Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Sep 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)

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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 Univercity 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
Anexiety
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 routin prenatal cares.
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, Aedebil 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 conseling in Midwifery
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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