

# 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**

###### **Street address**

Faculty of Nursing & Midwifery, South Shariati Street

###### **City**

Tabriz

###### **Postal code**

###### **Phone**

+98 41 3477 2699

###### **Fax**

###### **Email**

mahdireza1363@gmail.com

###### **Web page address**

## **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**

###### **Street address**

Faculty of Nursing & Midwifery, South Shariati Street

**City**

Tabriz

**Postal code****Phone**

+98 41 3479 6770

**Fax****Email**mirghafourvandm@tbzmed.ac.ir;  
mirg1385@yahoo.com**Web page address**

Tabriz

**Postal code****Phone**

+98 41 3479 6770

**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 &amp; 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*