

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

kowsar.qaderi@gmail.com

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 Committee 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

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6119 2993

Email

kqaderi@razi.tums.ac.ir

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.

City

Tehran

Province

Tehran

Postal code

1916893813

Phone

+98 21 2200 6660

Email

m.sahrai@sina.tums.ac.ir

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

+98 21 6105 4000

Email

kqaderi@razi.tums.ac.ir

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

Street address

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

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6105 4000

Email

mirmolaei@tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Kowsar Qaderi

Position

PhD candidate

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

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

City

Tehran

Province

Tehran

Postal code

61054000

Phone

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Kowsar Qaderi

Position

PhD candidate

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

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

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6105 4000

Email

kowsar.qaderi@gmail.com

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