

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)

Phone

+98 41 1479 6969

Email address

mirghafourvandm@tbzmed.ac.ir

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

Position
MSc student in Midwifery

Other areas of specialty/work

Street address
Nursing & Midwifery Faculty, South Shariati Street, Tabriz

City
Tabriz

Postal code
6615615733

Phone
+98 41 3776 9310

Fax

Email
ghasemisa9727@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Dr. Mojgan Mirghafourvand

Position
PhD of Reproductive Health

Other areas of specialty/work

Street address
Nursing & Midwifery Faculty, South Shariati Street, Tabriz

City
Tabriz

Postal code
6615615733

Phone
+98 41 3335 7582

Fax

Email
Mirghafourvandm@tbzmed.ac.ir;
mirg1385@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Dr. Mojgan Mirghafourvand

Position
PhD of Reproductive Health

Other areas of specialty/work

Street address

Nursing & Midwifery Faculty, South Shariati Street,
Tabriz

City

Tabriz

Postal code

Phone

+98 413335758

Fax

Email

Mirghafourvandm@tbzmed.ac.ir;

mirg1385@yahoo.com

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