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
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Mojgan Mirghafourvand
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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 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
1396/03/31

Approval date
2017-06-21

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

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

<table>
<thead>
<tr>
<th>Description</th>
<th>Delivery type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Timepoint</td>
<td>After childbirth</td>
</tr>
<tr>
<td>Method of measurement</td>
<td>Childbirth file</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Description</th>
<th>Weight gain rate during pregnancy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Timepoint</td>
<td>After childbirth</td>
</tr>
<tr>
<td>Method of measurement</td>
<td>Pregnancy file</td>
</tr>
</tbody>
</table>

### 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, Aedereb 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**
   N/A

   **Domestic or foreign origin**
   N/A

   **Category of foreign source of funding**
   N/A

   **Country of origin**
   N/A

   **Type of organization providing the funding**
   N/A

   **Person responsible for general inquiries**
   - **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

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   Faculty of Nursing & Midwifery, South Shariati Street

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     Dr. Mojgan Mirghafourvand
   - **Position**
     PhD of Reproductive Health

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Person responsible for updating data

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Full name of responsible person
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Position
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Other areas of specialty/work
Street address
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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