

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of midwifery " Supportive group therapy " on fear of delivery, Tendency to type of delivery and happiness in pregnant women

Protocol summary

Study aim

Determining the effectiveness of midwifery counseling in the form of "supportive group therapy" on fear of childbirth, desire for type of delivery and happiness of pregnant women

Design

A one-blind control group clinical trial in which the statistical analyzer did not know the content of the sessions. Randomized by block method to volume 4. on 90 patients

Settings and conduct

The study site is Kordkoy city in Golestan province. The study is done according to the corona virtually if the disease is not controlled. Sessions 5 sessions are managed with the help of the leader who is the executor of the project and the help of the leader who is a midwife with experience. 9 people participate in each session. Due to the nature of the study, it is not possible to be blind, but the statistical analyst but the person completing the questionnaire is not aware of the group of people.

Participants/Inclusion and exclusion criteria

- Preference for cesarean delivery or hesitation in choosing the type of delivery
- First pregnancy and twin pregnancy
- Being 18 to 35 years old
- Minimum literacy
- Gestational age 22 to 30 weeks
- Healthy and normal fetus in the first trimester ultrasound examinations
- Having computer information (if the class is held virtually)

Conditions of non-entry: smoking, alcohol and drugs. Having a history of recurrent miscarriage and infertility and neurological and psychological disorders

Intervention groups

Supportive group therapy is considered, which will be done in 5 sessions with the participation of pregnant women and the guidance of the leader and the help of the leadership. Questionnaires will be completed in the control and intervention group, and offline classes will also be held.

Main outcome variables

Fear of childbirth; The desire for the type of delivery; Happiness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201209049657N1**

Registration date: **2021-01-29, 1399/11/10**

Registration timing: **registered_while_recruiting**

Last update: **2021-01-29, 1399/11/10**

Update count: **0**

Registration date

2021-01-29, 1399/11/10

Registrant information

Name

Zahra Mousavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3434 7488

Email address

seyedezahramousavi87311@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-16, 1399/10/27

Expected recruitment end date

2021-08-20, 1400/05/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of midwifery " Supportive group therapy " on fear of delivery, Tendency to type of delivery and happiness in pregnant women

Public title

Evaluation of the effectiveness of supportive group therapy on fear of childbirth, tendency to type of childbirth and happiness of pregnant women

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Prefer cesarean delivery or be hesitant about choosing the type of delivery. Be the first and single pregnancy No history of recurrent miscarriage. Be at least literate. Her gestational age at the beginning of the study should be 22-30. The fetus is healthy and normal in the first trimester ultrasound examinations. Have computer information if the class is held virtually There are no obvious and recognizable barriers to normal delivery at the time of sampling.

Exclusion criteria:

Have an addiction to alcohol, cigarettes and drugs. Have a history of recurrent miscarriage or infertility. Have a neurology and psychiatry Disorder

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Using the allocation sequence that was produced based on the block method to volume 4. First, the city is divided into three regions in terms of socio-economic, then one center is selected at random from each region, and people are selected at random from each center.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the nature of the study, it is not possible to blind the participants. However, the data collector (person completing the questionnaire) will not be aware of the group of people. Thus, pre-intervention questionnaires are administered before random assignment of individuals to groups. After the intervention, the data collector is not aware of the group of people. The statistical analyzer will also be unaware of the group of people.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Shahroud University of Medical Sciences

Street address

12th flower alley, Pasdaran street

City

Kordkuy

Province

Golestan

Postal code

4881878879

Approval date

2020-12-07, 1399/09/17

Ethics committee reference number

IR.SHMU.REC.1399.130

Health conditions studied**1****Description of health condition studied****ICD-10 code****ICD-10 code description****2****Description of health condition studied****ICD-10 code****ICD-10 code description****3****Description of health condition studied****ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Fear of childbirth

Timepoint

This variable will be measured before the start of the study and after the intervention.

Method of measurement

Vijma Maternity Fear Questionnaire

2

Description

Tendency to type of delivery

Timepoint

This variable will be measured before the start of the study and after the intervention.

Method of measurement

By asking pregnant women about their desire for childbirth

3

Description

happiness

Timepoint

This variable will be measured before the start of the study and after the intervention.

Method of measurement

Through the Oxford Happiness Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

My intervention group consists of 5 groups of nine people who, in addition to participating in supportive therapy groups, also participate in offline training classes that are matched with the control group and complete a questionnaire. Supportive group therapy will be performed in 5 one-hour sessions per week for the intervention group. The group leader is the project manager himself, who is a graduate student in midwifery counseling, and the assistant midwife treatment partner has experience in natural childbirth. If a session is held to discuss unspecified topics, a session will be added to it. .) And Introducing the treatment method Session 2: Discussion and education about the benefits and complications of natural childbirth Session 3: Discussion and education about the complications of cesarean delivery Session 4: Skills training and stress management Muscle relaxation) Session 5: Reviewing the previous sessions, summarizing, completing the questionnaire. Will be asked before and after the intervention.

Category

Treatment - Other

2

Description

The control group consists of 5 groups of 9 people. Before the intervention and after the intervention, they will fill out the Vjima and Oxford Maternity Fear Questionnaire and will be asked about the desire for the type of delivery before participating in the research and after participating in the research. They will also participate in offline training classes.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan University of Medical Sciences, Health centers of Kordkoy city in Golestan province

Full name of responsible person

Dr. Arash Naghipour

Street address

in front of Telecommunication, Vali Asr Street

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seyedezahramousavi87311@gmail.com

Web page address

<http://www.goums.ac.ir/index.php?sid=45>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Emamian Mohammad Hasan

Street address

Haft Tir Square

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Shahroud

Province

Semnan

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Fax

+98 23 3239 5009

Email

info@shmu.ac.ir

Web page address

<https://www.shmu.ac.ir/fa>

Grant name

Grant code / Reference number

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

No

Title of funding source

Vice Chancellor for Research, Shahroud 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
Shahroud University of Medical Sciences
Full name of responsible person
Zahra Mousavi
Position
Student
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Other areas of specialty/work
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Person responsible for updating data

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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

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The data of each questionnaire and interviews with individuals who are not known due to blindness belong to whom. However, the data can be published if it is clear that it belongs to the intervention group or the control. Data related to the main outcome, etc. can also be published. In fact, all the data that we have, including questionnaires, etc., can be published.

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

The project data and documentation can be used by researchers working in academic and scientific institutions, as well as people working in health centers

and hospitals and management systems and private offices.

Under which criteria data/document could be used

The documentary can be used for further research and development of science in this field or for work in a private office, etc.

From where data/document is obtainable

To receive data and documents, contact Ms. Seyedeh Zahra Mousavi, the project manager, at the email

address Seyedezahramousavi87311@gmail.com and the mobile number 09112788820 and the postal address of 12th Gol Alley, Pasdaran St, Golestan province and postal code 4881878879.

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

The request for data will be provided to the applicant immediately upon observation by the developer.

Comments