Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jul 2026

The effect of virtual education to promote of sexual function, genital self – image and sexual distress in women with Rokitansky syndrome

Protocol summary

Study aim

Determining the effect of virtual education to promote of sexual function, genital self – image and sexual distress in women with Rokitansky syndrome

Design

This research is a randomized clinical trial with two groups; intervention and control. Sampling will be conducted by block design (with block size of 4) random allocation.

Settings and conduct

The research environment is pelvic floor clinic of Emem khomeini hospital.

Participants/Inclusion and exclusion criteria

- Inclusion criteria:Being Iranian/ Married and Monogamy/ Being in Reproductive age (15-49 years)/ Having media literacy/ Having a mobile phone with Android system/ Access to internet/ Check of medical documentation, including ultrasound or MRI or laparoscopic reports of the diagnosis of Rokitansky syndrome by the researcher/ Spending at least 6 months of vaginoplasty (surgically or non- surgically method)/ Having vaginal intercourse. exclusive criteria:Having the therapeutic course of ovule reservation, including puncture of ovarian and pick up ovum/ Having chronic diseases affecting on sexual function/ Using of drugs that affected on sexual function/ Having educational background related with this study.

Intervention groups

The intervention group, after installing the mobile app, will have access to the content as offline mode for 2 months, and during this 2 months, in online peer's telegram group, the content of the app will be analyzed by researcher for further training and the sexual problems of individuals will be solved in the group or, In case of reluctance, in private chat will be done.The control group will not receive any intervention until the end of the research. Then, based on the ethics of the research and their willingness can use the content of app.

Main outcome variables

Sexual function, Genital self - image, Sexual distress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160808029255N7**
Registration date: **2019-07-31, 1398/05/09**
Registration timing: **prospective**

Last update: **2019-07-31, 1398/05/09**
Update count: **0**

Registration date

2019-07-31, 1398/05/09

Registrant information

Name

Raziyeh Maasoumi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6105 4214

Email address

r_masoumi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of virtual education to promote of sexual function, genital self – image and sexual distress in women with Rokitansky syndrome

Public title
The effect of virtual education to promote of sexual function, genital self – image and sexual distress in women with Rokitansky syndrome

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Being Iranian Married and Monogamy Being in Reproductive age (15-49 years) Having media literacy Having a mobile phone with Android system Access to internet Check of medical documentation, including ultrasound or MRI or laparoscopic reports of the diagnosis of Rokitansky syndrome by the researcher Spending at least 6 months of vaginoplasty (surgically or non- surgically method) Having vaginal intercourse

Exclusion criteria:
Having the therapeutic course of ovule reservation, Including puncture of ovarian and pick up ovum Having chronic diseases that affected on sexual function Using of drugs that affected on sexual function Having educational background related with this study Unwillingness to continue cooperation Lack of comprehensive and regular study of the content of the mobile app

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: **38**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, randomization method will be randomized block design with block size of 4. The block randomization method is designed to randomize participants into groups that result in equal sample sizes. This method is used to ensure a balance in sample size across groups over time. in this clinical trial with control and treatment groups, a randomized block procedure would be as follows: (1) a block size of 4 will be chosen, (2) possible balanced combinations with 2 A (intervention) and 2 B (control) subjects will be calculated as 6 (BBAA, BABA, BAAB, ABBA, ABAB, AABB) and (3) blocks will be randomly chosen to determine the assignment of all participants.

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
Ethics committee of Tehran University of Medical Sciences, school of Nursing and Midwifery & Rehabil

Street address
Faculty of Nursing and Midwifery, South Nosrat Ave., Towhid Sq.

City
Tehran

Province
Tehran

Postal code
1419733171

Approval date
2019-06-26, 1398/04/05

Ethics committee reference number
IR.TUMS.FNM.REC.1398.067

Health conditions studied

1

Description of health condition studied
Sexual function

ICD-10 code

ICD-10 code description

2

Description of health condition studied
Genital self - image

ICD-10 code

ICD-10 code description

3

Description of health condition studied
Sexual distress

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Sexual function

Timepoint

Before the intervention, immediately and 4 weeks after the intervention

Method of measurement

Female Sexual Function Index questionnaire

2

Description

Genital self - image

Timepoint

Before the intervention, immediately and 4 weeks after the intervention

Method of measurement

Female Genital Self-Image Scale questionnaire

3

Description

Sexual distress

Timepoint

Before the intervention, immediately and 4 weeks after the intervention

Method of measurement

Female Sexual Distress Scale __ Revised questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group, after installing the mobile app, will have access to the content as offline mode for 2 months, and during this 2 months, in online peer's telegram group, the content of the app will be analyzed by researcher for further training and the sexual problems of individuals will be solved in the group or, In case of reluctance, in private chat will be done.

Category

N/A

2

Description

Control group: The control group will not receive any intervention until the end of the research. Then, based on the ethics of the research and their willingness can use the content of app.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Khomeini hospital

Full name of responsible person

Raziyeh Masoumi

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Tehran, Keshavarz Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Raziyeh Maasoumi

Position
Assisstant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Sexology, Sexual and Reproductive Health
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Person responsible for scientific inquiries

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Position
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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
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Data of the study would be available after unrecognizable process of participants.
When the data will become available and for how long
6 months after publishing the results
To whom data/document is available
Research results would be available for academic researchers
Under which criteria data/document could be used
Research results would be available for same researches
From where data/document is obtainable
Dr. Raziyeh Maasoumi email: r_masoumi@sina.tums.ac.ir
What processes are involved for a request to access data/document
Sending a request by email attendance to the office of corresponding of project presentation the reasons for similarity of two projects studying the proposal by corresponding of project final decision making with corresponding author access of data in office of corresponding author
Comments