

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Determining the effectiveness of acceptance and commitment-based therapy on improvement in demoralization syndrome, cancer-related trauma, benefit finding and adherence to treatment in breast cancer patients and survivors

Protocol summary

Study aim

Determining the effectiveness of acceptance and commitment-based therapy on improvement in demoralization syndrome, cancer-related trauma, benefit finding and adherence to treatment in breast cancer patients and survivors

Design

Clinical trial with control group, with parallel, randomized groups, on 64 patients (4 groups of 16 people). Excel software rand function was used for randomization.

Settings and conduct

Kosar Hospital Semnan; and Semnan Koomesh Cancer Patients Support Association.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of cancer by an oncologist; At least three months have passed since the illness; At least 20 years old. Exclusion criteria: Psychotic problems; Absence of more than two sessions of treatment sessions.

Intervention groups

Intervention group 1: This group includes breast cancer patients who are receiving treatment. According to the protocol, interviews based on acceptance and commitment therapy are conducted individually by the researcher for patients during 8 sessions (one 90-minute session per week). Control group 1: Only for comparison with intervention group 1, no treatment is performed. Intervention group 2: This group includes patients who have recovered from breast cancer. According to the protocol, interviews based on acceptance and commitment therapy are conducted individually by the researcher for patients during 8 sessions (one 90-minute session per week). Control group 2: Only for comparison with intervention group 2, no treatment is performed.

Main outcome variables

Fear of cancer recurrence; Existential Anxiety.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151228025732N60**

Registration date: **2020-10-27, 1399/08/06**

Registration timing: **registered_while_recruiting**

Last update: **2020-10-27, 1399/08/06**

Update count: **0**

Registration date

2020-10-27, 1399/08/06

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

Expected recruitment start date

2020-06-23, 1399/04/03

Expected recruitment end date

2021-03-19, 1399/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determining the effectiveness of acceptance and commitment-based therapy on improvement in demoralization syndrome, cancer-related trauma, benefit finding and adherence to treatment in breast cancer patients and survivors

Public title

Determining the effectiveness of acceptance and commitment-based therapy on improvement in demoralization syndrome, cancer-related trauma, benefit finding and adherence to treatment in breast cancer patients and survivors

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosis of cancer by an oncologist At least three months have passed since the illness At least 20 years old

Exclusion criteria:

Psychotic problems Absence of more than two sessions of treatment sessions

Age

From 20 years old

Gender

Female

Phase

N/A

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

Target sample size: 64

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization; Individual; Random Number Tables. Randomized permutation blocks (block 4). Using Excel software to generate random number tables

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

Province

Semnan

Postal code

3514799442

Approval date

2020-06-23, 1399/04/03

Ethics committee reference number

IR.SEMUMS.REC.1399.089

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**

Fear of cancer recurrence

Timepoint

Before and after the intervention

Method of measurement

Questionnaire fear of cancer recurrence

2**Description**

Existential Anxiety

Timepoint

Before and after the intervention

Method of measurement

Questionnaire fear of cancer recurrence

Secondary outcomes

empty

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

Intervention group 1: This group includes breast cancer patients who are receiving treatment. According to the protocol, interviews based on acceptance and commitment therapy are conducted individually by the researcher for patients during 8 sessions (one 90-minute session per week).

Category

Rehabilitation

2

Description

Control group 1: Only for comparison with intervention group 1, no treatment is performed.

Category

Lifestyle

3

Description

Intervention group 2: This group includes patients who have recovered from breast cancer. According to the protocol, interviews based on acceptance and commitment therapy are conducted individually by the researcher for patients during 8 sessions (one 90-minute session per week).

Category

Rehabilitation

4

Description

Control group 2: Only for comparison with intervention group 2, no treatment is performed.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Kowsar Hospital

Full name of responsible person

Eshagh Rahimian

Street address

Amin Street

City

Semnan

Province

Semnan

Postal code

3519899951

Phone

+98 23 3344 1022

Email

are20935@gmail.com

2

Recruitment center

Name of recruitment center

Semnan Koomeh Cancer Patients Support Association

Full name of responsible person

Eshagh Rahimian

Street address

Taleghani street

City

Semnan

Province

Semnan

Postal code

3519614175

Phone

+98 23 3333 2076

Email

info@es-semnan.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University

Full name of responsible person

Seyfollah Sadodin

Street address

Opposite the park Sokan

City

Semnan

Province

Semnan

Postal code

35131-19111

Phone

+98 23 3153 5859

Email

research@semnan.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Semnan University

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

Semnan University

Full name of responsible person

Eshagh Rahimian

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

Opposite Sokan Park

City

Semnan

Province

Semnan

Postal code

3514799442

Phone

+98 23 3345 1336

Email

are20935@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Semnan University

Full name of responsible person

Eshagh Rahimian

Position

Associate professor

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Person responsible for updating data

Contact

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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

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available