Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of expressive writing on anxiety, depression and quality of life in women with Human Papillomavirus Infection

Protocol summary

Study aim
This study aimed to determine the effect of expressive writing on anxiety, depression and quality of life in women with Human Papillomavirus infection.

Design
Randomized clinical trial, single-blind with parallel groups, including: one intervention group and one control group (72 participants in each group). Sampling will be simple random sampling. The allocation of individuals to the two groups will be done using the randomization website.

Settings and conduct
At baseline, all participants in both the intervention and control groups will complete the demographic questionnaire, Beck Anxiety Inventory (BAI), Beck Depression Inventory-II (BDI-II), and the WHO Quality of Life questionnaire (WHOQOL-BREF). Following a 4-week intervention period, participants in both groups will complete the same questionnaires again to assess changes.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age between 18 and 45 years old, Iranian nationality, diagnosis of Human Papillomavirus (HPV) infection. Exclusion criteria: presence of malignant and known diseases, concurrent sexually transmitted infections, presence of Cervical Intraepithelial Neoplasia Grade 3 (CIN3), consumption of alcohol and drugs, presence of known mental disorders (based on self-report of the participant), occurrence of a stressful event at least 2 months prior.

Intervention groups
The intervention group will be introduced to the intervention implementation method and written expression technique in a training session. Writing should be done using free association without deliberate thought, followed by 30 minutes of writing about their emotions and feelings without concern for spelling or grammar. Control group will be asked to write about their daily activities, once a week for four consecutive weeks, dedicating 30 minutes each session.

Main outcome variables
Depression, anxiety, quality of life.

General information

Reason for update
According to the beginning of the war, sampling time, sampling location, and sampling type were changed.

Acronym

IRCT registration information
IRCT registration number: **IRCT20090810002324N22**
Registration date: **2025-08-10, 1404/05/19**
Registration timing: **prospective**

Last update: **2026-06-20, 1405/03/30**
Update count: **1**

Registration date
2025-08-10, 1404/05/19

Registrant information

Name
Maryam Keshavarz
Name of organization / entity
Iran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 4365 1813
Email address
keshavarz@iums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-06-10, 1405/03/20

Expected recruitment end date
2026-09-11, 1405/06/20

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of expressive writing on anxiety, depression and quality of life in women with Human Papillomavirus Infection

Public title
Expressive writing, anxiety, depression and quality of life in women with Human Papillomavirus infection
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age Between 18 and 45 years old Iranian Nationality Ability to read and write Definite diagnosis of Human Papilloma virus (HPV), at least 3 months prior (confirmed by HPV test or diagnosis of genital warts), documented in the patient's file.
Exclusion criteria:
Presence of malignant diseases Concurrent sexually transmitted infections Presence of Cervical Intraepithelial Neoplasia Grade 3 (CIN3) Pregnancy Breastfeeding Presence of known mental disorders (based on self-report of the participant) Consumption of alcohol and drugs Contact with other individuals with HPV infection attending the clinic or membership in shared online groups Occurrence of a stressful event at least 2 months prior
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **144**
Randomization (investigator's opinion)
Randomized
Randomization description
Initially, the clinic manager will provide the researcher with the contact numbers of individuals who meet the inclusion criteria. The list of names will be randomly divided into two groups: experimental and control. The allocation of individuals to the two groups will be done using the randomization website (www.randomizer.org).
Blinding (investigator's opinion)
Single blinded
Blinding description
Participants and the researcher will be aware of how individuals are assigned to each of the two intervention and control groups. Before and after intervention, in order to blinding, all questionnaires will be presented and collected by a research assistant who is unaware of the allocation method and project objectives. Therefore this study is single-blind.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Iran University of Medical Sciences, next to Milad Tower, Hemmat Highway, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1996713883
Approval date
2025-06-29, 1404/04/08
Ethics committee reference number
IR.IUMS.REC.1404.351

Health conditions studied

1

Description of health condition studied
Human Papillomavirus Infection
ICD-10 code
A63.8
ICD-10 code description
Other specified predominantly sexually transmitted diseases

Primary outcomes

1

Description
The mean score and severity of depression
Timepoint
before the intervention and Immediately after the completion of the intervention.
Method of measurement
The Beck Depression Inventory II(BDI-II)

2

Description
The mean score and severity of anxiety

Timepoint
Before the intervention and Immediately after the completion of the intervention
Method of measurement
The Beck Anxiety Inventory (BAI)

3

Description
The mean score of quality of life
Timepoint
before the intervention and Immediately after the completion of the intervention
Method of measurement
The World Health Organization Quality of Life Brief Version (WHOQOL-BREF)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention group will practice the expressive writing technique once a week for four consecutive weeks, dedicating 30 minutes each session. Writing should be performed in the morning immediately after waking up, in a quiet environment. Initially, writing should be done using free association without deliberate thought, followed by 30 minutes of writing about their emotions and feelings without concern for spelling or grammar. The expressive writing tasks are as follows:• Day 1: Write about themselves (emotions, characteristics, strengths and weaknesses, goals, and aspirations).• Day 2: Write about their deepest feelings, thoughts, and concerns related to their illness.• Day 3: Write about their most difficult experience related to human papillomavirus (HPV).• Day 4: Write about positive thoughts and expectations regarding the treatment process related to HPV.
Category
Prevention

2

Description
Control group: To ensure consistency between groups participants in the control group will also receive an intervention. They will be asked to write about their daily activities، once a week for four consecutive weeks, dedicating 30 minutes each session.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Papilloma Clinic, Shahid Motahari Hospital
Full name of responsible person
Zahra Barjesteh
Street address
Valiasr Street, above Mirdamad Street, Shahid Rashid Yasemi Street, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1345943159
Phone
+98 21 6403 3000
Email
hosplo@iums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Majid Safa
Street address
Iran University of Medical Sciences, next to Milad Tower, Hemmat Highway, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 86701
Email
vcm@iums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Maryam Keshavarz
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
School of Nursing & Midwifery, Rashid Yasemi St., Valiasr St., Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1996713883
Phone
+98 21 4365 1139
Email
MKmarkesh@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Maryam Keshavarz
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
School of Nursing & Midwifery, Rashid Yasemi St., Valiasr St., Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1996713883
Phone
+98 21 4365 1139
Email
MKmarkesh@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Maryam Keshavarz
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
School of Nursing & Midwifery, Rashid Yasemi St., Valiasr St., Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1996713883
Phone
+98 912 573 2924
Email
MKmarkesh@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
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable