

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 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)

Phone

+98 24 3345 4264

Email address

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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sara1221hosseini@gmail.com

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

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Other areas of specialty/work

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Person responsible for updating data

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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