Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the Effect of Counseling Based on the Acceptance and Commitment Model versus the Self-Compassion Model on Quality of Life and Sexual Satisfaction in Women with Human Papillomavirus (HPV)

Protocol summary

Study aim
Determine and compare the effect of counseling based on the Acceptance and Commitment model versus the Self-Compassion model on the quality of life and sexual satisfaction of women with HPV.

Design
The sample size, accounting for attrition, will be 60 participants. The random allocation process consists of two steps: Generating a random allocation to the two intervention groups using Random Allocation software. Concealment: The sequence will be implemented in such a way that the interventions remain concealed until participants are officially assigned to the research groups. blinding of participants and intervention providers will not be possible.

Settings and conduct
This study is a randomized controlled trial with a pretest, post test, and follow-up design. The research setting is the Baghaipour Specialized and Subspecialized Women's Clinic in Yazd city.

Participants/Inclusion and exclusion criteria
Inclusion Criteria:Positive HPV test؛ Less than 12 months have passed since the positive test result؛Willingness to participate in the study and complete the informed consent form؛No diagnosis of another type of sexually transmitted infection (STI)؛Sexually active (self-reported) Exclusion Criteria: Development of HPV-related cancer during the study؛ Absence from more than 30% of sessions (more than two sessions missed)؛ Having a neurological or psychiatric disorder (self-reported)

Intervention groups
Women in the Acceptance and Commitment Therapy (ACT) intervention group will receive their intervention in a group format, both in-person and online, over six 90-minute sessions. The Self-Compassion intervention group will also receive their intervention in a group format, both in-person and online, over six 90-minute sessions.

Main outcome variables
Quality of Life - Sexual Satisfaction

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20260508069291N1**
Registration date: **2026-05-15, 1405/02/25**
Registration timing: **prospective**

Last update: **2026-05-15, 1405/02/25**
Update count: **0**
Registration date
2026-05-15, 1405/02/25

Registrant information
Name
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Name of organization / entity
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Recruitment status
recruiting
Funding source

Expected recruitment start date
2026-05-23, 1405/03/02
Expected recruitment end date
2027-05-23, 1406/03/02
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Counseling Based on the Acceptance and Commitment Model versus the Self-Compassion Model on Quality of Life and Sexual Satisfaction in Women with Human Papillomavirus (HPV)

Public title

Comparison of the Effect of Counseling Based on the Acceptance and Commitment Model versus the Self-Compassion Model on Quality of Life and Sexual Satisfaction in Women with Human Papillomavirus (HPV)

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

1.Positive HPV test 2.Less than 12 months have passed since the positive test result 3.Willingness to participate in the study and complete the informed consent form 4.No diagnosis of another type of sexually transmitted infection (STI) 5.Sexually active (self-reported)

Exclusion criteria:

1.Development of HPV-related cancer during the study 2.Absence from more than 30% of sessions (more than two sessions missed) 3.Having a neurological or psychiatric disorder (self-reported)

Age

From **15 years** old

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

Research participants will be divided into two intervention groups using random allocation: group counseling based on the Acceptance and Commitment model (n = 30) and group counseling based on the Self-Compassion model (n = 30). The random allocation process consists of two steps: 1. Generating a random allocation to the two intervention groups using Random Allocation software. 2.Concealment: The sequence will be implemented in such a way that the interventions remain concealed until participants are officially assigned to the research groups. Due to the nature of the topic, objectives, and hypotheses of the study, blinding of participants and intervention facilitators will not be possible

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 Shahid Sadoughi University of Medical Sciences, Yazd

Street address

Timsar Falahi Street, Boali Alley

City

Yazd

Province

Yazd

Postal code

8915818411

Approval date

2026-05-05, 1405/02/15

Ethics committee reference number

IR.SSU.REC.1405.020

Health conditions studied

1

Description of health condition studied

Human Papillomavirus (HPV)

ICD-10 code

R87.811

ICD-10 code description

Vaginal high risk human papillomavirus (HPV) DNA test positive

Primary outcomes

1

Description

Quality of life and sexual satisfaction based on a questionnaire

Timepoint

Before the start of the intervention, immediately after the intervention, and 8 weeks after the completion of the intervention

Method of measurement

Quality of Life and Sexual Satisfaction Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Group 1 (Acceptance and Commitment Therapy model) (30 participants) will receive their intervention in the form of six 90-minute sessions of group counseling based on the Acceptance and Commitment Therapy model. At the beginning of the first intervention session, the Quality of Life and Sexual Satisfaction Questionnaire will be completed by the participants. The sessions will be conducted in a hybrid format (online and in-person) as a pre-test, post-test, and follow-up period. At the end of the sessions and 8 weeks after the completion of the intervention, the variables of quality of life and sexual satisfaction will be reassessed using the relevant questionnaire.

Category
Other

2

Description
Intervention group: Group 2 (Self-Compassion model) (30 participants) will receive their intervention in the form of six 90-minute sessions of group counseling based on the Self-Compassion model. At the beginning of the first intervention session, the Quality of Life and Sexual Satisfaction Questionnaire will be completed by the participants. The sessions will be conducted in a hybrid format (online and in-person) as a pre-test, post-test, and follow-up period. At the end of the sessions and 8 weeks after the completion of the intervention, the variables of quality of life and sexual satisfaction will be reassessed using the relevant questionnaire.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Specialized and sub-specialized women's clinic in Baghaeipour, Yazd

Full name of responsible person
Leila Asadi

Street address
Timsar Falahi Street, Bo Ali Alley

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Deputy of Research and Technology

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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
Yazd 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
Yazd University of Medical Sciences

Full name of responsible person
Yazd University of Medical Sciences

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

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Person responsible for scientific inquiries

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Person responsible for updating data

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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