

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

The effect of health promotion awareness counseling with stress management on anxiety and reproductive and sexual self-care performance in women with human papiloma virus : a controlled clinical randomized trial

Protocol summary

Study aim

Determining the effect of health awareness counseling with a stress management approach on anxiety and fertility and sexual self-care performance in women with genital warts.

Design

A randomized controlled clinical trial with parallel groups of 64 women who have a positive HPV test result and referred to the oncology clinic of Al-Zahra Hospital.

Settings and conduct

Sampling will be done in the specialized clinic of Al-Zara Hospital in Tabriz, after reviewing the inclusion criteria, eligible individuals will complete and sign a written informed consent form. Other research questionnaires including demographics-midwifery, self-care and reproductive and sexual health literacy and quality of life and stress will be completed for both groups in a self administered manner.

Participants/Inclusion and exclusion criteria

inclusion criteria. Women with positive HPV test results and low-risk and high-risk groups with an anxiety score of 32-64. Having a contact number for follow-up. Reading and writing literacy Exclusion criteria. cancer disease or its history, history of participation in previous educational and intervention programs related to sexual health and fertility, mental disability, any mental illness according to the individual's statement. Any recent unfortunate incident including the loss of a loved one within the last 6 months

Intervention groups

For the intervention group (32 people), six group counseling sessions (4-6 people) will be held for 60-90 minutes in one of the clinic rooms of Al-Zara Hospital. The control group will receive routine care.

Main outcome variables

anxiety score, performance score of reproductive and

sexual self-care

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111122008170N14**

Registration date: **2024-01-29, 1402/11/09**

Registration timing: **prospective**

Last update: **2024-01-29, 1402/11/09**

Update count: **0**

Registration date

2024-01-29, 1402/11/09

Registrant information

Name

Jamileh Malakouti

Name of organization / entity

Nursing Faculty

Country

Iran (Islamic Republic of)

Phone

+98 41 1477 2699

Email address

malakoutij@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-12, 1402/11/23

Expected recruitment end date

2024-04-23, 1403/02/04

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of health promotion awareness counseling with stress management on anxiety and reproductive and sexual self-care performance in women with human papiloma virus : a controlled clinical randomized trial

Public title
The effect of health promotion awareness counseling with stress management on anxiety and reproductive and sexual self-care performance in women with human papiloma virus

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Women with positive HPV test results and low-risk and high-risk groups Anxiety score 32-64 Having a contact number for follow-up Literacy for reading and writing
Exclusion criteria:
Cancer disease or its history History of participating in previous training and intervention programs related to sexual health and fertility intellectual disability Any mental illness according to the person's statement Any recent unfortunate incident including the loss of a loved one within the last 6 months

Age
From **18 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
The women participating in the research will be assigned to two groups receiving counseling and the control group through 4 and 6 blocks with a ratio of 1:1 through 4 and 6 blocks using RAS software. The type of allocation will be written on paper and will be provided to the responsible author (the first guidance teacher) and the allocation of people to the intervention and control groups will be done by the same person in a central way (allocation concealment).

Blinding (investigator's opinion)
Single blinded

Blinding description
The person analyzing the data will not be aware of the type of group assignment.

Placebo
Not used

Assignment

Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tabriz University of Medical Sciences
Street address
Golgasht Street, Tabriz University of Medical Sciences
Vice President of Research and Technology
City
tabriz
Province
East Azarbaijan
Postal code
51665118
Approval date
2024-01-10, 1402/10/20
Ethics committee reference number
IR.TBZMED.REC.1402.772

Health conditions studied

1

Description of health condition studied
anxiety
ICD-10 code
F06.4
ICD-10 code description
Anxiety disorder due to known physiological condition

Primary outcomes

1

Description
Average anxiety score
Timepoint
Before the intervention and 4 weeks after the intervention
Method of measurement
Spielberger anxiety questionnaire

2

Description
Mean score of fertility and sexual self-care performance
Timepoint
Before the intervention and 4 weeks after the intervention
Method of measurement
assessment questionnaire Reproductive and sexual self-care

Secondary outcomes

1

Description

Sexual health literacy

Timepoint

Before the intervention and 4 weeks after the study

Method of measurement

Sexual health literacy questionnaire for adults, SHALE

2

Description

Quality of Life

Timepoint

Before the intervention and 4 weeks after the study

Method of measurement

Quality of life questionnaire for women with HPV
(HPV-QoL Human Papilloma Viral questionnaire)

3

Description

Stress

Timepoint

Before the intervention and 4 weeks after the study

Method of measurement

DASS-21 questionnaire

Intervention groups

1

Description

Intervention group: Intervention group: For the intervention group (32 people), six group counseling sessions (4-6 people) will be held for 60-90 minutes in one of the clinic rooms of Al-Zahra Hospital. In between the counseling sessions, the researcher will be in contact with the participants through telephone follow-ups so that they can participate in the counseling sessions on a regular basis. The researcher will provide his contact number to both intervention and control groups to answer the questions. The control group will receive routine care. If the positive effect of this approach in reducing anxiety and improving self-care performance in the intervention group is confirmed at the end of the study, counseling sessions will also be provided for the control group. The post-test questionnaires including Spielberger's anxiety, self-care and reproductive and sexual health literacy, and quality of life and stress will be completed by self-administered method. In case of incomplete participation in counseling sessions, the questionnaires will be completed and analyzed as Intention to Threat. Also, the missing cases will be investigated with the multiple imputation policy.

Category

Other

2

Description

Control group: . The control group will receive routine care. If the positive effect of this approach in reducing anxiety and improving self-care performance in the intervention group is confirmed at the end of the study, counseling sessions will also be provided for the control group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital super specialty clinic and clinic

Full name of responsible person

Maryam Vaez

Street address

East Azarbaijan - Tabriz city - South Army street -
Baghshamal intersection - Al-Zahra educational and
treatment center (S

City

tabriz

Province

East Azarbaijan

Postal code

5138663134

Phone

+98 41 3553 9161

Fax

+98 41 3556 6449

Email

alzahrahospital@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Parviz Shahabi

Street address

East Azarbaijan - Tabriz city - South Army street -
Baghshamal intersection - Al-Zahra educational and
treatment center

City

tabriz

Province

East Azarbaijan

Postal code

5138663134

Phone

+98 41 3556 6449

Email

alzahrahospital@tbzmed.ac.ir

Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

malakouti.jamileh

Position

master of midwifery

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

South Shariati Street, Faculty of Nursing and
Midwifery

City

tabriz

Province

East Azarbaijan

Postal code

66156-15733

Phone

+98 41 3479 6770

Email

jamilehmalakouti@yahoo.com

School of Nursing and Midwifery, South Shariati
Street, Tabriz

City

tabriz

Province

East Azarbaijan

Postal code

66156-15733

Phone

+98 41 3479 6770

Email

jamilehmalakouti@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Jamileh Malakouti

Position

Assistance professor of Tabriz University of Medical
Sciences

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

South Shariati Street / School of Nursing and
Midwifery

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Phone

+98 41 3479 6770

Email

hajmalakouti@gmail.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 no further information

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Malakouti.Jamileh

Position

Master of Midwifery

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address