Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of Acceptance and Commitment Therapy (ACT) on the Sexual Quality of Life in Women Infected with Human Papillomavirus (HPV)

Protocol summary

Study aim
Determining the effect of acceptance and commitment therapy on the sexual quality of life in women infected with human papillomavirus

Design
A randomized controlled clinical trial with intervention and control groups, including 48 participants

Settings and conduct
This research is a Randomized Controlled Trial (RCT). The study population consists of women with HPV attending the Ayatollah Mousavi Center in Zanjan. Participants will first be selected using convenience sampling and then allocated to two groups, intervention and control, via block randomization.

Participants/Inclusion and exclusion criteria
Inclusion: Minimum literacy; married women aged 18-45, sexually active, HPV positive, married ≥ 6 months, and poor/moderate SQOL-F score. Exclusion: Occurrence of stressful life events within the past 6 months, history of psychological disorders or underlying medical conditions, substance and alcohol addiction

Intervention groups
Participants in the intervention group will receive Acceptance and Commitment Therapy (ACT) in eight weekly 90-minute group sessions conducted by a trained researcher. Sessions include ACT principles, mindfulness, acceptance of negative emotions, reduction of experiential avoidance, identification of personal values, and committed action to improve sexual functioning. Questionnaires will be completed post-intervention and one month later (telephone follow-up). The control group will receive routine care only and complete questionnaires at the same time points. After the study, an educational booklet and optional training session will be provided for ethical considerations.

Main outcome variables
Quality of Sexual Life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201113049377N4**
Registration date: **2026-03-19, 1404/12/28**
Registration timing: **prospective**

Last update: **2026-03-19, 1404/12/28**
Update count: **0**

Registration date
2026-03-19, 1404/12/28

Registrant information

Name
Parvin Mohebbi
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-04-03, 1405/01/14

Expected recruitment end date
2027-03-16, 1405/12/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The Effect of Acceptance and Commitment Therapy (ACT) on the Sexual Quality of Life in Women Infected with Human Papillomavirus (HPV)

Public title
The Effect of Counseling on the Sexual Quality of Life of Women with Human Papillomavirus Infection
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Ability to read and write (minimum literacy level) Women aged 18–45 years (to reduce the potential impact of age-related changes on sexual function). Women who are married and sexually active Laboratory-confirmed positive test for Human Papillomavirus (HPV) At least six months since the initiation of marital life Poor to moderate sexual quality of life based on the Sexual Quality of Life–Female (SQOL-F) questionnaire
Exclusion criteria:
Occurrence of stressful life events within the past 6 months History of psychological disorders or underlying medical conditions Substance or alcohol abuse
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **48**
Randomization (investigator's opinion)
Randomized
Randomization description
After providing a comprehensive explanation of the study objectives and procedures to eligible clients, women who meet the inclusion criteria will be identified. Subsequently, the demographic information questionnaire and the Sexual Quality of Life questionnaire will be administered for completion. Eligible participants will be recruited during their routine and consecutive visits to the gynecology clinic. They will then be randomly allocated into intervention and control groups using block randomization method (block size: four). For this purpose, 12 blocks of four participants each will be generated using a table of random numbers, resulting in a total sample size of 48 participants. The block randomization process will be carried out by an individual who is not involved in the sampling or intervention procedures to minimize allocation bias. The generated random sequences will be recorded on individual cards and placed sequentially into sealed envelopes. After sealing, the envelopes will be stored in a box. At the initiation of the intervention, envelopes will be opened sequentially, and the participant’s group assignment will be determined accordingly.
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 Zanjan University of Medical Sciences
Street address
Zanjan University of Medical Sciences, Professor Dr. Yousef Sobhouti Boulevard, Zanjan, Iran
City
Zanjan
Province
Zanjan
Postal code
4513956184
Approval date
2026-02-03, 1404/11/14
Ethics committee reference number
IR.ZUMS.REC.1404.361

Health conditions studied

1

Description of health condition studied
Women Infected with Human Papillomavirus
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Quality of Sexual Life
Timepoint
Before, immediately and one month after the intervention
Method of measurement
Sexual Quality of Life–Female Questionnaire (SQOL-F) by Symonds

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Participants in this group will receive counseling based on Acceptance and Commitment Therapy (ACT). The intervention consists of eight weekly 90-minute group sessions conducted by a trained researcher. The session content includes introduction to the principles and concepts of the ACT approach, reduction of experiential avoidance, acceptance of negative emotions (such as shame and anxiety), mindfulness exercises, identification of personal values in the domains of health and intimate relationships, and planning for committed actions aimed at improving sexual functioning and sexual experience.

Category

Lifestyle

2

Description

Control group:Participants in this group will not receive any ACT-based educational or counseling intervention during the study period and will only receive routine care. To observe ethical considerations, after completion of the study an educational booklet containing the session content will be provided to participants in the control group, and if desired, an educational session will be held for them.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Mousavi Medical Center, Zanjan university of medical sciences,Zanjan

Full name of responsible person

Masud Hoseinlo

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Ayatollah Mousavi Specialized and Subspecialized Teaching and Medical Center, Gavazang Road, Zanjan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Mehrdad Hamidi

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First Floor, Building No. 1, Central Headquarters No. 2, Zanjan University of Medical Sciences and Health Services, Beginning of Jomhouri Eslami Street, Azadi Square, Zanjan, Iran

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Grant name

Grant code / Reference number

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

No

Title of funding source

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Parvin Mohebbi

Position

Instructor_Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Assistant Professor of Reproductive Health- Faculty member

Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available