

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

An Investigation into the Effectiveness of Emotion-Focused Couples Therapy on Marital Intimacy and Molecular Indices in Families of Women diagnosed with Breast Cancer

Protocol summary

Study aim

Determining the Effectiveness of Emotion-Focused Couples Therapy on Marital Intimacy and Molecular Indices in Families of Women diagnosed with Breast Cancer

Design

A randomized controlled clinical trial with parallel groups

Settings and conduct

30 couples who were diagnosed with breast cancer and randomly divided into experimental and control groups (15 couples each). Sample selection for this study would be to provide eligible patients admitted to the Breast Cancer Research Center of Tehran with brief information about the research plan, its goals, and the method of treatment. The levels of oxytocin and cortisol hormones in the two groups will be measured on the day before and after the intervention. Patients in the experimental group will receive weekly emotion-focused couple therapy sessions along with receiving routine medical care for 6 120-minute sessions weekly. However, patients in the control group will receive only routine medical care during this period. Patients in both groups will respond to the Marriage Intimacy Needs Questionnaire (2001) both at baseline and immediately after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Married female participants. Participants were sexually active and were less than 55 years of age. Participants had definitive diagnosis of stage two breast cancer. Participants had undergone mastectomy surgery. Minimum literacy. Normal listening ability. Written informed consent to attend therapy sessions. exclusion criteria: mental disorders that require urgent treatment, disruption of the normal course of treatment, lack of cooperation, and severe physical disability and unwillingness to continue to cooperate.

Intervention groups

For first group, emotion-focused couple therapy and for the second group (control), no intervention will be performed.

Main outcome variables

Marital Intimacy; Molecular Indices

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200207046406N1**

Registration date: **2020-03-21, 1399/01/02**

Registration timing: **retrospective**

Last update: **2020-03-21, 1399/01/02**

Update count: **0**

Registration date

2020-03-21, 1399/01/02

Registrant information

Name

Kobra Hajializadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4401 6438

Email address

m.hedayati@iaukishint.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-13, 1398/09/22

Expected recruitment end date

2020-03-07, 1398/12/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

An Investigation into the Effectiveness of Emotion-Focused Couples Therapy on Marital Intimacy and Molecular Indices in Families of Women diagnosed with Breast Cancer

Public title

An Investigation into the Effectiveness of Emotion-Focused Couples Therapy on Marital Intimacy and Molecular Indices in Families of Women diagnosed with Breast Cancer

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Participants are married women. Participants were sexually active and were less than 55 years of age. Participants had definitive diagnosis of stage two breast cancer. Participants had undergone mastectomy surgery. Minimum literacy. Normal listening ability. Written informed consent to attend therapy sessions.

Exclusion criteria:**Age**

To 55 years old

Gender

Female

Phase

N/A

Groups that have been masked*No information***Sample size**

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

The block randomization method is performed by the statistical consultant as follows: randomization is performed in three groups: music therapy, cognitive behavioral therapy, and control: First, a list of eligible individuals is provided and coded. In block randomization, the number of participants in all groups will be very close together by making blocks of sequences so that the same number of participants are assigned to study groups within each group. We first code the groups in Latin letters as follows: A = music therapy, B = cognitive behavioral therapy, and C control group. In this study with three groups A, B and C we create the following six groups and assign 1 to 6 each: ABC-ACB-BAC-BCA-CAB-CBA. Then, using the random number table, we choose one of these blocks whenever the numbers 1, 2, 3, 4, 5, 6 appear, and if the other number appears, consider null and go to the next choice. In fact, we have obtained a random sequence of numbers with a random number table that we consider the order of assignment for each number. This way the

number of people in the groups will be approximately equal.

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 Hormozgan University of Medical Sciences

Street address

No. 61, 24th Ave., Janbazan Street, South Kurdistan Highway

City

Tehran

Province

Tehran

Postal code

2248795045

Approval date

2019-12-07, 1398/09/16

Ethics committee reference number

IR.HUMS.REC.1398.328

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

Breast Cancer

ICD-10 code

D70.1

ICD-10 code description

Agranulocytosis secondary to cancer chemotherapy

Primary outcomes**1****Description**

Marital Intimacy

Timepoint

Measurement will be done in pre-test, post-test and follow-up three months after post-test

Method of measurement

Bagarouzi Intimacy Needs Questionnaire (2001)

2

Description

Molecular Indices

Timepoint

Measurement will be done in pre-test, post-test and follow-up three months after post-test

Method of measurement

Data on dependent variables including cortisol and oxytocin on venous blood samples will be obtained by laboratory assay methods.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group one: Emotion-focused therapy is an emotional understanding that affects the concept of security and vulnerability in relation to the spouse and creates a lasting state of interpersonal relationship chaos. The treatment process will be performed in six sessions based on Bagarouzi (2001) once a week for 90 minutes each session, and generally within a month and a half.

Category

Treatment - Other

2

Description

Control group: No Intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Breast Cancer Research Center

Full name of responsible person

Masoumeh Hedayati

Street address

No. 61, 24th Ave., Janbazan Street, South Kurdistan Highway

City

Tehran

Province

Tehran

Postal code

2246578941

Phone

+98 21 2288 1908

Email

m.hedayati@iaukishint.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Alireza Roosta

Street address

Islamic Azad University of Kish International Branch, Free Zone Organization Square, Sana'i Boulevard, Kish Island.

City

Kish

Province

Hormozgan

Postal code

7941775883

Phone

+98 76 4442 2720

Email

Info@iaukishint.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

20

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

Islamic Azad University

Full name of responsible person

Kobra Hajjalizadeh

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

No. 139, Taghdiri St., South Jahromi Salimi St., East Ferdows Blvd., Second Square Sadeghiyeh

City

Kish

Province

Hormozgan

Postal code
2246578941
Phone
+98 21 4401 6438
Fax
Email
m.hedayati@iaukishint.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
Kobra Hajializadeh
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
No. 139, Taghdiri St., South Jahromi Salimi St., East Ferdows Blvd., Second Square Sadeghiyeh
City
Kish
Province
Hormozgan
Postal code
2246578941
Phone
+98 21 4401 6438
Fax
Email
m.hedayati@iaukishint.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
Kobra Hajializadeh
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
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Fax
Email
m.hedayati@iaukishint.ac.ir

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

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

Only part of the data, such as information about the main outcome or the like, can be shared.

When the data will become available and for how long

Start of access period 6 months after printing results

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

Any type of analysis on the data delivered is permitted

From where data/document is obtainable

Kobra Hajializadeh No. 139, Taghdiri St., South Jahromi Salimi St., East Ferdows Blvd., Second Square Sadeghiyeh Postal code: 2246578941 Tel: +98 21 4401 6438 Email: m.hedayati@iaukishint.ac.ir

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

The request will be sent by email to:
m.hedayati@iaukishint.ac.ir

Comments