approach, two midwifery- based counseling sessions will be presented in 24 and 34 pregnancy weeks and in addition, one phone call consulting session in each week will be held during 24 to 36 weeks of pregnancy.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Municipal Health Service Center No. 3

Full name of responsible person

Laya firouzan

Street address

The beginning of north Saadi, Cross road Sadi,
Municipal Health Service Center No. 15

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Province

Zanjan

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4515613191

Phone

+98 24 3345 1805

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L.firouzan6008@gmail.com

2

Recruitment center

Name of recruitment center

Municipal Health Service Center No. 15

Full name of responsible person

Laya Firouzan

Street address

Yasmine one, Farhang alley, Municipal Health Service
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3

Recruitment center

Name of recruitment center

Municipal Health Service Center No. 11

Full name of responsible person

Laya Firouzan

Street address

Second floor, Next to the gas pump, 45 meters,
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4

Recruitment center

Name of recruitment center

Municipal Health Service Center No. 18

Full name of responsible person

Laya firouzan

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Piece 4142, East Tulue Ave., Phase 3, Kazemeie
Golshahr, Municipal Health Service Center No. 18

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Ali Reza Shogli

Street address

Zanjan University of Medical Sciences Research & Technology Center, Azadi Square

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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

Zanjan 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**

Zanjan University of Medical Sciences

Full name of responsible person

Laya Firouzan

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Zanjan Nursing and Midwifery Faculty, End of Ahmad Mahdavi Ave, KarmandanTownship

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Zanjan University of Medical Sciences

Full name of responsible person

Laya Firouzan

Position

student

Latest degree

Bachelor

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

student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The data is not completed yet.

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