

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

"The Effectiveness Of Solution-focused Group Counseling on Fear of Childbirth&Selfefficacy in Nulliparous Women"

Protocol summary

Registration timing: **prospective**

Study aim

Establishing the Impact of Response Group counseling on the self - efficacy in primiparous women Establishing the Impact of Response Group counseling on the Fear of childbirth in primiparous women

Last update: **2019-04-18, 1398/01/29**

Update count: **0**

Registration date

2019-04-18, 1398/01/29

Design

Randomized Clinical trials with control groups, based on Participants in preparation classes for childbirth and solution - Focused Group counseling .

Registrant information

Name

Najme Heidari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Settings and conduct

centers for providing physiological delivery services in Yazd. The Intervention group will participate in preparation classes for delivery and solution - Focused counseling & The control group just participates in preparation classes for childbirth

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Age range between 18 and 35 years.Gestational age at least 20 weeks and a maximum of 28 weeks.First Pregnancy & Singleton Pregnancy.Having read and write literacy.Tendency to Participate in Antenatal Preparation Classes.Multipara Addiction Use of psychiatric drugs in The last six months Big stress in The last six months Such as Death of kin Early medical conditions(Diabetes .Chronic hypertension history.

Expected recruitment start date

2019-05-08, 1398/02/18

Expected recruitment end date

2019-08-09, 1398/05/18

Intervention groups

The Intervention group will participate in preparation classes for delivery and solution - Focused counseling & The control group just participates in preparation classes for childbirth.

Actual recruitment start date

empty

Actual recruitment end date

empty

Main outcome variables

Childbirth self - efficacy, Fear of childbirth

Trial completion date

empty

General information

Scientific title

"The Effectiveness Of Solution-focused Group Counseling on Fear of Childbirth&Selfefficacy in Nulliparous Women"

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190203042607N1**

Registration date: **2019-04-18, 1398/01/29**

Public title

"The Effect Of Solution-focused Group Counseling on Fear of Childbirth & Selfefficacy"

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
 Age range between 18 and 35 years First pregnancy
 Gestational age at least 20 weeks and a maximum of 28 weeks Singleton Pregnancy Having read and write literacy Tendency to Participate in Antenatal Preparation Classess

Exclusion criteria:
 Multipara Addiction Use of psychiatric drugs in The last six months Big stress in The last six months Such as Death of kin Early medical conditions(Diabetes.Chronic hypertension history&..)

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: **68**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Simple Randomized Two State-run who had the highest statistics for pregnant women was chosen as a statistical society And then by chance, by drawing the lottery, One center was selected as the test group and a center as 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 Yazd University of Medical Sciences

Street address

Imam Reza Educational Center.Student Blvd, Imam hosein Squ

City

Yazd

Province

Yazd

Postal code

8916998949/638

Approval date

2018-11-13, 1397/08/22

Ethics committee reference number

IR.SSU.REC.1397.096

2

Ethics committee

Name of ethics committee

Ethics committee of Yazd University of Medical Sciences

Street address

Imam Reza Educational Center.Student Blvd, Imam hosein Squ

City

Yazd

Province

Yazd

Postal code

8916998949/638

Approval date

2018-11-13, 1397/08/22

Ethics committee reference number

IR.SSU.REC.1397.096

Health conditions studied

1

Description of health condition studied

Childbirth Self-efficacy

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Fear of Child Birth

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Efficacy Score according to Loe Child Birth self - efficacy questionnaire

Timepoint

Before intervention, immediately after the intervention was over and two weeks after the intervention ended

Method of measurement

Loe Child Birth self - efficacy questionnaire

2

Description

Fear of Child Birth

Timepoint

Before intervention, immediately after the intervention was over and two weeks after the intervention ended

Method of measurement

Wijma Fear of Child Birth questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The Intervention group will Participate in preparation Classes for childbirth and Participants in Solution Focused Group Counseling Classes

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaye Kargar Hospital

Full name of responsible person

Khoshbin Azam

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Namaz Squ, Modarres Blv

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Province

Yazd

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1457965595

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2

Recruitment center

Name of recruitment center

Imam Ali specialized clinic

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd 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

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Khoshbin Azam

Position

Faculty Member

Latest degree

Master

Other areas of specialty/work

Midwifery

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College of Nursing & Midwifery, Boali Lane, Timsar
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Latest degree
Master
Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Najme
Position
Msc Student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
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nheidari1373dsh@gmail.com

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

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

Title and more details about the data/document

The Whole data is Available After identifying individuals such as: Birth Type, Fear score, Self-Efficacy score, level of education, Income rate,Employment status

When the data will become available and for how long

6 months after the results were published.

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

The data are available only to rely on the future papers of individuals.

From where data/document is obtainable

Email: nheidari1373dsh@gmail.com Mobile number:09139687304

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

A maximum of a week after your email is sent or the phone call is called.

Comments