

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### Educational lifestyle intervention (health promotion model-based) concern to vaginitis in reproductive-age women : provide an appropriate model

#### Protocol summary

##### Summary

This study is an intervention survey. Objectives of this study is effectiveness determination of educational intervention (Health Promotion Model-based) on lifestyle related to vaginitis and relapse of disease in reproductive age women with vaginitis . Questionnaire is the instrument for gathering data. This questionnaire has designed according literature review, qualitative interviews and expert's panel. After Psychometric (validity -reliability (pre-test is distributing in both intervention and control groups .These questionnaires will be completed by researcher through interview and observation. Sampling procedure is a two-stage clustered sampling. Ten health centers in five regions of North, South, East, West and center of Kermanshah will be chosen randomly. Each center is closed to another will be chosen randomly as a control center and another center as the intervention. The sample size is 340 and 170 sample in each group will examined randomly. Inclusion criteria are: reproductive age (10 to 49 years old), marital status, vaginitis diagnosed, intention to participate in the study, settlement in Kermanshah, no risk of certain diseases (cancer, diabetes, deficiency of the immune systems). After completing the pre-test in both of two groups, intervention will be performed as face to face education, group training and presenting pamphlet. Both of two groups will receive standard treatment in health center. After 4 to 8 months, post-test questionnaire will be completed in both of them. Impact of this intervention on health promoting lifestyle regards vaginitis and relapse of this disease will be measured and results will be analyzed and interpret.

#### General information

##### Acronym

non acronym

#### IRCT registration information

IRCT registration number: **IRCT2015012620817N1**

Registration date: **2015-06-24, 1394/04/03**

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

Last update:

Update count: **0**

#### Registration date

2015-06-24, 1394/04/03

#### Registrant information

##### Name

Roxana Parsapour

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8895 1403

##### Email address

roxanaarya@gmail.com

#### Recruitment status

##### Recruitment complete

#### Funding source

personal finance and chancellor for education in Tehran University of Medical Science

#### Expected recruitment start date

2014-12-31, 1393/10/10

#### Expected recruitment end date

2015-07-01, 1394/04/10

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

## Scientific title

Educational lifestyle intervention (health promotion model-based) concern to vaginit in reproductive-age women : provide an appropriate model

## Public title

Effect of educational lifestyle intervention (health promotion model-based) concern to vaginit in reproductive-age women : provide an appropriate model

## Purpose

Prevention

## Inclusion/Exclusion criteria

reproductive age( 15-49 years old ; being married; diagnosed vagini in health center during sampling; tendency to participation in research ;living in kermanshah city; having no specific disorder or disease such as cancer,diabetes,immune deficiency disease

## Age

From **10 years** old to **50 years** old

## Gender

Female

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **340**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

non

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee, Tehran University of Medical Sciences

##### Street address

Central Building Tehran University of Medical Sciences, Ghods Street, Keshavarz Bulvar, Tehran, Iran

##### City

Tehran

##### Postal code

14155-6446

#### Approval date

2014-12-30, 1393/10/09

## Ethics committee reference number

9021108004-133603

## Health conditions studied

### 1

#### Description of health condition studied

vaginit

#### ICD-10 code

N77.1\*

#### ICD-10 code description

Vaginitis, vulvitis and vulvovaginitis in infectious and parasitic diseases classified elsewhere

## Primary outcomes

### 1

#### Description

lifestyle related to vaginitis

#### Timepoint

4-8 mounth

#### Method of measurement

interview.observation

## Secondary outcomes

### 1

#### Description

relapse

#### Timepoint

4-8mounth

#### Method of measurement

observation.examination

## Intervention groups

### 1

#### Description

educational intervention include: face to face education for 170 case, group education in 20 secession for 20 minutes, provide pamphlet, phone contact and responsibility

#### Category

Lifestyle

### 2

#### Description

Control group doesn't get any intervention. They receive just routine drug treatment.

#### Category

N/A

## Recruitment centers

## 1

### Recruitment center

**Name of recruitment center**

Kermanshah Health Center

**Full name of responsible person**

Roxana Parsapour

**Street address**

Health Promotion Department, Floor 4, Health Faculty, Tehran University of Medical Science, Poorsina Street, KeshavarzBulva, Tehran, Iran

**City**

Tehran

## Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Deputy of Chancellor for Education of Tehran Medical University

**Full name of responsible person**

Mohammad Jalili

**Street address**

Number701, Central Building, Tehran Medical University, Ghods Street

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Deputy of Chancellor for Education of Tehran Medical University

**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**

Tehran University of Medical Sciences, Health Faculty

**Full name of responsible person**

Fereshteh Majlesi

**Position**

Professor

**Other areas of specialty/work****Street address**

Health Faculty of Tehran Medical University, Poorsina, Keshavarz Bulvar, Tehran

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dr\_f\_majlessi@yahoo.com

**Web page address**

non

## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Roxana Parsapour

**Position**

PhD Student of Health Promotion

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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*