

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### The effect of preconception counseling on women lifestyle: a single-blind randomized controlled trial

#### Protocol summary

##### Summary

**Objectives:** To determine the effect of preconception counseling on women lifestyle. **Design:** A randomized controlled trial. **Conduct:** This study will be conducted on healthy women and having plan to become pregnant in the next one year. The researcher will attend in health centers of Bonab and will provide a list of women ages 18-35 years old then will call them and if they comply with the inclusion criteria and have tendency to participate in study, they will be invited to be present at the health center. Pre-test questionnaires will be completed and preconception lifestyle questionnaire will be analyzed and women with low and middle lifestyle score will be included in the study. Then women will be randomly assigned to two groups (one group receiving counseling and other group receiving routine care or no care) using block randomization stratified by history of pregnancy. A person from research team not involved in the sampling will generate allocation sequence. **Participants:** 152 women ages 18 - 35 and having plan to become pregnant. **Intervention:** Group counseling will be provided to intervention group at six sessions twice a week in three consecutive weeks about topics of nutrition and acid folic use, physical activity, stress management, smoking and second hand smoking, alcohol, medication, dental care and safety observation. The main outcome variable is preconception lifestyle and secondary outcomes are perceived stress, preconception lifestyle knowledge and Locus of control that will be assessed before, 4 and 8 weeks after the intervention by questionnaires.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016012610324N28**

Registration date: **2016-04-10, 1395/01/22**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-04-10, 1395/01/22

##### Registrant information

###### Name

Mojgan Mirghafourvand

###### Name of organization / entity

Tabriz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

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##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

##### Expected recruitment start date

2016-04-10, 1395/01/22

##### Expected recruitment end date

2016-10-10, 1395/07/19

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of preconception counseling on women lifestyle: a single-blind randomized controlled trial

##### Public title

The effect of preconception counseling on women lifestyle

##### Purpose

Prevention

### **Inclusion/Exclusion criteria**

Inclusion criteria: Non pregnant women ages 18-35 years old; Having secondary school and higher education level; Having ability to becoming pregnant (no history of hysterectomy, tubectomy and other reasons of infertility); Having plan to become pregnant in the next one year; Having health record in health center; Being interested in participating in the study; Having a contact number for follow-up. Exclusion criteria: Having any diseases including cardio-vascular, hypertension, diabetes and mental diseases according to the woman expression.

### **Age**

From **18 years** old to **35 years** old

### **Gender**

Female

### **Phase**

2-3

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **152**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Single blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

Stratified by existence of prior pregnancy

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

##### **Street address**

Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Goltasht Street, Azadi Avenue, Tabriz,

##### **City**

Tabriz

##### **Postal code**

#### **Approval date**

2010-09-23, 1389/07/01

#### **Ethics committee reference number**

TBZMED.REC.1394.1057

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Lifestyle

#### **ICD-10 code**

Y98

#### **ICD-10 code description**

Lifestyle-related condition

## **Primary outcomes**

### 1

#### **Description**

Preconception lifestyle

#### **Timepoint**

Before, 4 and 8 week after intervention

#### **Method of measurement**

Preconception lifestyle questionnaire

## **Secondary outcomes**

### 1

#### **Description**

Perceived Stress

#### **Timepoint**

Before, 4 and 8 week after intervention

#### **Method of measurement**

Perceived Stress Scale (PSS)

### 2

#### **Description**

Preconception lifestyle knowledge

#### **Timepoint**

Before, 4 and 8 week after intervention

#### **Method of measurement**

Preconception lifestyle knowledge questionnaire

### 3

#### **Description**

Locus of control

#### **Timepoint**

Before, 4 and 8 week after intervention

#### **Method of measurement**

Multidimensional health locus of control scale B (MHLC)

## **Intervention groups**

### 1

#### **Description**

The intervention group will receive group counseling at six sessions twice a week in three consecutive weeks about topics of nutrition and acid folic use, physical activity, stress management, smoking and second hand smoking, alcohol, medication, dental care and safety observation.

**Category**  
Lifestyle

**2**

**Description**

گروه کنترل مداخله ای دریافت نخواهد کرد

**Category**  
N/A

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**  
Health centers of Bonab city  
**Full name of responsible person**  
Sakineh Ghasemi  
**Street address**  
Bonab city, East Azerbaijan  
**City**  
Bonab

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**  
Vice chancellor for research, Tabriz University of Medical Sciences  
**Full name of responsible person**  
Mohammad Reza Rashidi  
**Street address**  
Research department, third floor, central construction number 2, Tabriz medical science university, Golgasht Street, Azadi Avenue, Tabriz  
**City**  
Tabriz

**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, 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**  
Nursing & Midwifery Faculty, Tabriz University of Medical Sciences  
**Full name of responsible person**  
Sakineh Ghasemi  
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**Web page address**

**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*