

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Investigation of emotion regulation educations' effect on fear of childbirth in primigravida women

Protocol summary

Study aim

Determining the emotion regulation educations' effect on fear of childbirth in primigravida women

Design

Field trial with control group, with parallel groups, first stage in accessible manner, randomized allocation method based on CAQ questionnaire scoring questionnaire

Settings and conduct

This study will be carried out in health centers of Gorgan. Blind will not be done in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Be single Her pregnancy is low risk. According to her pregnant mother, she and her husband have not consumed drugs, psychotropic substances and alcohol in the last two months. You do not have a history of infertility Ask your pregnancy. Minimum reading and writing education. Exclusion criteria: Until the end of the study, they intend to migrate from Gorgan. His wife and wife suffer from a known psychiatric illness, taking psychiatric medications or physical illnesses (cancers) and chronic illness over the past two months. Have a degree in medical sciences, psychology, or counseling. Have a history of infertility.

Intervention groups

The intervention group of the Gress-based Emotion-based Learning Training is taught to the test group. The control group does not receive any intervention.

Main outcome variables

Fear of giving birth

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190210042672N1**

Registration date: **2019-03-09, 1397/12/18**

Registration timing: **retrospective**

Last update: **2019-03-09, 1397/12/18**

Update count: **0**

Registration date

2019-03-09, 1397/12/18

Registrant information

Name

Fatemeh bayenat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3242 8056

Email address

f.bayenat@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-01, 1397/08/10

Expected recruitment end date

2019-01-30, 1397/11/10

Actual recruitment start date

2018-11-01, 1397/08/10

Actual recruitment end date

2019-01-30, 1397/11/10

Trial completion date

2019-01-30, 1397/11/10

Scientific title

Investigation of emotion regulation educations' effect on fear of childbirth in primigravida women

Public title

Investigation of emotion regulation educations' effect on fear of childbirth in primigravida women

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Be single Her pregnancy is low risk. According to her pregnant mother, she and her husband have not consumed drugs, psychotropic substances and alcohol in the last two months. You do not have a history of infertility Ask your pregnancy. Minimum reading and writing education.

Exclusion criteria:

Until the end of the study, they intend to migrate from Gorgan. His wife and wife suffer from a known psychiatric illness, taking psychiatric medications or physical illnesses (cancers) and chronic illness over the past two months. Have a degree in medical sciences, psychology, or counseling. Have a history of infertility.

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: **64**

Actual sample size reached: **62**

Randomization (investigator's opinion)

Not randomized

Randomization description

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 Golestan University of Medical Sciences

Street address

Golestan University of Medical Sciences, Higher Education Complex, 1st Road of Shast Kola, Km 5 Gorgan Road to Sari

City

gorgan

Province

Golestan

Postal code

4934174515

Approval date

2018-10-09, 1397/07/17

Ethics committee reference number

IR.GOUMS.REC.1397.150

Health conditions studied

1

Description of health condition studied

Fear of childbirth

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Fear of childbirth in the CAQ delivery fear questionnaire

Timepoint

Before the intervention begins and immediately after the intervention is completed

Method of measurement

CAQ delivery fear questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Grass Exercise Therapy Initially, Grass's Modeling Excitement (8 sessions, two sessions per week and each session for 120 minutes in groups of 6-12 people who met during the first familiarization session) Communicating with each other, expressing the main and subordinate goals of the group, expressing the framework and rules of the participant in the group, expressing the logic and the stages of intervention, starting the relationship between the leader of the group, discussing the members about the sub-goals and the collective, the second meeting of the choice of position-goal , Emotional education, Third-session selection of target-position selection, assessment of the degree of emotional vulnerability, assessment of the emotional level of the members, the meeting. E-mail: Modifying Location-Target, Creating Change in Emotion-Driven Position, Fifth Session, Attention-Target Exercise, Teaching Skills, Sixth Session, Cognitive Evaluation-Objective, Modifying Cognitive Assessments, Seventh-Tentative Adjustment-Target, Modifying Consequences of Behavior and Physiological excitement, Eighth Assessment and Application-Purpose, Re-evaluation and Planning for the Application of Training) are taught by the researcher. Then, the difference in fear of delivery with the CAQ questionnaire is measured in the pre-test and post-test phase and compared with each other.

Category

Other

2

Description

Control group: There is no intervention. The difference in fear of delivery is measured by the CAQ questionnaire on pre-test and post-test phases and compared with each other.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Deputy of Health of Golestan University of Medical Sciences

Full name of responsible person

fatemeh bayenat

Street address

Golestan University of Medical Sciences, Higher Education Complex, 1st Road of Shast Kola, Km 5 Gorgan Road to Sari

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Email

f.bayenat@goums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Mohammad reza Honarvar

Street address

Golestan University of Medical Sciences, Higher Education Complex, 1st Road of Shast Kola, Km 5 Gorgan Road to Sari

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honarvar@goums.a.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Gorgan 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

Gorgan University of Medical Sciences

Full name of responsible person

fatemeh bayenat

Position

Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

آسیه سادات بنی عقیل Asieh Sadat Baniaghil

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for updating data

Contact

Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
fatemeh bayenat
Position
midwifery
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
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Golestan University of Medical Sciences, Higher
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

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