

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 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 University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+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

Number 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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hamidijavad1983@yahoo.com

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Contact

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

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Position

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www.shmu.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

Akram Aslani

Position

Master of science student

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

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+98 32394088

Email

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