

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 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 Sciences

Street address

Shahroud 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

Shahroud 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

Shahroud 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

Shahroud 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

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

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