

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

The effectiveness comparison of sexual health empowerment model via DEEP model (Natural Differences, Emotional Sensitivities, External Stressors, Patterns of Communication) on sexual function and attitude and performance of condom use in papillomavirus infected women

Protocol summary

Study aim

The effectiveness comparison of sexual health empowerment model versus DEEP model (Natural Differences, Emotional Sensitivities, External Stressors, Patterns of Communication) on sexual function and attitude and performance of condom use in papillomavirus infected women

Design

Parallel randomized clinical trial with control group, permutation block method, sample size of 34 women in each intervention group (total sample size: 68 women).

Settings and conduct

Women suffering from papillomavirus referred to Baqaeipour clinic in Yazd, will recruited and convenience sampling is used. They will be randomized into two intervention groups using permutation block method who will receive online counseling for 8 consecutive weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having a medical record of being infected and diagnosed by the treating physician, reproductive age, being married, having sufficient sexual intercourse with the spouse in the past 4 weeks, willingness to participate in the study, owning a smartphone, and being able to use online counseling, literacy in reading and writing, proficiency in speaking Persian, sexual dysfunction. Exclusion criteria: Pregnancy, condom use, diagnosis of psychological disorders in the past year according to women's statements, participation in similar studies, experiencing stressful events during the study, addiction to drugs and alcohol, and patients with hearing problems

Intervention groups

The first intervention group: The first group will receive DEEP model in 8 consecutive weeks (one session per week) and 90-minute online counseling. The second intervention group (active control) will receive sexual

health empowerment model in 8 consecutive weeks and 90-minute online counseling.

Main outcome variables

Sexual function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230710058738N1**

Registration date: **2023-08-22, 1402/05/31**

Registration timing: **prospective**

Last update: **2023-08-22, 1402/05/31**

Update count: **0**

Registration date

2023-08-22, 1402/05/31

Registrant information

Name

Zahra Bakrani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-02, 1402/07/10

Expected recruitment end date

2023-12-31, 1402/10/10 Actual recruitment start date empty Actual recruitment end date empty Trial completion date empty	number between 1to 68. The women will be allocated in two groups DEEP model or Sexual health empowerment model (34 women in each group). Allocation concealment is used, so no women and researcher don't know each woman will allocate to each group.
Scientific title The effectiveness comparison of sexual health empowerment model via DEEP model (Natural Differences, Emotional Sensitivities, External Stressors, Patterns of Communication) on sexual function and attitude and performance of condom use in papillomavirus infected women	Blinding (investigator's opinion) Not blinded Blinding description Placebo Not used Assignment Parallel Other design features
Public title Sexual health empowerment model versus DEEP model (Natural Differences, Emotional Sensitivities, External Stressors, Patterns of Communication) on sexual function and attitude and performance of condom use in Papillomavirus infected women	Secondary Ids empty
Purpose Education/Guidance	Ethics committees
Inclusion/Exclusion criteria Inclusion criteria: Having a medical record of being infected with papillomavirus (infection with low-risk or high-risk types of the virus and type 1 and 2 dysplasia) at Baghaeipour Clinic in Yazd, diagnosed by the physician Women in reproductive age (15 to 49 years) Being married Having sufficient sexual intercourse with the spouse in the past 4 weeks Willingness to participate in the study Owning an Android or iOS smartphone Being able to use online counseling via a smartphone Literacy in reading and writing Proficiency in speaking Persian Sexual dysfunction Exclusion criteria: Pregnancy Condom use Diagnosis of psychological disorders in the past year according to women's statements Participation in similar studies Occurrence of stressful events during participation in the study (such as the death of family members or divorce) Addiction to drugs and alcohol Patients with hearing problems	1 Ethics committee Name of ethics committee Research Ethics Committee of Shahid Sadoughi University of Medical Sciences, Yazd Street address Bahonar Square, Yazd City Yazd Province Yazd Postal code 8916189165 Approval date 2023-07-12, 1402/04/21 Ethics committee reference number IR.SSU.REC.1402.037
Age From 15 years old to 49 years old Gender Female Phase N/A	Health conditions studied
Groups that have been masked No information Sample size Target sample size: 68 Randomization (investigator's opinion) Randomized	1 Description of health condition studied Human Papilloma Virus ICD-10 code B97.7 ICD-10 code description Papillomavirus as the cause of diseases classified elsewhere
Randomization description Eligible women, referring to Baqaeipour clinic in Yazd, are recruited according to the criteria of participating in the study. Convenience sampling is used. The ones with size 4 are obtained using the software www.random.org/sequences. Each woman is given a	Primary outcomes 1 Description Sexual function (primary outcome variable) Timepoint Baseline, completion of the intervention in the eighth week and follow-up at the end of the study in the twelfth week Method of measurement

