Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effectiveness of group counseling with problem solving approach to management of prenatal stress

Protocol summary

Summary

Objective: The aim of this randomized controlled experimental study will be determined the effectiveness of group counseling using solution-oriented approach for managing stress during pregnancy. Design: The statistic population of study will include pregnant women of Bojnoord who will come to health centers of the city. PSS-14 questionnaire will be the tool for stress evaluation Setting and conduct: The method of collecting samples is in a way that we will choose all the health care centers of the city. then mothers will be asked to complete two questionnaires, one is about demographic information and the other one will be perceived stress scale questionnaire. When the number of mothers with high stress will reach to 54, then we randomly divide them to two controlled and experimental groups. Major inclusion and exclusion criteria: at least 18 years old and they mothers should be in 17 to 20 weeks of their gestational age and have no known mental illness and accruing the mark above 8 out of 21 in PSS-14 questionnaire, and they can leave the study if they experience the stressful events during the study. Intervention: For control group regular prenatal care will be done and for experimental group will have the group counseling sessions of solution.The group counseling sessions will be 4, each one 90 minutes and in 4 following weeks will be held Main outcome measures: Stress management

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2015062022828N1**
Registration date: **2015-09-16, 1394/06/25**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2015-09-16, 1394/06/25

Registrant information

Name
Akram Aslani
Name of organization / entity
Shahroud Univercity of Medical Sciences
Country
Iran (Islamic Republic of)
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+98 23 3239 0428
Email address
aslani@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahroud University of Medical Sciences

Expected recruitment start date

2015-08-12, 1394/05/21

Expected recruitment end date

2015-10-22, 1394/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of group counseling with problem solving approach to management of prenatal stress

Public title

The effect of counseling on prenatal stress

Purpose

Prevention

Inclusion/Exclusion criteria
Inclusion criteria: minimum 18 years old, 17 to 20 weeks of gestational age, willingness to participate in the study, accruing the mark above 8 out of 21 in PSS-14 questionnaire, No formal consultation before entering the study, not having a known mental illness, no treating with tranquilizers. Exclusion criteria: the death of one of close relatives or any stressful events that happen during the study, the need to prescribe any medication or psychotherapy counseling during the study, irregular attendance in solution-oriented group counseling.

Age
From **18 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **54**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Will be randomized by Random numbers table

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahroud University of Medical Sciences

Street address
7 Tir Square headquarters of Medical Sciences university of shahroud

City
Shahroud

Postal code
3614773955

Approval date
2015-06-10, 1394/03/20

Ethics committee reference number
ir.shmu.rec.1394.51

Health conditions studied

1

Description of health condition studied
Anxiety

ICD-10 code
F41.9

ICD-10 code description
Anxiety disorder, unspecified

Primary outcomes

1

Description
Stress management

Timepoint
Before the intervention, one month after the started of the intervention and one month after the end of the intervention

Method of measurement
pss-14 Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this study the intervention is via holding group counseling sessions with solution-oriented approach (4 sessions and each one 90 minutes) for experimental group.

Category
Prevention

2

Description
Control group: There is no intervention for control group and they only receive routine pregnancy care.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Health center Shahid Kamyab

Full name of responsible person
Akram Aslani

Street address
Telephone center opposite, Settlements intersection shahed

City
Bojnoord

2

Recruitment center
Name of recruitment center
Health center Shahid Madani
Full name of responsible person
Akram Aslani
Street address
Molla sadra street, after bascool intersection, Imam Khomeini street
City
Bojnoord

3

Recruitment center
Name of recruitment center
Health center Shahid Fayyaz bakhsh
Full name of responsible person
Akram Aslani
Street address
Behzisty street
City
Bojnoord

4

Recruitment center
Name of recruitment center
Health center Olia
Full name of responsible person
Akram Aslani
Street address
Health old alley, Ferdosi street
City
Bojnoord

5

Recruitment center
Name of recruitment center
Health center Javadiyeh
Full name of responsible person
Akram Aslani
Street address
javadiyeh Square
City
Bojnoord

6

Recruitment center
Name of recruitment center
Health center Boali
Full name of responsible person
Akram Aslani
Street address
Yas alley, Between ghiam and kargar square
City
Bojnoord

7

Recruitment center
Name of recruitment center
Health center Horr
Full name of responsible person
Akram Aslani
Street address
Horr street
City
Bojnoord

8

Recruitment center
Name of recruitment center
Health center Mehre salamat
Full name of responsible person
Akram Aslani
Street address
Golestanshahr
City
Bojnoord

9

Recruitment center
Name of recruitment center
Health center Taleghani
Full name of responsible person
Akram Aslani
Street address
Nomber 103, Mehr 10, Mehr street, Bazargani square
City
Bojnoord

10

Recruitment center
Name of recruitment center
Health center Sharghe Sepah
Full name of responsible person
Akram Aslani
Street address
Sharghe Sepah
City
Bojnoord

11

Recruitment center
Name of recruitment center
Health center Farhangian
Full name of responsible person
Akram Aslani
Street address
Farhangian Settlements
City
Bojnoord

12

Recruitment center
Name of recruitment center
Health center Mahoor
Full name of responsible person

Akram Aslani

Street address

Mahoor Alley, Boulevard Moallem

City

Bojnoord

13

Recruitment center

Name of recruitment center

Health center Shahre bazi

Full name of responsible person

Akram Aslani

Street address

17 Shahrivar square

City

Bojnoord

14

Recruitment center

Name of recruitment center

Health center Bagherkhan

Full name of responsible person

Akram Aslani

Street address

Next Yenge ghaleah park

City

Bojnoord

15

Recruitment center

Name of recruitment center

Health center Malkesh

Full name of responsible person

Akram Aslani

Street address

Malkesh

City

Bojnoord

16

Recruitment center

Name of recruitment center

Health center Imam Hossein

Full name of responsible person

Akram Aslani

Street address

Shahede 13, Intersection shahed

City

Bojnoord

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahroud University of Medical Sciences

Full name of responsible person

Mohammad Hasan Emamian

Street address

7 Tir Square, headquartersshahroud University of Medical Sciences

City

Shahroud

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, Shahroud 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

Shahroud University of Medical Sciences

Full name of responsible person

Akram Aslani

Position

Master of science student

Other areas of specialty/work

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Akram Aslani

Position
Master of science student
Other areas of specialty/work
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www.shmu.ac.ir

Person responsible for updating data

Contact
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Other areas of specialty/work
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akramaslani92@gmail.com; aslani@shmu.ac.ir; hamidijavad1983@yahoo.com
Web page address
www.shmu.ac.ir

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