

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Effect of counselling with men on the perceived stress and social support of their pregnant wives: a randomized controlled trial

Protocol summary

Summary

Objectives: To determine the effect of counseling with men on perceived stress and social support of their pregnant wives. **Design:** Randomized controlled trial. **Conduct:** This study will be conducted on spouses of pregnant women referring to health centers of Ardebil city. The researcher will refer to health centers and will select pregnant women with gestational age of 20 to 24 weeks according to their records, then will call them and they will be invited to be present at the health center with their spouses. In face to face session, the questionnaires of social support will be completed and the women who obtain low and moderate score will be included in study and written consent will be obtained. Other questionnaires including perceived stress, Edinburgh depression and anxiety for pregnant women and perceived stress and anxiety questionnaires for men will be completed. Participants will be randomly assigned into two groups of counseling and control through block randomization. **Participants:** 102 pregnant women with gestational age of 20 to 24 weeks. **Intervention:** For the intervention group will be provided six 60-minute group sessions once a week. The control group will receive routine cares. The main outcome variables include stress and social support that will be assessed four weeks after the intervention through perceived stress and social support questionnaires. The secondary outcomes are depression and anxiety that will be assessed through questionnaires of Edinburgh depression and Spielberger anxiety. The neonatal anthropometric indices, delivery type and mothers' weight gain will be recorded according to childbirth file.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017042910324N38**

Registration date: **2017-06-25, 1396/04/04**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-06-25, 1396/04/04

Registrant information

Name

Mojgan Mirghafourvand

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1479 6969

Email address

mirghafourvandm@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2017-07-01, 1396/04/10

Expected recruitment end date

2017-12-22, 1396/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of counselling with men on the perceived stress and social support of their pregnant wives: a randomized controlled trial

Public title

Effect of counselling with men on the perceived stress and social support of their pregnant wives

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Singleton pregnancy; Gestational age between 20 to 24 weeks; Husband's willingness to participate in counseling classes; First pregnancy.
Exclusion criteria: History of mental illness or current mental illness, Taking psychiatric drugs or psychotropic substances; History of depression or current depression; Having obstetric complication including preterm labor, diabetes, hypertension, etc.; Unwanted pregnancy.

Age

No age limit

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 102

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**

Ethics committee of Tabriz University of Medical Sciences

Street address

Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz, East azerbaijan

City

Tabriz

Postal code**Approval date**

2017-06-21, 1396/03/31

Ethics committee reference number

IR.TBZMED.REC.1396.240

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

Stress

ICD-10 code

Z73.3

ICD-10 code description

Stress, not elsewhere classified

Primary outcomes**1****Description**

Perceived stress

Timepoint

Before intervention and 4 weeks after the end of intervention

Method of measurement

Perceived Stress Scale

2**Description**

Perceived social support

Timepoint

Before intervention and 4 weeks after the end of intervention

Method of measurement

Perceived social support scale

Secondary outcomes**1****Description**

Anxiety

Timepoint

Before intervention and 4 weeks after the end of intervention

Method of measurement

Spielberger State-Trait Anxiety Inventory

2**Description**

Depression

Timepoint

Before intervention and 4 weeks after the end of intervention

Method of measurement

Edinburgh Depression Scale

3**Description**

Neonatal anthropometric indices

Timepoint

After childbirth

Method of measurement

Childbirth file

4

Description

Delivery type

Timepoint

After childbirth

Method of measurement

Childbirth file

5

Description

Weight gain rate during pregnancy

Timepoint

After childbirth

Method of measurement

Pregnancy file

Intervention groups

1

Description

For the intervention group will be provided six 60-minute group sessions once a week.

Category

Behavior

2

Description

The control group will receive routine prenatal care.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Health centers in the city of Ardebil

Full name of responsible person

Maryam Mohammadpour

Street address

Ardebil city, Ardebil province

City

Ardebil

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University Of Medical Science

Full name of responsible person

Maragheh city, East Azerbaijan

Street address

Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Tabriz University Of Medical Science

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

Faculty of Nursing & Midwifery, Tabriz University of Medical Sciences

Full name of responsible person

Maryam Mohammadpour

Position

MSc student of counseling in Midwifery

Other areas of specialty/work

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Faculty of Nursing & Midwifery, South Shariati Street

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Faculty of Nursing & Midwifery, Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mojgan Mirghafourvand

Position

PhD of Reproductive Health

Other areas of specialty/work

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Fax**Email**Mirghafourvandm@tbzmed.ac.ir;
mirg1385@yahoo.com**Web page address****Person responsible for updating data****Contact****Name of organization / entity**Faculty of Nursing & Midwifery, Tabriz University of
Medical Sciences**Full name of responsible person**

Dr. Mojgan Mirghafourvand

Position

PhD of Reproductive Health

Other areas of specialty/work**Street address**

Faculty of Nursing & Midwifery, South Shariati Street

City**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*