

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effectiveness of sexual health intervention on sexual awareness, sexual depression and high-risk behaviors of abused women in Tehran

Protocol summary

Registration timing: **retrospective**

Study aim

Investigating the Effectiveness of Sexual Interventions on Sexual Awareness, Sexual Depression, and High-Risk Behaviors of Abused Women

Last update: **2023-11-27, 1402/09/06**

Update count: **0**

Registration date

2023-11-27, 1402/09/06

Design

A clinical trial was conducted with a control group and parallel groups, non-blinded, randomized, involving 100 patients. The randomization was performed using the rand function in Excel software.

Registrant information

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Romina Mostafaei

Name of organization / entity

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Settings and conduct

The research population includes women who have visited clinics in Tehran. The sampling method used is convenience sampling, with a sample size of 100 individuals. The study follows a quasi-experimental design with an approach involving an experimental group and a control group. The research data will be analyzed using the statistical software SPSS, and inferential statistics along with multiple analyses of covariance (ANCOVA) will be employed.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Inclusion criteria : abused woman ,minimum literacy, Having a sexual partner Exclusion criteria : Observing symptoms of psychiatric disorders ; addiction

Expected recruitment start date

2023-04-02, 1402/01/13

Expected recruitment end date

2023-08-22, 1402/05/31

Intervention groups

The effectiveness of sexual intervention on sexual awareness, sexual depression, and risky sexual behaviors is being investigated in the intervention group consisting of single mothers. This intervention is carried out on them in 6 sessions, each lasting 1.5 hours.

Actual recruitment start date

empty

Actual recruitment end date

empty

Main outcome variables

Sexual awareness Sexual depression High risk behaviors

Trial completion date

empty

General information

Scientific title

Effectiveness of sexual health intervention on sexual awareness, sexual depression and high-risk behaviors of abused women in Tehran

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230613058472N1**

Registration date: **2023-11-27, 1402/09/06**

Public title

Effectiveness of sexual education in promoting sexual health and sexual awareness

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Abused women Having literacy skills (reading and writing) Age 18 up to and 45 years old Informed consent of the individual Having a sexual partner

Exclusion criteria:

Observing psychotic symptoms despite the presence of other severe psychiatric disorders based on a psychiatric interview according to the DSM Addition issues

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Clinical trial with a control group, parallel groups, non-blinded, simple individual randomization, unstratified and unmasked was conducted on 100 patients.

Randomization was performed using the rand function in Excel and R software. The intervention was conducted in six sessions for the first group, while the control group was placed on a waiting list for treatment and education after the study. The sample size of the study is 100 individuals, and random assignment of individuals to the two groups was done using Excel and R software version 4.0.3. Using the code [c("a", "b"), 100, replace = TRUE, prob = c(.5, .5)], the output generated random assignments such as "a", "a", "b", "a", etc. The first person was assigned to group "a", the second person to group "b", the third person to group "a", and the fourth person to group "a". This process was repeated until all 100 individuals were randomly assigned to the two groups of 50 individuals each.

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

Street address

No 13, 31 Sharghi Ave, Saadat abad Blv

City

Tehran

Province

Tehran

Postal code

1998815958

Approval date

2023-05-23, 1402/03/02

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1402.033

Health conditions studied

1

Description of health condition studied

Sexual dysfunction

ICD-10 code

F52

ICD-10 code description

Sexual dysfunction not due to a substance or known physiological condition

2

Description of health condition studied

The outcome of reducing risky sexual behaviors involves a decrease in the risk of sexually transmitted infections and negative consequences associated with such behaviors, such as unintended pregnancies. It also entails an increase in sexual safety awareness and knowledge about protective measures. Reducing risky sexual behaviors implies making smarter and more responsible choices in sexual relationships, utilizing contraception methods, and being aware of the risks associated with inappropriate sexual behaviors. Increasing sexual awareness can also have positive effects on sexual relationships and sexual satisfaction

ICD-10 code

Z72.5

ICD-10 code description

High risk sexual behavior

3

Description of health condition studied

The consequences of increasing sexual awareness are multifaceted and can have positive impacts on individuals and their sexual experiences. Here are some potential outcomes of increasing sexual awareness: 1. Improved Sexual Satisfaction: By enhancing their understanding of their own bodies, desires, and preferences, individuals can experience increased sexual satisfaction. They become more aware of what brings them pleasure and are better able to communicate their needs to their partners. 2. Enhanced Communication and Intimacy: Sexual awareness promotes open and effective communication about sexual desires, boundaries, and

consent. This improved communication fosters a deeper sense of intimacy and trust in sexual relationships.3. Increased Sexual Health: Sexual awareness involves knowledge about safe sex practices, contraception methods, and sexually transmitted infections (STIs). With increased awareness, individuals are more likely to engage in responsible sexual behavior, reducing the risk of STIs and unplanned pregnancies.4. Empowerment and Confidence: Understanding and accepting one's own sexuality can boost self-esteem and confidence. Increased sexual awareness allows individuals to embrace their desires without shame or guilt, leading to a healthier and more positive sexual self-image.5. Cultivation of Healthy Relationships: Sexual awareness encourages individuals to seek out and maintain healthy, consensual relationships. They become more attuned to their own needs and are better equipped to create mutually satisfying sexual experiences within a relationship.6. Prevention of Sexual Coercion and Abuse: With increased sexual awareness, individuals are more likely to recognize and resist situations involving sexual coercion or abuse. They become aware of their rights, boundaries, and the importance of enthusiastic consent. Overall, increasing sexual awareness can contribute to a more fulfilling and empowered sexual life, fostering healthier relationships and promoting personal well-being.

