Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effectiveness of meaning-centered therapy in existential anxiety and Fear of cancer recurrence of Breast cancer survivors

Protocol summary

Summary

Objective: The effectiveness of meaning-centered therapy in existential anxiety and Fear of cancer recurrence of Breast cancer survivors. Design, Setting and conduct: Randomized (Randomization-Table of random numbers), non-placebo controlled, single-center. Study population: women with breast cancer, referring to Cancer and Hematology Clinic affiliated by Semnan University of Medical Sciences. Inclusion criteria: being at age 20 to 45 years, cancer diagnosis by a cancer specialist, having minimum 8 class education. Exclusion criteria: having a concurrent medical or psychiatric disorder, serious disease or cancer morbidity. Sample size, intervention, time of intervention, outcomes studied: 28 cases with breast cancer, refereed to Cancer and Hematology Clinic at Semnan University of Medical Sciences will be selected and will be randomly assigned to two intervention and one control group through table of random numbers. The study was conducted from April to June 2016 in Semnan. Intervention 1: 7 patients will be put under meaning-centered individual psychotherapy. At the first meeting, the required measures will be done to determine the baseline status. Then eight Meaning-centered individual psychotherapy sessions will be held every week (a 90-minute session in each week) for two months. Intervention 2: 7 patients will be put under meaning-centered group psychotherapy. At the first meeting, the required measures will be done to determine the baseline status. Then eight Meaning-centered group psychotherapy sessions will be held every week (a 90-minute session in each week) for two months. Control group: 14 patients will not be put under any interventions. Measurements will be repeated at the middle and at the end of the treatment process and two months after the end of the treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016122225732N9**
Registration date: **2017-01-26, 1395/11/07**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-01-26, 1395/11/07

Registrant information

Name

Alireza Emadi

Name of organization / entity

Semnan University of Medical Sciences, Semnan, Iran

Country

Iran (Islamic Republic of)

Phone

+98 23 3345 1336

Email address

are20935@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Semnan University

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2016-06-20, 1395/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of meaning-centered therapy in existential anxiety and Fear of cancer recurrence of

Breast cancer survivors

Public title
Psychotherapy effect on anxiety and fear of recurrence of breast cancer
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: being at age 20 to 45 years, cancer diagnosis by cancer specialist, having minimum 8 class education. Exclusion criteria: having a concurrent medical or psychiatric disorder, serious disease or cancer morbidity.
Age
From **25 years** old to **45 years** old
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **28**
Randomization (investigator's opinion)
Randomized
Randomization description
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 Semnan University of Medical Sciences
Street address
Semnan University of Medical Sciences, Basij Blvd, Semnan
City
Semnan
Postal code
3514799442
Approval date
2016-05-25, 1395/03/05
Ethics committee reference number
IR.SEMUMS.REC.1395.50

Health conditions studied

1

Description of health condition studied
breast cancer
ICD-10 code
C50
ICD-10 code description
Malignant neoplasm of breast

Primary outcomes

1

Description
Existential Anxiety
Timepoint
The middle of treatment, after treatment and two months after the end of treatment
Method of measurement
Questionnaire fear of cancer recurrence

2

Description
Fear of cancer recurrence
Timepoint
The middle of treatment, after treatment and two months after the end of treatment
Method of measurement
Questionnaire fear of cancer recurrence

Secondary outcomes

empty

Intervention groups

1

Description
Intervention 1: 7 patients will be put under meaning-centered individual psychotherapy. At the first meeting, the required measures will be done to determine the baseline status. Then eight Meaning-centered individual psychotherapy sessions will be held every week (a 90-minute session in each week) for two months. Measurements will be repeated at the middle and at the end of the treatment process and two months after the end of the treatment.
Category
Behavior

2

Description
Intervention 2: 7 patients will be put under meaning-centered group psychotherapy. At the first meeting, the required measures will be done to determine the baseline status. Then eight Meaning-centered individual group psychotherapy sessions will be held every week (a 90-minute session in each week) for two months. Measurements will be repeated at the middle and at the end of the treatment process and two months after the

end of the treatment.

Category

Behavior

3

Description

Control group: 14 patients will not be put under any interventions.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Cancer and Hematology Clinic

Full name of responsible person

Ehsagh Rahimian

Street address

17 Shahrivar Blvd, Semnan

City

Semnan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Semnan University

Full name of responsible person

Eshagh Rahimian

Street address

Semnan University, 5th km of Damghan Road, Semnan

City

Semnan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research of Semnan University

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Semnan University

Full name of responsible person

Eshagh Rahimian

Position

Health Psychology

Other areas of specialty/work

Street address

Semnan University, 5th km of Damghan Road, Semnan

City

Semnan

Postal code

Phone

+98 23 3345 1336

Fax

+98 23 3344 8999

Email

are20935@semums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Semnan University

Full name of responsible person

Eshagh Rahimian

Position

PhD in health Psychology

Other areas of specialty/work

Street address

Semnan University, 5th km of Damghan Road, Semnan

City

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Phone

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Fax

+98 23 3344 8999

Email

are20935@semums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty