Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The efficacy of psychological intervention on pregnancy outcomes and stress reduction in pregnant women during the 1st trimester at General Women Hospital

Protocol summary

Summary

Objectives: Stress management on pregnant women during the first trimester. Design: This project is a clinical trial with pre-test and post- test. This is a pilot study, The sampling is convenient.The subjects are pregnant women whose stress level will be measured by Hamilton inventory and Spielberger state anxiety inventory. We will have two groups, intervention group(n=25) with moderate stress level and control group (n=25) with mild stress level. Only intervention group will be trained with psychological interventions. Both groups receive usual prenatal care. Setting and conduct: They will be trained the stress management techniques in 5 sessions by psychologist, every session will be 60 minute. After training, Their stress level will be measured by Hamilton inventory and Spielberger state anxiety inventory again. All group members will be received usual prenatal care. we will check preterm labor, preeclampsia during pregnancy; in addition, we will check bilateral uterine artery doppler before and after intervention; then, we will compare them with themselves, besides we will measure infant's weight ,height and hospitalization rate in NICU, moreover we will check the admission rate in high risk ward for icter in neonates. Participants including major eligibility criteria: Gestational age<14w; Education=High school degree and upper; 25.4 ≥BMI ≥19.3; 37 ≥Maternal age≥19; Having informed consent. Exclusion criteria: Having psychological disorders such as depression, psychos, cognitive disorder and drug abuse. History of any medical disease such as Thyroid disease, Cardiac disease, Hepatic disease, Chronic renal disease; BMI<19 or BMI>25.3; Abortion>2; Poor pregnancy history such as IUFD. Intervention: Training stress management techniques in five sessions, every session is 60 minutes. Some of mindfulness and cognitive techniques are used for training them. main outcome variables: Management stress

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013081814174N2**
Registration date: **2013-12-20, 1392/09/29**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-12-20, 1392/09/29

Registrant information

Name

Mohamad Naser Jalalian

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research,Tehran University of Medical Sciences

Expected recruitment start date

2013-09-23, 1392/07/01

Expected recruitment end date

2013-11-21, 1392/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The efficacy of psychological intervention on pregnancy outcomes and stress reduction in pregnant women during the 1st trimester at General Women Hospital

Public title
Stress managament on pregnant women
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: Gestational age<14w; Education=High school degree and upper; 25.4 ≥BMI ≥19.3; 37 ≥Maternal age≥19;Having informed consent. Exclusion criteria: Having psychological disorders such as depression, psychos, cognitive disorder and drug abuse. History of any medical disease such as Thyroid disease, Cardiac disease, Hepatic disease,Chronic renal disease; BMI<19 or BMI>25.3; Abortion>2; Poor pregnancy history such as IUFD.
Age
From **19 years** old to **37 years** old
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
N/A
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,Tehran University of Medical Sciences
Street address
No 21, Qods St, Keshavarz Blvd, Tehran.
City
Tehran
Postal code
1417653761

Approval date
2013-07-10, 1392/04/19
Ethics committee reference number
88593

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
Measuring the level of stress before and after Intervention
Method of measurement
Hamilton inventory, Spielberger state anxiety inventory

Secondary outcomes

1

Description
Infant's height & weight.
Timepoint
After Delivery
Method of measurement
We will measure infant's weight and height.

2

Description
Measuring bilateral uterine artery
Timepoint
Before and after intervention sessions
Method of measurement
Sonography

3

Description
preeclampsia
Timepoint
During of pregnancy
Method of measurement
control of blood pressure in prenatal care

4

Description
Preterm labour
Timepoint

After intervention, during of pregnancy

Method of measurement

Prenatal care

5

Description

Hospitalization rate in NICU.

Timepoint

After Delivery.

Method of measurement

Controlling hospitalization rate in NICU after delivery.

Intervention groups

1

Description

Intervention: Training stress managament techniques in five sessions, evrey session is 60 minute.some of mindfulness and cognitive techniques use for training them.

Category

Prevention

2

Description

Control: NO treatment

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

General Hospital Women

Full name of responsible person

Dr Mahboobeh Shirazy

Street address

Ostad Njatollahi Av, Karim khan St, Tehran.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research,Tehran University of Medical Sciences

Full name of responsible person

Dr Mahboobeh Shirazy

Street address

North of Ostad Njatollahi Av, Karim khan St, Tehran

City

Tehran

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,Tehran 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

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MS student

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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