

# 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)

**Phone**

+98 41 3477 2699

**Email address**

alizades@tbzmed.ac.ir

**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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**City**

Tabriz

**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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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Full name of responsible person**

Sakineh Mohammad-Alizadeh Charandabi

**Position**

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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*