

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

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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