

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Evaluation of the effectiveness of the educational intervention of emotional regulation strategies based on Gross model on emotion regulation strategies and psycho-social burden of women infected with human papillomavirus

Protocol summary

Study aim

Determining the effectiveness of the educational intervention of emotional regulation strategies based on Gross model on emotion regulation strategies and psycho-social burden of women infected with human papillomavirus referring to Kousar Urmia educational-medical center in Urmia-2022

Design

Single-group, single-blind, randomized controlled clinical trial of 100 patients. Sealed envelopes will be used for randomization.

Settings and conduct

Kousar Urmia educational-medical center The educational intervention will be carried out based on the educational protocol of grass-roots emotion regulation strategies. One-way blinding and not informing the participants about the randomization method

Participants/Inclusion and exclusion criteria

Inclusion criteria: having a written informed consent, married, age range of 15-49 years, the husband knowing that his wife is infected with HPV disease, living in Urmia, having at least fifth grade education, definite diagnosis of HPV type in the last three months Exit criteria: pregnancy, unwillingness to cooperation, not participating in more than two sessions, divorce, not having sex during life, Occurrence of an acute psychological event

Intervention groups

For the control and intervention groups, after obtaining the written consent, the demographic information questionnaire, the HIP questionnaire and the Gross Emotion Regulation Scale will be completed. The educational intervention will be carried out based on the educational protocol of grass-roots emotion regulation strategies.

Main outcome variables

Reducing the psycho-social burden caused by HPV; Modifying or removing incompatible strategies and teaching adaptive emotion regulation strategies; preventing social isolation and avoiding emotional situations; Taking advantage of problem solving skills and interpersonal skills; Conducting cognitive reappraisal; Taking advantage of mindfulness methods

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221230056982N1**

Registration date: **2023-01-16, 1401/10/26**

Registration timing: **prospective**

Last update: **2023-01-16, 1401/10/26**

Update count: **0**

Registration date

2023-01-16, 1401/10/26

Registrant information

Name

Daniz Montakhabi Oskoui

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-26, 1401/11/06

Expected recruitment end date

2023-06-20, 1402/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of the educational intervention of emotional regulation strategies based on Gross model on emotion regulation strategies and psycho-social burden of women infected with human papillomavirus

Public title

Evaluation of the effectiveness of the educational intervention of emotional regulation strategies based on Gross model on emotion regulation strategies and psycho-social burden of women infected with human papillomavirus

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Having written informed consent to participate in the study age range of 15-49 years and married The husband knowing that his wife is infected with HPV disease The husband is infected with HPV disease Having Iranian nationality Being a resident of Urmia Having at least fifth grade literacy Definite diagnosis (by a gynecologist) during the last three months with HPV type The absence of malignant diseases Living with husband

Exclusion criteria:

Occurrence of pregnancy during the study Unwillingness to cooperate in the continuation of the project Not participating in more than two educational intervention sessions Getting divorced and separated from the husband Not having sex during life Having an acute psychological incident such as losing a family member Having mental illnesses such as severe depression and consuming addictive substances during the study and the last 6 months

AgeFrom **15 years** old to **49 years** old**Gender**

Female

Phase

N/A

Groups that have been masked

- Participant

Sample sizeTarget sample size: **100****Randomization (investigator's opinion)**

Randomized

Randomization description

To select participants, the researcher will go to the specialized clinic of Kausar Medical Training Center in

Urmia every day of the week. Among the clients of the clinic, women who meet the criteria for entering the study will be selected, then a brief explanation will be given to them about the goals and the work method. If there is no agreement, another person will be replaced. People will be randomly divided into two control groups (50 people) and intervention group (50 people). In this way, closed envelopes will be used for random allocation. Participants pick one envelope from among 100 envelopes in the box, 50 of which contain card "A" and the other 50 contain card "B". If they pick up the "A" card, they will be placed in the intervention group, and if they pick up the "B" card, they will be placed in the control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

The participants of the intervention group will be trained in 5 sessions of 45-60 minutes with a frequency of once a week, which are in the form of one-person classes, and to prevent the possibility of publishing information, the control group will be questioned first, so no one of the participants in the control and intervention groups will not be aware of the allocation of the study groups.

