

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Investigating the Effectiveness of Supportive Counseling on the Fear and Psychological Distress of Colposcopy in Women

Protocol summary

Study aim

Determining the effectiveness of Supportive counseling on the Fear and Psychological distress of Colposcopy in Women

Design

Clinical trial with control group, intervention, simple randomization, 40 Patients in the intervention group under consultation, 40 Patients in the control group

Settings and conduct

In the women's clinic of Afzalipur Hospital, Kerman, women candidates for colposcopy are randomly divided into control and intervention groups. Both groups fill out the colposcopy fear questionnaire one week before colposcopy. The intervention group receives counseling. Then both groups fill out the fear questionnaire again before colposcopy. Both groups fill in the Psychological distress questionnaire immediately after colposcopy

Participants/Inclusion and exclusion criteria

Entry criteria: Having the age of 18 to 65 years, performing colposcopy for the first time, Being able to read and write, Not suffering from hearing or speaking disorders, Not having medical problems such as acute cardiovascular disease, Not suffering from neurological and mental disorders and Not using neurological and mental drugs. Conditions of non-entry: suffering from any type of cancer, addiction and positive HPV test.

Intervention groups

The effect of supportive counseling on the Fear and Psychological distress of Colposcopy in the intervention group and Lack of advice in the control group and just filling in the questionnaire

Main outcome variables

Supportive counseling, Fear, Psychological distress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151103024866N18**

Registration date: **2024-02-17, 1402/11/28**

Registration timing: **prospective**

Last update: **2024-02-17, 1402/11/28**

Update count: **0**

Registration date

2024-02-17, 1402/11/28

Registrant information

Name

Katayoun Alidousti

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 3132 5219

Email address

alidoosti@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-04-08, 1403/01/20

Expected recruitment end date

2024-09-10, 1403/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Effectiveness of Supportive Counseling on the Fear and Psychological Distress of Colposcopy in Women

Public title

Effect of Supportive Counseling on the Fear and Psychological Distress of Colposcopy

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Desire to Participate In the Study Having the Age of 18 to 65 Years Colposcopy for the First time Literacy for Reading and Writing Not Having a Hearing or Speaking disorder Absence of Medical Problems such as Known Chronic systemic diseases,Heart disease,Acute Lung disease Not Suffering from Nervous and Mental disorders Not use of Neuroleptics

Exclusion criteria:

Having any type of cancer Addicted people People with a positive HPV test result

Age

From **18 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling will be available and allocating the samples to two intervention and Control groups will be done in a simple random manner on Colposcopy candidate women. The Randomization tool is a table of Random numbers. In order to assign people to two intervention and Control groups, block method will be used. In this method, Blocks of 4 are used. In each Block, two people are randomly placed in the intervention group and two people in the Control group

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Kerman University of Medical Sciences Et

Street address

Kerman University of Medical Sciences, Medical

University Campus, Haft Bagh Highway, Kerman, Iran

City

kerman

Province

Kerman

Postal code

7616913555

Approval date

2023-12-23, 1402/10/02

Ethics committee reference number

IR.KMU.REC.1402.355

Health conditions studied**1****Description of health condition studied**

Fear

ICD-10 code

F40.233

ICD-10 code description

Fear of injury

2**Description of health condition studied**

psychological distress

ICD-10 code

F68.13

ICD-10 code description

Factitious disorder with combined psychological and physical signs and symptoms

Primary outcomes**1****Description**

Fear score from the fear questionnaire

Timepoint

Before the intervention and after completion of counseling sessions

Method of measurement

questionnaire

2**Description**

psychological distress score from Cervical Dysplasia Distress Questionnaire

Timepoint

Immediately after colposcopy

Method of measurement

Cervical Dysplasia Distress Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The people who are placed in the intervention group are placed under the group counseling of the first session a week before the appointment given for colposcopy. They will be asked to participate in the second session that will be held in the week of the colposcopy appointment. Therefore, the number of counseling sessions is 2, and each session lasts about 60-90 minutes.

Category

Behavior

2

Description

Control group: No intervention will be received and only completes the questionnaire

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipur Medical Education Center

Full name of responsible person

Effat Sotoodehnia

Street address

Imam Khomeini Highway, next to Shahid Bahonar University, Afzalipur Medical Education Center

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Web page address

<http://bankpezeshtkan.com>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abedin Iranpour

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Deputy of research and technology., Somayeh Crossroads

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vcr@kmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Katayoun Alidousti

Position

Instructor of the midwifery faculty

Latest degree

Master

Other areas of specialty/work

Midwifery

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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

Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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