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)

Phone
+98 35 3825 8404

Email address
z.bakrani@stu.ssu.ac.ir

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

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

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

Purpose

Education/Guidance

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

Age

From **15 years** old to **49 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

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 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.

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

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

Health conditions studied

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

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

Rosen et al Sexual Functioning Questionnaire (1997)

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
Yazd
Province
Yazd

Postal code
۸۹۱۶۸۷۷۴۴۳
Phone
+98 35 3822 9105
Email
baghaei@ssu.ac.ir

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
City
Yazd
Province
Yazd
Postal code
8916978477
Phone
+98 35 3733 3726
Fax
+98 35 3732 3726
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
Clinical Psychologist
Street address
Bu Ali St
City
Yazd
Province
Yazd
Postal code
۸۹۱۶۸۷۷۴۴۳
Phone
+98 35 3824 1751
Email
farajkhoda_t@yahoo.com

Person responsible for scientific 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
Clinical Psychologist
Street address
Bu Ali St
City
Yazd
Province
Yazd
Postal code
۸۹۱۶۸۷۷۴۴۳
Phone
+98 35 3824 1751
Email
farajkhoda_t@yahoo.com

Person responsible for updating data

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
Clinical Psychologist
Street address
Bu Ali St
City
Yazd
Province
Yazd
Postal code
۸۹۱۶۸۷۷۴۴۳

Phone
+98 35 3824 1751
Email
farajkhoda_t@yahoo.com

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