Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of in-person and couples counseling on anxiety, depression and quality of life in HPV-positive women

Protocol summary

Study aim
Comparison of the effect of two methods of individual and couple counseling in reducing anxiety, depression and improving the quality of life of women with HPV

Design
Randomized Clinical trial with control group, one-blind with parallel groups

Settings and conduct
HPV-positive women referred to the gynecological oncology clinic of Valiasr Hospital (located in Imam Khomeini Hospital) are invited to participate in the study. If the company agrees, they will be in the group of individual or couple counseling.

Participants/Inclusion and exclusion criteria
Admission Requirements: positive HPV test result literacy Understanding Persian language No chronic disease and mental illness

Intervention groups
Intervention group 1: This intervention will run virtually and individually in 6 sessions (30 minutes for each session) as a day in between. Telephone counseling to support women with HPV to overcome their fears and worries will be conducted and answering their questions (about 4 times) . An educational intervention based on correcting the myths of the disease will be designed to change misunderstandings and negative perceptions about the disease, eliminate misconceptions and relieve stigma. The second part of the training will be based on lifestyle to strengthen the body immune system (nutrition, exercise, sleep hygiene and sexual health). The educational booklet compiled by the researcher is presented to the patients at the end of the second session for study, which is designed based on a review of the texts and using the opinion of experts. Intervention group 2: This intervention will run virtually and couple in 6 sessions (30 minutes for each session) as a day in between. Control group: In the control group, no intervention will be performed by the researcher and patients will receive only routine care.

Main outcome variables
Anxiety and depression in women with HPV

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201012049002N1**
Registration date: **2021-01-09, 1399/10/20**
Registration timing: **prospective**

Last update: **2021-01-09, 1399/10/20**
Update count: **0**

Registration date
2021-01-09, 1399/10/20

Registrant information

Name
Kowsar Qaderi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 6105 4203

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-01-14, 1399/10/25

Expected recruitment end date
2021-01-24, 1399/11/05

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of in-person and couples counseling on anxiety, depression and quality of life in HPV-positive women

Public title
Comparison between in-person and couples counseling in reducing anxiety depression and quality of life of HPV positive women

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Receiving Positive result of HPV test Being literate Understanding Persian language no chronic illness no known mental illness

Exclusion criteria:

Age
From **18 years** old to **55 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
Block Randomization: With the size of blocks 3, 6 and 9, 40 people will be randomly assigned to 3 groups. A member of the research team who is not involved in the selection of samples, will determine the random allocation sequence using a computer program, and opaque envelopes in the package will be numbered in order to allocation concealment.

Blinding (investigator's opinion)
Single blinded

Blinding description
The statistical analyst is blinded to the allocation of study groups. In this way, the statistical analyzer does not know which of the data belongs to the control or experimental group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethical Commitee of School of Nursing and Midwifery and School of Rehabilitation - National Ethics C

Street address
Nursing and Midwifery School, Mirkhani St., Nosrat St., Tehran

City
Tehran

Province
Tehran

Postal code
1419733171

Approval date
2018-10-31, 1397/08/09

Ethics committee reference number
IR.TUMS.FNM.REC.1397.139

Health conditions studied

1

Description of health condition studied
Anogenital (venereal) warts

ICD-10 code
A63.0

ICD-10 code description
Anogenital (venereal) warts

2

Description of health condition studied
Mild cervical dysplasia

ICD-10 code
N87.0

ICD-10 code description
Mild cervical dysplasia

Primary outcomes

1

Description
Anxiety and Depression

Timepoint
Before the intervention and 8 weeks after the intervention

Method of measurement
Hospital Anxiety and Depression Scale (HADS)

Secondary outcomes

1

Description
Quality of life

Timepoint
Before and 10 weeks after intervention

Method of measurement
QoL SF-36

Intervention groups

1

Description

Intervention group 1: This intervention will run virtually and individually in 6 sessions (30 minutes for each session) as a day in between. Telephone counseling to support women with HPV to overcome their fears and worries will be conducted and answering their questions (about 4 times) . Six training sessions consist of two parts, each of which will be three sessions: In the first part, an educational intervention based on correcting the myths of the disease will be designed to change misunderstandings and negative perceptions about the disease, eliminate misconceptions and relieve stigma. The second part of the training will be based on lifestyle to strengthen the body immune system and eliminate the virus from the body (nutrition, exercise, sleep hygiene and sexual health). The educational booklet compiled by the researcher is presented to the patients at the end of the second session for study, which is designed based on a review of the texts and using the opinion of experts.

Category

Lifestyle

2

Description

Intervention group 2: This intervention will run virtually and couple in 6 sessions (30 minutes for each session) as a day in between. Telephone counseling to support women with HPV to overcome their fears and worries will be conducted and answering their questions (about 4 times) . Six training sessions consist of two parts, each of which will be three sessions: In the first part, an educational intervention based on correcting the myths of the disease will be designed to change misunderstandings and negative perceptions about the disease, eliminate misconceptions and relieve stigma. The second part of the training will be based on lifestyle to strengthen the body immune system and eliminate the virus from the body (nutrition, exercise, sleep hygiene and sexual health). The educational booklet compiled by the researcher is presented to the patients at the end of the second session for study, which is designed based on a review of the texts and using the opinion of experts.

Category

Lifestyle

3

Description

Control group: In the control group, no intervention will be performed by the researcher and patients will receive only routine care. After the trial, educational content will be provided to them.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr gynecology oncology clinic at Imam Khomeini Hospital

Full name of responsible person

Kowsar Qaderi

Street address

Imam Khomeini Hospital, Mirkhani St., Nosrat St., Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraian

Street address

North Door, Poursina St.,, Ghods St., Enghelab St.

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m.sahrai@sina.tums.ac.it

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Seyedeh Tahereh Mirmolaei

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

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Person responsible for scientific inquiries

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PhD candidate

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Master

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Person responsible for updating data

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Latest degree
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Other areas of specialty/work
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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