

# 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

Sexual function, Genital self - image, Sexual distress

##### 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

#### 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  
**Street address**  
Tehran, Keshavarz Blvd.  
**City**  
TEHRAN  
**Province**  
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r\_masoumi@sina.tums.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**  
**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Dr. Sahraian, the Vice Chancellor of Research at Tehran University of Medicine Sciences  
**Street address**  
Keshavarz Blv., Qods St.,  
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1417653761  
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msahrai@sina.tums.ac.ir  
**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**  
Assistant Professor

**Latest degree**  
Ph.D.

**Other areas of specialty/work**  
Sexology, Sexual and Reproductive Health

**Street address**  
Faculty of Nursing and Midwifery, East Nosrath.,  
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## Person responsible for scientific inquiries

### Contact

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Assistant Professor

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Ph.D.

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences

**Full name of responsible person**  
Raziyeh Maasoumi

**Position**

Assistant Professor

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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