

# 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

+98 34 3132 5205

###### 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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Kerman University of Medical Sciences, Haft Bagh  
Alavi

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+98 34 3132 5700

**Fax**

+98 34 3132 5219

**Email**

a.ahmadi@kmu.ac.ir

**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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Kerman University of Medical Sciences, Haft Bagh  
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**Phone**

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**Email**

intdep2@gmail.com

**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**

Kerman University of Medical Sciences

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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**