

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

The Effect of Integrative Therapy of Emotional-Focused Couple Therapy and Sex Therapy Masters and Johnson on Couples' Interactions and Sexual Desire

Protocol summary

Study aim

Explaining the affectability of the designed integrated therapeutic on couples' interactions and sexual desire with the control group

Design

This study was a clinical trial with simple random allocation, which will be done using a pre-test, post-test, and control group and it was done in parallel. The sample size was 13 pairs in each group. A table of random numbers was used to randomize the samples.

Settings and conduct

Sampling was performed in the mental health department of Ibn Sina Health Center in Isfahan, the Behavior Therapy Clinic of Khorshid Hospital in Isfahan, and the Preventive Medicine and Health Promotion Behsa Clinic in Tehran.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Couples with sexual desire deficiency disorder. Exclusion criteria: Chronic physical or psychological diseases; Taking hormonal drugs and drugs that affect sexual function; History of substance abuse or physical aggression; Participation in Couples Therapy and Sex Therapy classes before entering the study; History of infertility; Pregnancy

Intervention groups

For the experimental group, integrated therapy intervention will be designed and for the control group, Sex Therapy with the approach of Masters and Johnson will be performed for ten sessions one meeting a week. Standard questionnaires will be completed before and immediately after the ten sessions of the intervention. Also, to evaluate the long term effects of the therapeutic intervention 8 weeks after the intervention, the questionnaires will be completed again by the participants

Main outcome variables

Marital Satisfaction; Sexual Knowledge and Attitude;

Marital Adjustment; Intimacy Needs; Spouses Sexual Disclosure; Female Sexual Function; Male Sexual Function; Female Sexual Desire and Male Sexual Desire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160808029255N11**

Registration date: **2021-01-12, 1399/10/23**

Registration timing: **retrospective**

Last update: **2021-01-12, 1399/10/23**

Update count: **0**

Registration date

2021-01-12, 1399/10/23

Registrant information

Name

Raziyeh Maasoumi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-04-04, 1396/01/15

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

2017-04-04, 1396/01/15
Actual recruitment end date
2018-03-20, 1396/12/29
Trial completion date
2018-03-20, 1396/12/29

Scientific title
The Effect of Integrative Therapy of Emotional-Focused Couple Therapy and Sex Therapy Masters and Johnson on Couples' Interactions and Sexual Desire

Public title
The Effect of Integrated Therapy on Couples' Sexual Interactions and Desire

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
18-55 years old for men 18 years old until premenopausal for women Having criteria (SIAD) for women and (HSDD) for men according to DSM-V criteria Moderate and lower sexual desire by the Halbert Questionnaire for men (score 50 and below) Moderate or less sexual desire or arousal by the Female Sexual Function Index (score less than 3.4 for sexual arousal or score less than 3.3 for libido, or both) Interested in attending therapy sessions At least one year of living together as a permanent marriage Ability to write and read Couple age difference less than or equal to 10 years Duration of marriage between one to 30 years 6 months since the last pregnancy
Exclusion criteria:
History of acute and chronic physical illness Major psychiatric or psychological illnesses that interfere with treatment Using drugs that affect sexual function History of substance abuse or physical aggression Attending Emotional Focused Therapy for couples or Masters and Johnson sex therapy before studying History of infertility Using oral contraception pills Pregnancy

Age
From **18 years** old to **55 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **52**
Actual sample size reached: **48**

Randomization (investigator's opinion)
Randomized

Randomization description
Sampling will be conducted by Simple random allocation. After identification of couples who have eligible to enter the study, each person will select one card among cards which including A or B character. In person select a card with A character it means she/he will be included to the intervention group and if the card with B character be selected the person will be included to the control group. this process will be continue to all of sample classified in two groups.

