

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Investigating the effect of increasing awareness based on Acceptance and Commitment Therapy on the quality of life of women with HPV referring to the Kerman women's oncology subspecialties, 2023

Protocol summary

Study aim

Determining the effect of awareness-raising based on acceptance and commitment on the quality of life of women with HPV

Design

A clinical trial with a control group, without blinding, randomized, on 60 women with papilloma virus. Excel software was used for randomization

Settings and conduct

Available sampling, group consultation room of Afzalipur Hospital, women with HPV

Participants/Inclusion and exclusion criteria

Entry: positive HPV test; less than 6 months have passed since the positive test result; willingness to participate in the study and complete the informed consent form; not having a neurological or mental illness; not suffering from another type of sexually transmitted diseases; being sexually active. Exit: getting HPV-related cancer while studying; getting pregnant while studying; in case of missing more than one session and not doing homework.

Intervention groups

6 group and face-to-face counseling sessions per week, one 90-minute session. Control without intervention

Main outcome variables

Awareness; acceptance and commitment; quality of life

General information

Reason for update

Acronym

HPV(human papilloma virus)

IRCT registration information

IRCT registration number: **IRCT20170611034452N16**

Registration date: **2023-11-18, 1402/08/27**

Registration timing: **registered_while_recruiting**

Last update: **2023-11-18, 1402/08/27**

Update count: **0**

Registration date

2023-11-18, 1402/08/27

Registrant information

Name

Atefeh Ahmadi

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

a.ahmadi@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-14, 1402/08/23

Expected recruitment end date

2025-11-14, 1404/08/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of increasing awareness based on Acceptance and Commitment Therapy on the quality of life of women with HPV referring to the Kerman women's oncology subspecialties, 2023

Public title

Investigating the effect of increasing awareness based

on Acceptance and Commitment Therapy on the quality of life of women with HPV

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Positive HPV test confirmed by gynecological oncology specialist Less than 6 months have passed since the positive test result Willingness to participate in the study and complete the informed consent form Not having any neurological or mental illness Not suffering from the type Another sexually transmitted disease Being sexually active

Exclusion criteria:

Getting HPV-related cancer while studying Getting pregnant while studying If you miss more than one session and don't do your homework

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Women who meet the inclusion criteria will continue to use the available sampling method until the sample size (at least 30 people) is reached in each group. Using Excel software, they are placed in two intervention and control groups by simple random method (block of four).

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

The work of the research ethics committee of Kerman University of Medical Sciences

Street address

Kerman University of Medical Sciences campus, beginning of Haft Bagh Alavi axis

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2023-11-04, 1402/08/13

Ethics committee reference number

IR.KMU.REC.1402.288

Health conditions studied

1

Description of health condition studied

Human papilloma virus (HPV) infection

ICD-10 code

R87.810

ICD-10 code description

Cervical high risk human papillomavirus (HPV) DNA test positive

Primary outcomes

1

Description

Quality of Life

Timepoint

The first session of the intervention and 2 weeks after the completion of the intervention sessions

Method of measurement

Quality of life questionnaire (EQUALI-HPV)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: They receive 6 group and face-to-face counseling sessions, one 90-minute session per week

Category

Behavior

2

Description

Control group: There is no intervention for the control group

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Women's oncology specialist office

Full name of responsible person

Atefeh Ahmadi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

Reza Malekpour Afshar

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Web page address

<http://vresearch.kmu.ac.ir/fa>

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

Atefeh ahmadi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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

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Full name of responsible person

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after de-identifying individuals

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

By prior agreement with the corresponding author

From where data/document is obtainable

email

What processes are involved for a request to access data/document

email

Comments