

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Sep 2026

Effect of group counseling based on protection-motivation theory versus no counseling on cervical cancer screening in postmenopausal women: a randomized clinical trial

Protocol summary

Study aim

To assess the effect of group counseling based on protection-motivation theory versus no counseling on cervical cancer screening in postmenopausal women

Design

This is a randomized clinical trial, phase II, in which 108 eligible postmenopausal women will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible postmenopausal women who will refer to Hamedan Comprehensive Health Center during the study period will be enrolled in the trial

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 50 to 60 years; Cessation of menstruation for more than a year; Literate. Exclusion criteria: Physical or mental diseases; A history of cancer in the patient or her family; A history of regular screening; A previous history of counseling.

Intervention groups

Intervention group: Routine care and group counseling based on protection-motivation theory for 45 to 60 minutes per week for 4 weeks. Control group: Just routine care.

Main outcome variables

Primary outcome: participants' attitude and function toward cervical cancer screening

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N251**

Registration date: **2018-11-22, 1397/09/01**

Registration timing: **registered_while_recruiting**

Last update: **2018-11-22, 1397/09/01**

Update count: **0**

Registration date

2018-11-22, 1397/09/01

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2019-05-21, 1398/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of group counseling based on protection-motivation theory versus no counseling on cervical cancer screening in postmenopausal women: a randomized clinical trial

Public title

Effect of group counseling based on protection-

motivation theory versus no counseling on cervical cancer screening in postmenopausal women

Purpose

Screening

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 50 to 60 years; Cessation of menstruation for more than a year; Being literate

Exclusion criteria:

Physical or mental diseases; A history of cancer in patient or her family; A history of regular screening; A previous history of counseling.

Age

From **50 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of the patients to the intervention and control groups through the drawing of lots

Blinding (investigator's opinion)

Not 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 Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2018-11-03, 1397/08/12

Ethics committee reference number

IR.UMSHA.REC.1397.495

Health conditions studied

1

Description of health condition studied

Cervical cancer

ICD-10 code

C53

ICD-10 code description

Malignant neoplasm of cervix uteri

Primary outcomes

1

Description

Participants' attitude and function toward cervical cancer screening

Timepoint

Before and after group counseling

Method of measurement

Using a standard questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine care and group counseling based on protection-motivation theory for 45 to 60 minutes per week for 4 weeks

Category

Other

2

Description

Control group: Just routine care

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamedan Comprehensive Health Center

Full name of responsible person

Sorooh Rahmani

Street address

School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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6517838695

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Hamedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Sorooh Rahmani

Position

Midwifery Student

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Parisa Parsa

Position

Maternal and Child Health Specialist

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available