Secondary outcomes

1

Description

Attitude toward condom use (Secondary outcome variable)

Timepoint

Baseline, completion of the intervention in the eighth week and follow-up at the end of the study in the twelfth week

Method of measurement

Attitude of Condom Use Questionnaire

2

Description

The frequency of condom use (Secondary outcome variable)

Timepoint

Baseline, completion of the intervention in the eighth week and follow-up at the end of the study in the twelfth week

Method of measurement

Performance of Condom Use Questionnaire

Intervention groups

1

Description

The first intervention group: The first group will receive the DEEP model in the form of 8 online and consecutive sessions, once a week for 90 minutes, by the second researcher, a senior midwife counseling student who has completed the sexual disorders course and obtained the necessary certificate, under the supervision of the first researcher, the supervisor (reproductive health specialist and clinical psychologist) and the third researcher, the consultant professor (reproductive health specialist) will be held in the sky room. The content of the sessions will be in the format of educational videos, PowerPoint presentations, and questions and answers. At the beginning of each session, a summary of the contents of the previous sessions will be reviewed, and the assignments related to the previous session will be reviewed by the first and second researcher to measure their improvement in each session. Women are asked to participate in counseling discussions and raise their questions. The second researcher will ask questions about the topics of the meeting for the participation of more people in the meeting. To learn more, the relevant educational video will also be presented to them. At the end of each meeting, a summary of the important topics mentioned is presented and the questions of the people are answered, and the women are asked to do their homework until the next meeting. The content of the sessions of the DEEP model includes the description of the Deep model and the conceptualization of each word, pair evaluation, teaching strategies for acceptance,

empathic attachment and creating empathy, controlling external factors, creating tolerance, creating change, and more preparation.

Category

Behavior

2

Description

The second intervention group: the second group (control group) will receive the Sexual Health Empowerment model in the form of 8 online and consecutive sessions, once a week for 90 minutes, by the second researcher, a senior midwife counseling student who has completed the sexual disorders course and obtained the necessary certificate, under the supervision of the first researcher, the supervisor (reproductive health specialist and clinical psychologist) and the third researcher, the consultant professor (reproductive health specialist) will be held in the sky room. The content of the sessions will be in the format of educational videos, PowerPoint presentations, and questions and answers. At the beginning of each session, a summary of the contents of the previous sessions will be reviewed, and the assignments related to the previous session will be reviewed by the first and second researcher to measure their improvement in each session. Women are asked to participate in counseling discussions and raise their questions. The second researcher will ask questions about the topics of the meeting for the participation of more people in the meeting. To learn more, the relevant educational video will also be presented to them. At the end of each meeting, a summary of the important topics mentioned is presented and the questions of the people are answered, and the women are asked to do their homework until the next meeting. The content of the Sexual Health Empowerment model sessions includes getting to know this concept and its goals, recognizing and adapting to physiological and sexual differences in couples, correcting false beliefs and changing attitudes, explaining sexual concerns in these couples, learning skills to communicate effectively and negotiate with each other, to resolve conflicts and reduce risky behaviors, description of marital intimacy and its dimensions.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqaipour Clinic, Shahid Sadoughi Hospital, Yazd

Full name of responsible person

Dr. AbulHasni

Street address

Bu Ali St

City

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Province

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۸۹۱۶۸۷۷۴۴۳
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Dr Amin Salehi Abargouei
Street address
Bahonar Squar Central Organization of Shahid
Se,adougi University of Medical Sciences, Yazd
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Email
abargouei@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yazd 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
Yazd University of Medical Sciences
Full name of responsible person
Tahmineh Farajkhoda
Position
Professor
Latest degree
Ph.D.
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)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

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

Data Dictionary

Not applicable

Title and more details about the data/document

All individual data of study participants can be shared after de-identification.

When the data will become available and for how long

After publishing the results

To whom data/document is available

The data will be available to researchers working in academic and scientific institutions, and people working in industry can apply to receive them.

Under which criteria data/document could be used

Scientific application

From where data/document is obtainable

farajkhoda_t@yahoo.com

What processes are involved for a request to access data/document

One week after receiving the applicant's email

Comments