Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effectiveness of mindfulness counselling on shame and sexual self-esteem in women with Human papillomavirus

Protocol summary

Study aim
The effectiveness of mindfulness counselling on shame and sexual self-esteem in women with Human papillomavirus

Design
A clinical trial with a control group, with a parallel and randomized group will be conducted on 138 women (69 people in each group) with a positive human papillomavirus test. Eligible people will be selected during routine visits and then will be assigned to two intervention and control groups using a random sampling method of 4 blocks. A table of random numbers will be used to create blocks of 4. There is no blinding in this study.

Settings and conduct
The setting includes the Specialized gynaecology and obstetrics clinic of Ayatollah Mousavi Hospital in Zanjan. Eligible people will be allocated to two intervention and control groups using a random sampling method of 4 blocks. A table of random numbers will be used to create blocks of 4. There is no blinding in this study. The intervention group will receive 8 counselling sessions based on mindfulness and the control group will receive standard treatment.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Positive human papillomavirus test in the last 6 months, Having a spouse or sexual partner, Having primary education and more. Exclusion criteria: Women with Human immunodeficiency virus, Having a Marital discord or the verge of divorce, Having a debilitating disease, Diagnosed mental illness, Alcohol consumption, Experienced psychological trauma in the past three months,

Intervention groups
The intervention group: They will receive 8 group counselling sessions based on the mindfulness approach, one session per week and each session for 90 minutes in person. The control group: They will receive standard treatment including drug therapy, counselling, additional diagnostic tests, and personal hygiene education.

Main outcome variables
Sexual self-esteem, Shame

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150731023423N23**
Registration date: **2024-02-03, 1402/11/14**
Registration timing: **prospective**

Last update: **2024-02-03, 1402/11/14**
Update count: **0**

Registration date
2024-02-03, 1402/11/14

Registrant information

Name
Azam Maleki

Name of organization / entity
Zanjan University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 24 3345 4264

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malekia@zums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-02-09, 1402/11/20

Expected recruitment end date
2024-12-22, 1403/10/02

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effectiveness of mindfulness counselling on shame and sexual self-esteem in women with Human papillomavirus

Public title
The effectiveness of mindfulness counselling on shame and sexual self-esteem in women with Human papillomavirus
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Positive human papillomavirus test in the last 6 months Having a spouse or sexual partner Having primary education and more
Exclusion criteria:
Women with Human immunodeficiency virus Having a Marital discord or the verge of divorce Having a debilitating disease Diagnosed mental illness Alcohol consumption Experience psychological trauma in the past three months Unwillingness to continue participation in the study
Age
From **18 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **138**
Randomization (investigator's opinion)
Randomized
Randomization description
Eligible people will be selected during routine visits and then will be assigned to two intervention and control groups using a random sampling method of 4 blocks. Blocks of 4 will be selected using a table of random numbers in the size of 17 blocks so that the sample size reaches 69 people. Blocking will be done by a person not involved in sampling.
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 Zanjan University of Medical Sciences
Street address
Jomhori Eslami Ave, Azadi Square,The first floor of Deputy of research and technology of Zanjan University of Medical sciences
City
Zanjan
Province
Zanjan
Postal code
4515613191
Approval date
2024-01-16, 1402/10/26
Ethics committee reference number
IR.ZUMS.REC.1402.249

Health conditions studied

1

Description of health condition studied
Shame
ICD-10 code
ICD-10 code description

2

Description of health condition studied
Sexual self-esteem
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Sexual self-esteem
Timepoint
Before the intervention and 4 weeks after intervention
Method of measurement
Sexual self-esteem Questionnaire

2

Description
External shame
Timepoint
Before the intervention and 4 weeks after intervention
Method of measurement
External shame Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Control group: They will receive standard treatment including drug therapy, complementary testing, diagnostic and personal health education.
Category
Prevention

2

Description
Intervention group: They will receive 8 group counselling sessions based on the mindfulness approach as one session per week and each session lasts 90 minutes in the form of face-to-face meetings. The content of the sessions is a form of mindfulness and acceptance therapy. In the counselling sessions, self-acceptance strategies, practice of three steps of mindfulness development, training of observation exercises, familiarization with the concept of self-care and its necessity in improving sexual self-esteem, familiarity with the concept of compassion and self-compassion and its relationship with self-esteem and shame will be discussed.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Mousavi Hospital of Zanjan
Full name of responsible person
Sara Hosseini
Street address
Blvd. 22 Bahman., Sarbaz Gomnam Square, Prof. Sobouti Blvd, Ayatollah Mousavi Zanjan Hospital, Zanjan University of Medical Sciences, Zanjan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Samad Nadri
Street address
Islamic Jamhmouri St., Corner of Azadi Square, first floor of academic headquarters, vice president for research and technology of Zanjan University of Medical Sciences, Zanjan
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research@zums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zanjan 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
Zanjan University of Medical Sciences
Full name of responsible person
Azam Maleki
Position
Assistant Professor of Reproductive Health
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Zanjan University of Medical Sciences

Full name of responsible person
Azam Maleki

Position
Assistant Professor in Reproductive Health

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

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Person responsible for updating data

Contact

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Full name of responsible person
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Position
Assistant Professor in Reproductive Health

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

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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
The possibility of dissatisfaction of the participants

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available