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 Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jerib Street, Azadi Square

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Isfahan

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Isfahan

Postal code

8174673465

Approval date

2015-05-25, 1394/03/04

Ethics committee reference number

IR.MUI.REC.1394.3.488

Health conditions studied

1

Description of health condition studied

Marital Satisfaction

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Sexual Knowledge and Attitude

ICD-10 code

ICD-10 code description

3

Description of health condition studied

Marital Adjustment

ICD-10 code

ICD-10 code description

4

Description of health condition studied

Intimacy

ICD-10 code

ICD-10 code description

5

Description of health condition studied

Sexual Disclosure

ICD-10 code

ICD-10 code description

6

Description of health condition studied

Female Sexual Function

ICD-10 code

ICD-10 code description

7

Description of health condition studied

Male Sexual function

ICD-10 code

ICD-10 code description

8

Description of health condition studied

Female Sexual Desire

ICD-10 code

ICD-10 code description

9

Description of health condition studied

Male Sexual Desire

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Marital Satisfaction of Couples

Timepoint

Before the intervention, immediately and 8 weeks after the intervention

Method of measurement

ENRICH Marital Satisfaction Scale

2

Description

Sexual Knowledge and Attitude of Couples

Timepoint

Before the intervention, immediately and 8 weeks after the intervention

Method of measurement

Sexual Knowledge and Attitude Scale (SKAS)

3

Description

Marital Adjustment of Couples

Timepoint

Before the intervention, immediately and 8 weeks after the intervention

Method of measurement

Dyadic Adjustment Scale (DAS)

4

Description

Marital Intimacy of Couples

Timepoint

Before the intervention, immediately and 8 weeks after the intervention

Method of measurement

Marital Intimacy Needs Questionnaire

5

Description

Spouses Sexual Disclosure

Timepoint

Before the intervention, immediately and 8 weeks after the intervention

Method of measurement

Spouses Sexual Disclosure Scale

6

Description

Female Sexual Function

Timepoint

Before the intervention, immediately and 8 weeks after the intervention

Method of measurement

Female Sexual Function Index (FSFI)

7

Description

Male Sexual Function

Timepoint

Before the intervention, immediately and 8 weeks after the intervention

Method of measurement

International Index of Erectile Function (IIEF)

8

Description

Female Sexual Desire

Timepoint

Before the intervention, immediately and 8 weeks after the intervention

Method of measurement

Female Sexual Function Index (FSFI)

9

Description

Male Sexual Desire

Timepoint

Before the intervention, immediately and 8 weeks after the intervention

Method of measurement

Hurlbert Index of Sexual Desire (HISD)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: For the experimental group, integration of Masters and Johnson Sex Therapy and Emotional Focused Therapy for Couples treatments were held for 10 sessions. Treatment was performed separately for each couple once a week. Standard questionnaires were completed before and after 10 sessions of intervention and also to evaluate the long-term effects of treatment, 8 weeks after the intervention.

Category

Treatment - Other

2**Description**

Control group: For the control group, Masters and Johnson Sex Therapy treatment was held for 10 sessions. Treatment was performed separately for each couple once a week. Standard questionnaires were completed before and after 10 sessions of intervention and also to evaluate the long-term effects of treatment, 8 weeks after the intervention.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Navaab Safavi Healthcare Center of Isfahan

Full name of responsible person

Dr. RaziyeH Maasoumi

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Navab Safavi Healthcare Center, Ahmadabad Square, Bozorgmehr St.

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2**Recruitment center****Name of recruitment center**

Behsa clinic

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Esfahan 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

Esfahan 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

Dr. Raziye Maasoumi

Position

Pos.doc of Sexology, PhD of Reproductive Health,
Assistant Professor of Reproductive Health Department

Latest degree

Ph.D.

Other areas of specialty/work

Sexual Health

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Tehran University of Medical Sciences

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

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Position

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Other areas of specialty/work

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Web page address**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 the unrecognizable process of participants.

When the data will become available and for how long

6 months after publications of findings

To whom data/document is available

Data of this research would be available for academic researchers.

Under which criteria data/document could be used

Data of this study would be available for some research.

From where data/document is obtainable

Dr. Raziye 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

Person responsible for updating data**Contact****Name of organization / entity**

corresponding author

Comments