

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Comparison survey the effectiveness of online counseling the Practical Application of Intimate Relationship Skills (PAIRS) versus the Training in marriage Enrichment (TIME) on marital intimacy.

Protocol summary

Study aim

Comparison effectiveness of online counseling the Practical Application of Intimate Relationship Skills (PAIRS) versus Training in marriage Enrichment (TIME) on marital intimacy

Design

This is an experimental study using the method of parallel clinical trial. Participants are women in their reproductive age who have mentioned the marital intimacy problems both in the initial interview and on the Bagarozzi questionnaire. participants are randomly assigned to one of the two intervention groups receiving two methods of online counseling: practical application of intimate relationship skills (PAIRS) and training in marriage enrichment (TIME). Women and their husbands complete the marital intimacy questionnaire at baseline, when the intervention is completed at week 8, and at follow-up of the study in week 12.

Settings and conduct

3 Comprehensive healthcare centers of Gerash. Sessions of intervention are conducted online one day in a week by the second author under the supervision of the supervisor and the consultant.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Married women of 15 - 49 who mentioned intimacy problems in the initial interview and on the Bagarozzi questionnaire; internet literacy; owning a smartphone; sexual relationship with their husbands; couple's consent; completing Marital Intimacy Questionnaire. Exclusion criteria: Pregnancy; acute psychological and personality disorders; substance abuse, tobacco use; systemic diseases.

Intervention groups

The intervention group A receives the online program of Practical Application of Intimate Relationship Skills (PAIRS) and the intervention group B receives the online program of Marriage Enrichment (TIME) in 8 sessions of

90 minutes each, one day in a week.

Main outcome variables

Change in the average scores of marital intimacy in women and their husbands, measured by the Bagarozzi Marital Intimacy Questionnaire.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220217054048N1**

Registration date: **2022-04-29, 1401/02/09**

Registration timing: **prospective**

Last update: **2022-04-29, 1401/02/09**

Update count: **0**

Registration date

2022-04-29, 1401/02/09

Registrant information

Name

Leila Shiravan

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-20, 1401/02/30

Expected recruitment end date

2022-08-21, 1401/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison survey the effectiveness of online counseling the Practical Application of Intimate Relationship Skills (PAIRS) versus the Training in marriage Enrichment (TIME) on marital intimacy.

Public title

Comparison of the effectiveness of Intimate Relationship skills versus the Training in marriage Enrichment on marital intimacy.

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Iranian nationality Married women between the ages of 15 and 49 who had mentioned marital intimacy problems both in the initial interview and on the Bagarozzi questionnaire. Fluency in Persian language Internet literacy and owning a smartphone Having lived together for at least one year Having a sexual relationship with husband Being Interested in participating in training courses and attending the training sessions Consent of both partners to participate in the study; completing the Marital Intimacy Questionnaire.

Exclusion criteria:

Pregnancy women who have, or their husbands have, acute psychological and personality disorders, or a history of substance abuse and tobacco use Having systemic diseases

AgeFrom **15 years** old to **49 years** old**Gender**

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **88****Randomization (investigator's opinion)**

Randomized

Randomization description

The specified sample size includes 88 people (women). The participants are randomized in two groups using the permuted block randomization method by the use of the software "Random Allocation" version 1, <https://random-allocation-software.software.informer.com/1.0/>. Considering the sample size (88 people) and also the similar size of blocks (due to having two intervention groups of A and B, the size of the block is 2 by the power of 4 which is 16) the software calculated the number of blocks to be 6. Randomization is done in this way: women who have mentioned marital intimacy problems both in the initial interview and on the Bagarozzi questionnaire get a number from 1 to 88 according to

the order of their attendance. Then, from among the 6 blocks, one block is chosen randomly which contains the name of the intervention group according to the patient's code; therefore, each participant is randomly allocated to one of the intervention groups. After the completion of the first block, the second block is chosen randomly and the process of randomization continues. Also, since the randomization of participant in two intervention groups is carried out separately in each of the Comprehensive Healthcare Centers, two blocks are randomly allocated to each center and participants are divided into intervention group based on their numbers in the chosen blocks in each center. Blinding is not possible since women are aware of the type of intervention.

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

College of Nursing and Midwifery, Bo Ali Sina alley, Timsar Fallahi street, Safaieh neighborhood

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Province

Yazd

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8916978477

Approval date

2022-01-26, 1400/11/06

Ethics committee reference number

IR.SSU.REC.1400.234

Health conditions studied**1****Description of health condition studied**

Marital intimacy counseling

ICD-10 code**ICD-10 code description****Primary outcomes**

1

Description

Measuring the average scores of intimacy in women and their husbands

Timepoint

At baseline, the completion of intervention in week 8, and follow-up of the study in week 12.

Method of measurement

Bagarozzi Marital Intimacy Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group A receives the online program of the Practical Application of Intimate Relationship Skills (PAIRS) which includes these sessions: trust therapy, the importance of communication, personal history, bonding, clarification of mental imagery, clarification of expectations and days of love, adaptation to family functioning, summarizing and conclusion. Intervention is carried out in 8 sessions of 90 minutes each. The contents of online sessions in Skyroom are presented in the form of text, graphics, videos, clips, group chats and questions and answers. In every session, homework is presented and corrected via WhatsApp application by the second author under the supervision of the first and the third authors. Participants are provided with free weekly internet packages.

Category

Behavior

2

Description

The intervention group B receives the online program of Training in Marriage Enrichment (TIME) which include these sessions: responsibility, encouragement, preferences and values, effective communication skills, choices, conflict resolution, application of conflict resolution skills, and equal marital bonding. Intervention is carried out in 8 sessions of 90 minutes each. The contents of online sessions in Skyroom are presented in the form of text, graphics, videos, clips, group chats and questions and answers. In every session, homework is presented and corrected via WhatsApp application by the second author under the supervision of the first and the third authors. Participants are provided with free weekly internet packages.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali ibn Abi Talib Comprehensive Healthcare Center

Full name of responsible person

Ali Reza Massah

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Recruitment center

Name of recruitment center

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3

Recruitment center

Name of recruitment center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd 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

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

Leila Shiravan

Position

university student

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

leila shiravan

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Person responsible for updating data

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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