

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Sep 2026

### .The Effectiveness Comparison of Emotion-Focused Therapy Based on Islamic view and Sexual Health Education on Sexual Intimacy in Pregnant Women

#### Protocol summary

##### Study aim

Comparison of emotion-based couple therapy based on Islamic perspective and sexual health education on sexual intimacy of pregnant women

##### Design

Clinical trial with control group, parallel groups, randomized on 52 pregnant women. Use random number table and spss software for randomization

##### Settings and conduct

Sampling from Amir Yazd Social Security Clinic and virtual counseling sessions is done through the Iranian version of the virtual network software.

##### Participants/Inclusion and exclusion criteria

Admission requirement: with a smartphone and a pregnancy record of more than 20 weeks, Shia, obtaining a score of invalidity questionnaire less than 100  
Exclusion criteria: History of alcohol, tobacco and drugs that affect sexual desire such as antidepressant and antihypertensive, according to the mother, receiving interventions related to couple therapy in the last 6 months.

##### Intervention groups

Using a table of random numbers of pregnant women are divided into two groups. The first group of the intervention under the counseling of emotion-oriented couple therapy is virtual and the second group, which is the control group, is under the virtual sexual health training package. Meetings of the two groups are held in parallel, each lasting 6 sessions of 90 minutes. Finally, the effectiveness of counseling on sexual intimacy of pregnant women is examined.

##### Main outcome variables

Sexual intimacy of pregnant women Satisfaction of pregnant women with the interventions performed

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200112046091N1**

Registration date: **2020-10-02, 1399/07/11**

Registration timing: **prospective**

Last update: **2020-10-02, 1399/07/11**

Update count: **0**

##### Registration date

2020-10-02, 1399/07/11

##### Registrant information

##### Name

Zahra Masaeli

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 3824 1751

##### Email address

masaelizahra485@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-10-24, 1399/08/03

##### Expected recruitment end date

2020-10-29, 1399/08/08

##### Actual recruitment start date

2020-10-24, 1399/08/03

##### Actual recruitment end date

2020-10-29, 1399/08/08

##### Trial completion date

2021-02-07, 1399/11/19

## Scientific title

.The Effectiveness Comparison of Emotion-Focused Therapy Based on Islamic view and Sexual Health Education on Sexual Intimacy in Pregnant Women

## Public title

"Comparison of Emotion-Focused Therapy Based on Islamic View in Pregnant Women"; "Sexual Health Education in Pregnant Women";

## Purpose

Education/Guidance

## Inclusion/Exclusion criteria

### Inclusion criteria:

Married pregnant mothers Gestational age of at least 24-20 weeks based on first trimester ultrasound and pregnancy record Iranian ethnicity and resident of Yazd Muslims and Shiites and having religious beliefs Have minimal literacy Interest in attending counseling sessions and not attending the same study at the same time Obtain a score of less than 100 invalid questionnaires Healthy pregnant mother based on pregnancy file Conscious satisfaction and willingness to participate in research Having a smartphone and internet literacy (skills of using cyberspace like WhatsApp)

### Exclusion criteria:

History of alcohol and tobacco use and drugs that affect sexual desire, such as Anti-Depressant and Anti-Hypertensive, according to the mother Receive couples therapy interventions in the last 6 months

## Age

No age limit

## Gender

Female

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: **52**

Actual sample size reached: **52**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Using a table of computer random numbers, the researcher first determined the framework of his statistical community and determined the exact number of people in the community, which was 52 people, and assigned a code to them, and placed the numbers in a table with rows and columns. . The researcher placed a finger or the tip of a pen on the table to select the sample people with their eyes closed. The movement in the direction of the row or column did not matter and was at the request of the researcher. The number selected was the individual code of the community that was selected as the sample. Each code was randomly assigned to an emotion-driven virtual counseling or sex education group until the sample size of each group was 26. Final samples are called at a specific location. The purpose, method of work and the right to participate or not to participate in the research were explained to them. Samples who did not want to attend the sessions were excluded from the study. Then the required number

of samples (26 people for each group) were selected. Again, we divided the people of each group into two groups of thirteen (B and A) by tossing a coin, so that if the surface of the lion was visible, it belonged to group A, and if the surface of the line was visible, it belonged to group B.

## 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 Shahid Sadoughi University of Medical Sciences, Yazd

##### Street address

School of Midwifery Nursing., Bouali Alley., Teymsar Fallahi St., Safaieh., Yazd

##### City

Yazd

##### Province

Yazd

##### Postal code

۸۹۱۶۸۷۷۴۳

#### Approval date

2020-01-06, 1398/10/16

#### Ethics committee reference number

IR.SSU.REC.1398.169

## Health conditions studied

### 1

#### Description of health condition studied

Sexual intimacy

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

The percentage of people whose sexual intimacy score is below 100 is invalid

#### Timepoint

Measurement of sexual intimacy score at the beginning of the study (before the intervention) and 6 and 10 weeks after the start of online counseling

#### Method of measurement

## Secondary outcomes

### 1

#### Description

Satisfaction scores from the counseling method

#### Timepoint

Determining and comparing the mean scores of satisfaction with the counseling method at the end of the sixth week and the end of the tenth week of the intervention in the two groups

#### Method of measurement

Satisfaction Questionnaire

## Intervention groups

### 1

#### Description

"Intervention group:" 26 pregnant women in the intervention group who are in absentia (online) under the emotional counseling based on the Islamic perspective are given weekly in 6 sessions of 90 minutes.

#### Category

Behavior

### 2

#### Description

Control group: 26 people in the control group who receive offline (online) sexual health training on a weekly basis for 6 sessions of 90 minutes.

#### Category

Behavior

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Amir Yazd Social Security Clinic

##### Full name of responsible person

Farajkhoda Tahmineh

##### Street address

School of Midwifery Nursing., Bouali Alley., Teymsar  
Fallahi St., Safaieh., Yazd

##### City

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Yazd

##### Postal code

۸۹۱۶۸۷۷۴۴۳

##### Phone

+98 35 3824 1751

##### Fax

+98 35 3824 9705

##### Email

z.masaeli@stu.ssu.ac.ir

##### Web page address

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Yazd University of Medical Sciences

##### Full name of responsible person

Dr. Reza Malekzadeh

##### Street address

School of Midwifery Nursing., Bouali Alley., Teymsar  
Fallahi St., Safaieh., Yazd

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##### Web page address

<https://web.ssu.ac.ir>

#### 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

Farajkhoda Tahmineh

##### Position

Associate professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Midwifery

##### Street address

School of Midwifery Nursing., Bouali Alley., Teymsar

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**Province**

Yazd

**Postal code**

۸۹۱۶۸۷۷۴۴۳

**Phone**

+98 35 3824 1751

**Fax**

+98 35 3824 9705

**Email**

t.farajkhoda@ssu.ac.ir

**Web page address**

<https://web.ssu.ac.ir>

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Farajkhoda Tahmineh

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**Fax**

+98 35 3824 9705

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t.farajkhoda@ssu.ac.ir

**Web page address**

<https://web.ssu.ac.ir>

## Person responsible for updating data

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**Email**

t.farajkhoda@ssu.ac.ir

**Web page address**

<https://web.ssu.ac.ir>

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

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

**Study Protocol**

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

**Statistical Analysis Plan**

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

**Informed Consent Form**

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

**Clinical Study Report**

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

**Analytic Code**

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

**Data Dictionary**

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