Placebo

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Urmia University of Medical Sciences

Street address

Urmia University Of Medical Sciences, Emergency Alley, Resalat Blvd., Urmia, Iran

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West Azarbaijan

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5175754584

Approval date

2022-12-03, 1401/09/12

Ethics committee reference number

IR.UMSU.REC.1401.322

Health conditions studied**1****Description of health condition studied**

Human Papillomavirus

ICD-10 code

B97.7

ICD-10 code description

Papillomavirus as the cause of diseases classified to other chapters

Primary outcomes

1

Description

General psycho-social burden score of women infected with human papillomavirus

Timepoint

Measuring the general psycho-social burden score of infected women at the beginning of the study (before the start of the intervention) and 5 weeks later at the end of the last counseling session and 3 months later

Method of measurement

HIP questionnaire

2

Description

Gross's emotional regulation strategies

Timepoint

Measurement of the Gross's emotional regulation strategies score of infected women at the beginning of the study (before the start of the intervention) and 5 weeks later at the end of the last counseling session and 3 months later

Method of measurement

Gross's emotion regulation questionnaire

Secondary outcomes

1

Description

Worries and concerns

Timepoint

Measurement of the Worries and concerns score of infected women at the beginning of the study (before the start of the intervention) and 5 weeks later at the end of the last counseling session and 3 months later.

Method of measurement

HIP questionnaire

2

Description

Emotional impact

Timepoint

Measurement of the emotional impact score of infected women at the beginning of the study (before the start of the intervention) and 5 weeks later at the end of the last counseling session and 3 months later.

Method of measurement

HIP questionnaire

3

Description

Sexual impact

Timepoint

Measurement of the sexual impact score of infected women at the beginning of the study (before the start of the intervention) and 5 weeks later at the end of the last counseling session and 3 months later.

Method of measurement

HIP questionnaire

4

Description

Self image

Timepoint

Measurement of the self image score of infected women at the beginning of the study (before the start of the intervention) and 5 weeks later at the end of the last counseling session and 3 months later.

Method of measurement

HIP questionnaire

5

Description

Partner and transmission

Timepoint

Measurement of the partner and transmission score of infected women at the beginning of the study (before the start of the intervention) and 5 weeks later at the end of the last counseling session and 3 months later.

Method of measurement

HIP questionnaire

6

Description

Interactions with doctors

Timepoint

Measurement of the interactions with doctors score of infected women at the beginning of the study (before the start of the intervention) and 5 weeks later at the end of the last counseling session and 3 months later.

Method of measurement

HIP questionnaire

7

Description

Control/life impact

Timepoint

Measurement of the control/life impact score of infected women at the beginning of the study (before the start of the intervention) and 5 weeks later at the end of the last counseling session and 3 months later.

Method of measurement

HIP questionnaire

8

Description

Cognitive reappraisal

Timepoint

Measurement of the cognitive reappraisal score of infected women at the beginning of the study (before the start of the intervention) and 5 weeks later at the end of the last counseling session and 3 months later.

Method of measurement

Gross's emotion regulation questionnaire

9

Description

Expressive suppression

Timepoint

Measurement of the expressive suppression score of infected women at the beginning of the study (before the start of the intervention) and 5 weeks later at the end of the last counseling session and 3 months later.

Method of measurement

Gross's emotion regulation questionnaire

Intervention groups

1

Description

Intervention group: After obtaining the written consent, the demographic information questionnaire, the HIP questionnaire and the Gross Emotion Regulation Scale will be completed through self-reporting. The educational intervention will be carried out based on the educational protocol of Gross's emotional regulation strategies (individually). Participants of the intervention group will be trained in 5 sessions of 45 to 60 minutes with a frequency of once a week, which are in the form of one-on-one classes. In this intervention, educational aids such as PowerPoint, animation and brochures will be used. In the last session of the intervention and three months later, the questionnaires related to the post-test will be presented and completed again.

Category

Behavior

2

Description

Control group: After obtaining the written consent, the demographic information questionnaire, the HIP questionnaire and the Gross Emotion Regulation Scale will be completed through self-reporting. No intervention will be done for this group. At the same time as the last intervention session and 3 months later, questionnaires related to the post-test will also be presented and completed for the control group. At the end of the study and after the completion of the training sessions, in order to maintain mental health and comply with ethical principles, a training session will be conducted for the participants of the control group and training content will be provided to them.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Kousar hospital

Full name of responsible person

Dr. Koroush Ghasemi

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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Oroumia 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

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Person responsible for general inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Dr. Roghaye Bayrami

Position

Assistant Professor

Latest degree

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Other areas of specialty/work

Reproductive Health

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City

Urmia

Province

West Azarbaijan

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

