Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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
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