

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

The Effect of Family Support Based Counselling on Postnatal Perceived Stress in Nulliparous Women Referred to Health Centers

Protocol summary

Summary

Purpose of the study: The effect of family support based counselling on postnatal perceived stress Study design: Random Main inclusion criteria: Iranian nationality, Age between 20-35 , Nulliparous women Main exclusion criteria: Anomaly detection, Preterm delivery, Mental illnesses, Absence of more than two meeting Target sample size: 330 Intervention: 4-6 counseling meeting individual and group for delivery women and their families Time intervention: Two counseling meeting 45-60 a week Primary outcome: Reduce perceived stress

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017031720778N18**
Registration date: **2017-04-19, 1396/01/30**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-04-19, 1396/01/30

Registrant information

Name

Fatemeh Moghaddam Tabrizi

Name of organization / entity

Uromia University of Medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 44 3275 4964

Email address

moghaddam.f@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Urmia University of Medical Sciences

Expected recruitment start date

2017-04-05, 1396/01/16

Expected recruitment end date

2017-06-21, 1396/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Family Support Based Counselling on Postnatal Perceived Stress in Nulliparous Women Referred to Health Centers

Public title

The Effect of Family Support Based Counselling on Postnatal Perceived Stress

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Iranian nationality, Age between 20-35, Nulliparous women Exclusion criteria: Anomaly detection, Preterm delivery, Mental illnesses, Absence of more than two meeting

Age

From **20 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **330**

Randomization (investigator's opinion)

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

Urmia University of Medical Sciences

Street address

Orjhans Street, Resalat Blvd, Urmia , Iran

City

Urmia

Postal code

Approval date

2016-11-10, 1395/08/20

Ethics committee reference number

IR.umsu.rec.1394.283

Health conditions studied

1

Description of health condition studied

Stress

ICD-10 code

F43.1

ICD-10 code description

Arises as a delayed or protracted response to a stressful event or situation (of either brief or long duration) of an exceptionally threatening or catastrophic nature, which is likely to cause pervasive distress in almost anyone.

Predisposing factors, suc

Primary outcomes

1

Description

Perceived Stress

Timepoint

After Intervention

Method of measurement

Post natal Perceived Stress

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 4-6 sessions of individual and group counseling for 45-60 minute, twice a week

Category

Prevention

2

Description

control group :The control group do not receive any intervention

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Centers of Urmia University of Medical Sciences

Full name of responsible person

Fatemeh Moghaddam Tabrizi

Street address

City

Urmia

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Urmia University of Medical Sciences

Full name of responsible person

Iraj Mohebbi

Street address

Orjhans Street, Resalat Blvd

City

Urmia

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Urmia University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Urmia University of Medical Sciences

Full name of responsible person

Fateme Mogaddam Tabrizi

Position

Assistant Professor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty