

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of lifestyle-based education to women and their husbands on the anxiety and depression during pregnancy and postpartum: a randomized controlled trial

Protocol summary

Summary

This randomized controlled trial aims to determine the effect of lifestyle-based education to women and their husbands on anxiety and depression during pregnancy and postpartum. 189 pregnant women at gestational age of 24 to 28 weeks with depression score less than 12 in the Edinburgh Inventory will be selected from public health centers of Bookan, Iran and will be randomly assigned into 3 groups of 63 people with a block size of 3, 6 and 9. Sequentially numbered sealed opaque envelopes will be used to conceal the allocation sequence. Interventions: Group 1: lifestyle-based education for the women and their husbands, Group 2: lifestyle-based education for only women, and Group 3: routine care. The women in the interventional groups will attend the educational classes once a week for four first weeks after recruitment. The main outcomes are depression and anxiety 8 weeks after intervention and 6 weeks postpartum which will be assessed using Edinburgh inventory and Spielberger's State-Trait Anxiety Inventory, respectively.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201410113706N23**

Registration date: **2014-12-12, 1393/09/21**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-12-12, 1393/09/21

Registrant information

Name

Sakineh Mohammad-Alizadeh-Charandabi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Research Deputy, Tabriz University of Medical Sciences

Expected recruitment start date

2014-12-20, 1393/09/29

Expected recruitment end date

2015-04-20, 1394/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of lifestyle-based education to women and their husbands on the anxiety and depression during pregnancy and postpartum: a randomized controlled trial

Public title

The effect of lifestyle-based education to women and their husbands on the anxiety and depression during pregnancy and postpartum

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: gestational age of 24 to 28 weeks; singleton pregnancy; first or second pregnancy, having a care record at one of the public health centers in Bookan,

Iran; no participation in other similar studies; having a phone number for follow up; willingness to participate in the study. Exclusion criteria: high risk for preterm birth; a history of depression or history of hospital admission due to psychiatric problems; suffering from depression (the Edinburgh Inventory score>12); addiction or habitual use of alcohol and drugs by the woman or her spouse; having a history of infertility and assisted reproductive technology; participation in childbirth preparation classes; having any chronic diseases (such as diabetes and ...); occurrence of death of first degree relatives; divorce or other serious emotional problems in the past month.

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **189**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single 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 Deputy, 3rd floor, Central building No 2 ,
Tabriz University of Medical Sciences, Golgasht st.,
Tabriz, Iran

City

Tabriz

Postal code

Approval date

2014-11-10, 1393/08/19

Ethics committee reference number

93124

Health conditions studied

1

Description of health condition studied

Pregnancy- related psychiatric disorders

ICD-10 code

O26.9

ICD-10 code description

Pregnancy-related condition, unspecified

Primary outcomes

1

Description

Depression

Timepoint

8 weeks after intervention (32-36 weeks of pregnancy)
and 6 weeks post-partum

Method of measurement

Edinburgh Inventory scale

2

Description

Anxiety

Timepoint

8 weeks after intervention (32-36 weeks of pregnancy)
and 6 weeks post-partum

Method of measurement

Spielberger's State-Trait Anxiety Inventory

Secondary outcomes

empty

Intervention groups

1

Description

Group 1: lifestyle-based education (on nutrition, exercise, sleep health, and sexual health) for the women and their husbands; including four 60-90 minutes group education sessions in four consecutive weeks held by a midwife and giving an educational booklet to women in the first session to be read by them and their husbands, two educational group sessions for their husbands held by a male psychiatrist, active telephone counselling with the women and passive telephone counselling with their husbands

Category

Prevention

2

Description

Group 2: lifestyle-based education (on nutrition, exercise, sleep health, and sexual health) for only the women; including four 60-90 minutes group education sessions in four consecutive weeks held by a midwife and giving an educational booklet to the women in the first session to be read by them and their husbands, telephone counselling with the women

Category

Treatment - Drugs

3

Description

Group 3: Only routine care

Category

Prevention

Recruitment centers

1

Recruitment center**Name of recruitment center**

Public Health Centers of Bookan

Full name of responsible person

Foziye Sanaati

Street address

Tabriz University of Medical Sciences, Nursing & Midwifery Faculty

City

Tabriz

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Research deputy of Tabriz University of Medical Sciences

Full name of responsible person

Mohammad-Reza Rashidi

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Research Deputy, 3rd floor, Central building No 2 ,
Tabriz University of Medical Sciences, Golgasht st.,
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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Research deputy of Tabriz 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**

Tabriz University of Medical Sciences, Nursing & Midwifery Faculty

Full name of responsible person

Foziye Sanaati

Position

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Sakineh Mohammad-Alizadeh Charandabi

Position

PhD of Reproductive Health

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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