ICD-10 code

Z70.1

ICD-10 code description

Counseling related to patient's sexual behavior and orientation

Primary outcomes

1

Description

Sexual depression

Timepoint

Before the intervention and one week after the intervention

Method of measurement

Snell Sexual Problems Scale

2

Description

Risky sexual behaviors/practices.

Timepoint

Before the intervention and one week after the intervention

Method of measurement

High risk behaviors Scale

3

Description

Sexual awareness

Timepoint

Before the intervention and one week after the intervention

Method of measurement

Snell sexual Problems Scale

Secondary outcomes

1

Description

Sexual and emotional relationships

Timepoint

Before the intervention and one week after the intervention

Method of measurement

Sexual Problems Scale

2

Description

Prevention of sexually transmitted diseases

Timepoint

Before the intervention and one week after the intervention

Method of measurement

Sexual Problems Scale

3

Description

Change in negative and discriminatory attitudes

Timepoint

Before the intervention and one week after the intervention

Method of measurement

Sexual Problems Scale

4

Description

Reduction of sexual anxiety and concerns

Timepoint

Before the intervention and one week after the intervention

Method of measurement

Sexual Problems Scale

5

Description

Increasing sexual respect

Timepoint

Before the intervention and one week after the intervention

Method of measurement

Sexual Problems Scale

6

Description

Sexual mental engagement

Timepoint

Before the intervention and one week after the intervention

Method of measurement

Sexual Problems Scale

7

Description

Internal sexual control

Timepoint

Before the intervention and one week after the intervention

Method of measurement

Sexual Problems Scale

8

Description

Sexual motivation

Timepoint

Before the intervention and one week after the intervention

Method of measurement

Sexual Problems Scale

9

Description

Sexual supervision

Timepoint

Before the intervention and one week after the intervention

Method of measurement

Sexual Problems Scale

10

Description

Fear of sexual intercourse

Timepoint

Before the intervention and one week after the intervention

Method of measurement

Sexual Problems Scale

Intervention groups

1

Description

Intervention Group: Six sessions of sexual education and intervention based on a prepared educational package aimed at increasing sexual awareness and health, reducing risky behaviors, and addressing sexual depression. Each session lasts one and a half hours, with one day in between sessions. Session 1: Sexual Awareness- Individual aspects of sexual life and sexual health education- Sexual hygiene education- Sexual health during different stages of life (adolescence, menstruation, menopause)- Genital system: male and female reproductive organs, breasts Session 2: Sexual Behavior- Understanding sexual behavior and relationships- Stages of sexual relationships- Sexual response cycle- Types of sexual relationships (oral sex, anal sex, intercourse)- Sexuality in specific life periods- Sexual misconduct- Misconceptions about sexual

relationships- Comparison of sex and pornography Sessions 3 and 4: Sexual Diseases and Disorders- Prevention, diagnosis, and treatment of sexually transmitted diseases- Sexual disorders and deviations- Risk factors for sexual disorders- Common sexual disorders- Paraphilic disorders- Sexual depression- Risk factors for sexual diseases- Sexually transmitted diseases (STDs)- Sexual treatments and interventions Session 5: Pregnancy, Birth Control, and Abortion- Important aspects of pregnancy- Birth control methods and prevention of pregnancy- Methods of abortion Note: The provided translation is an approximation of the original text, and some terms may vary depending on context.

Category

Treatment - Other

2

Description

Control Group: The control group is placed in the waiting list and will participate in psychotherapy sessions after the research is completed.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mehramana specialized psychology clinic

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

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Web page address
 http://www.mehrclinicmana.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 No
Title of funding source
 Tehran University of Medical Science
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
 Mehremana clinic
Full name of responsible person
 Romina Mostafaei
Position
 Psychologist
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Other areas of specialty/work
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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
 No - There is not a plan to make this available
Clinical Study Report
 Yes - There is a plan to make this available
Analytic Code
 Yes - There is a plan to make this available
Data Dictionary
 Yes - There is a plan to make this available
Title and more details about the data/document

The entire research process includes sampling, intervention, pre-test and post-test, data collection, statistical analysis and conclusions.

When the data will become available and for how long

One year after the research

To whom data/document is available

Researchers and specialists in the field of mental health and treatment staff

Under which criteria data/document could be used

Having a history related to psychology, psychiatry and social sciences

From where data/document is obtainable

rominamostafaei@yahoo.com

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

After sending the request, the researcher will check it and answer it

Comments