Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effect of motivational interviewing on improving the reproductive health of women with HPV

Protocol summary

Study aim
Determining the effect of motivational interviewing on improving the reproductive health of women with human papilloma virus

Design
Clinical trial, with parallel groups, without blinding, phase three, randomized, which will be performed on 62 patients randomly.

Settings and conduct
The study population is women infected with the human papilloma virus, who will be randomly divided into two groups by computer using the random number table method.

Participants/Inclusion and exclusion criteria
Inclusion criteria: infection with human papilloma virus; Reading and writing literacy Exclusion criteria: unwillingness to continue cooperation during the study; Extreme physical or mental conditions

Intervention groups
Intervention group: will receive 5 individual motivational interview sessions, twice a week, each session lasting 45 minutes. Control group: The control group only receives routine training about the virus.

Main outcome variables
Sexual dysfunction of women with HPV, anxiety, depression and stress of women with HPV

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230531058348N1**
Registration date: **2023-06-11, 1402/03/21**
Registration timing: **registered_while_recruiting**

Last update: **2023-06-11, 1402/03/21**
Update count: **0**

Registration date
2023-06-11, 1402/03/21

Registrant information

Name
Mina Galeshi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 11 3233 8301

Email address
m.galeshi@mubabol.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-06-10, 1402/03/20

Expected recruitment end date
2023-08-11, 1402/05/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of motivational interviewing on improving the reproductive health of women with HPV

Public title
The effect of motivational interviewing on improving the reproductive health of women with HPV

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Human papilloma virus infection Reading and writing literacy

Exclusion criteria:
Reluctance to continue cooperation during the study
Extreme physical or mental conditions

Age
No age limit

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **62**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be done using permutation blocks of size 4. (AABB) in such a way that blocks of 4 consist of random combinations of 2 A (intervention) and 2 B (control). Patients will be randomly assigned to two groups of 31 people using 16 blocks with a size of 4 and a ratio of 1:1. The randomization list is prepared by a statistician.

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 Shahroud University of Medical Siences

Street address
Shahrud University Of Medical Science, 7 Tir Square, Tehran street

City
shahroud

Province
Semnan

Postal code
۳۶۱۴۷-۷۳۹۴۳

Approval date
2021-10-10, 1400/07/18

Ethics committee reference number
IR.SHMU.REC.1400.154

Health conditions studied

1

Description of health condition studied
Human papillomavirus

ICD-10 code
R87.810

ICD-10 code description
Cervical high risk human papillomavirus (HPV) DNA test positive

Primary outcomes

1

Description
Sexual dysfunction

Timepoint
Before the intervention and after the completion of 5 sessions

Method of measurement
Female Sexual Function Index (FSFI)

2

Description
Stress, anxiety, depression

Timepoint
Before the intervention and after the completion of 5 sessions

Method of measurement
Stress-anxiety-depression DASS-21

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: will receive 5 motivational interview (motivational interviewing in the experimental group runs in accordance with the principles of Miller and Rollnick in the fifth sessions. Contents of the Motivational interviewing session: • First session (dating): A group norms and processes, facilitates the philosophy, practice of freedom, the exercise of the Dimensions of behavior influence, the exercise of change cycle assessment of commitment and confidence. • Second session (emotion): Feelings Practice identifying, practicing and perfecting the exercise of influence dimension and emotional dimension and homework. • The third session (positive and negative aspects of behavior and change): Practice of brainstorming of Short-term and long-term profit and losses, Practice of a complete table of the positive and negative aspects, describe and Practice of corrective options and alternatives one. • Fourth session (values): Definition of values, Practice identifying and prioritizing notch values, practice to define values and value-behavior consistency. • Fifth session (closing Landscape): Summarizing and concluding of previous training Sessions in a Landscape practice and

preparation for the start of behavior change programs) individual, twice a week, each session lasting 45 minutes.

Category
Behavior

2

Description
Control group: The control group only receives routine training about the virus

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Women's Clinic of Ayatollah Rouhani Hospital

Full name of responsible person
Zahra Motaghi

Street address
Ruhani Hospital, Daneshgah Square, Ganjafrooz Avenue

City
Babol

Province
Mazandaran

Postal code
47176-41367

Phone
+98 11 3233 8301

Email
galeshi_m@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahroud University of Medical Sciences

Full name of responsible person
Mohammad Hassan Emamian

Street address
Shahrud University Of Medical Science, 7 Tir Square, Tehran street

City
Shahroud

Province
Semnan

Postal code
۳۶۱۴۷-۷۳۹۴۳

Phone
+98 23 3239 5054

Email
emamian@shmu.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Shahroud 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
Shahroud University of Medical Sciences

Full name of responsible person
Mina Galeshi

Position
student

Latest degree
Master

Other areas of specialty/work
Midwifery

Street address
Shahrud University Of Medical Science, 7 Tir Square, Tehran street

City
Shahroud

Province
Semnan

Postal code
۳۶۱۴۷-۷۳۹۴۳

Phone
+98 23 3239 5054

Email
galeshi_m@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahroud University of Medical Sciences

Full name of responsible person
Zahra Motaghi

Position
Associated Professor

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

Street address
Shahrud University Of Medical Science, 7 Tir Square, Tehran street

City
Shahroud

Province
Semnan
Postal code
۳۶۱۴۷-۷۳۹۴۳
Phone
+98 23 3239 5054
Email
galeshi_m@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Mina Galeshi
Position
Student
Latest degree
Master
Other areas of specialty/work
Midwifery
Street address
Shahrud University Of Medical Science, 7 Tir Square, Tehran street
City
Shahroud
Province
Semnan
Postal code
۳۶۱۴۷-۷۳۹۴۳
Phone
+98 23 3239 5054
Email
galeshi_m@yahoo.com

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 still no plan for its publish
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
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